DSNC

IRAQ DRUG GUIDE

2024-2025

VITAL INFORMATION ON 572 DRUGS AVAILABLE IN IRAQ

DRUG GUIDE 24-25

THIRD EDITION 24-25

مركز الدكتور سامر نوري

DR. SAMER NOORI CENTER I DSNC

إبْدَاعٌ بلَاحدُودْ

2021

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2025 - 2024

تتبنى مؤسسة DSNC ضمن خطتها التنفيذية مجموعة من المشاريع الريادية المتميزة في مجالات نشر الكتب والذكاء الاصطناعي و التطبيقات الالكترونية و صناعة المحتوى.

IRAQ DRUG GUIDE

THIRD EDITION 2024-2025

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FOR SCIENTIFIC PUBLICATION

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FOR SCIENTIFIC PUBLICATION

Published by DSNC

Third Published 2024-2025

ISBN 978-9922-8999-0-9
Consignment Number in the Iraqi National Books and Archives for the year 2024 is: 4119

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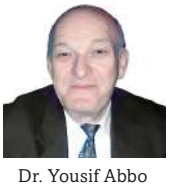
Preface

The Iraq Drug Guide 2024-2025 committee extends its thanks and appreciation to the colleagues who preceded us in authoring the Iraq Drug Guide 1990, including Professor Dr. Alaadin Alwan and the late Professor Dr. Yousif Abbo, and the Iraqi Medicines Guide 2016, which included Professor Dr. Alaa Abdul Hussein Abdul Rasool, Professor Dr. Abdul Rasool Mahmoud Wais, Professor Dr. Haider Kazem Abbas, Professor Dr. Mohammed Dakhil Al-Rikabi, Professor Dr. Ahmed Hashim Hussein, Professor Dr. Dargham Qasim Shahid, and Dr. Samer Noori Hashim – a selection of esteemed professors from Iraqi universities.

Thanks also extend to our dear colleagues, including doctors, pharmacists, dentists, and other specialists who contributed to the review and authoring of the Iraq Drug Guide 2021.

Continuing the efforts of the professors who came before us in this field, we present to you an updated and comprehensive version of the Iraq Drug Guide 2024-2025 , which aims to provide accurate information about drugs registered with the Iraqi Ministry of Health up to the start date of the composition of this guide. We hope it will be a useful resource for all colleagues in the medical field. We also hope for the continuation of this scientific effort and the ongoing publication of updated versions in the future, serving the scientific progress in our beloved Iraq.


Dr. Alaadin Alwan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Foreword

It is a matter of pride that a group of specialized physicians , dentists, pharmacists, and supporting specialties have come together to author the Iraq Drug Guide. This guide serves as a reliable and significant source for medication information (registered and approved in Iraq by the National Committee for Drug Selection in the Ministry of Health).

The Ministry of Health recognizes the utmost importance of adhering to appropriate protocols in the scientific use of medications. This ensures safe and effective drug consumption, alongside providing an independent source for pharmaceutical products with their scientific names and pharmaceutical forms, in addition to other vital and fundamental medical information.

The Ministry of Health has taken upon itself to elevate health services and care and professional development to achieve a health system characterized by efficiency and effectiveness in our beloved homeland.

We hope that this drug guide will be continuously updated to serve as an important pharmaceutical reference and that it will encompass all pharmaceutical preparations, herbal medicines, and officially approved dietary supplements use in Iraq.

In conclusion, we hope that the efforts exerted in this guide have achieved the purpose for which it was prepared.

We ask God for success,

Dr. Saleh Mahdi Al-Hassanawi
Minister of Health

How to Use Drug Guide

Iraq Drug Guide 2024-2025 is a comprehensive pharmaceutical directory, serving as an essential reference for doctors, dentists, pharmacists, and all those involved in providing health care for patient. The guide offers details about 572 medications endorsed by the National Committee for Drug Selection and registered with the Iraqi Ministry of Health. This introduction is crafted to assist professionals in effortlessly accessing pharmaceutical information and effectively utilizing the guide to find the medication details they are looking for.

Alphabetical Listing

Every medication in this guide is listed alphabetically to ease your search. Each drug occupies a one page, ensuring detailed and concise information.

Name of Drug

Each page starts with the scientific name of the drug. The term scientific name referring to "active ingredient" or the main component that provides the therapeutic effect of the drug. For example: Ibuprofen is the active ingredient of many trade name like Advil, Brufen, Captain, Ibufen, Ibun, Ibuphil, Piofen, Prof, Profedain, Profedin, Rupan, Suprafen and Taskine. On the bottom right corner of the page, there is an information box containing the (Dosage forms and trade names available in iraq) depicted with an icon to quickly show you what dosage forms the medication is available in, with the commercial names under which the drug is marketed and nd name of the company that produces the drug, including the country of origin.

Classification

Top right corner of each page has the drug's classification. We've adopted the ATC code system, The ATC code, or Anatomical Therapeutic Chemical Classification System, is a taxonomy used internationally for the classification of drugs. This system is endorsed by the World Health Organization (WHO) and is used for drug utilization research to improve the quality of drug use.

The ATC code system classifies active ingredients of drugs based on the organ or system on which they act and their therapeutic, pharmacological, and chemical properties. The classification system is hierarchical with five levels:

1st level: Anatomical main group (1 letter). For example, "C" stands for "Cardiovascular System".

2nd level: Therapeutic main group (2 digits). For example, "C03" denotes "Diuretics."

3rd level: Therapeutic/pharmacological subgroup (1 letter). For example, "C03C" represents "High-ceiling diuretics."

4th level: Chemical/therapeutic/pharmacological subgroup (1 letter). For example, "C03CA" indicates "Sulfonamides."

5th level: Chemical substance (2 digits). For example, “C03CA01” is the code for “Furosemide.”

It’s a standard way to communicate the properties and uses of drugs.

FDA Pregnancy Classification

The U.S. Food and Drug Administration (FDA) has used a letter-based classification system to provide information about the potential risks of drugs during pregnancy. Here’s a detailed overview of the FDA pregnancy classification:

1) Category A: Adequate, well-controlled studies in pregnant women have not shown an increased risk of fetal abnormalities. It’s important to note that very few drugs qualify for Category A, since testing drugs on pregnant women is fraught with ethical issues.

2) Category B: Animal reproduction studies have not shown a risk to the fetus, but there are no adequate and well-controlled studies in pregnant women. OR Animal reproduction studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester (and there is no evidence of a risk in later trimesters).

3) Category C: Animal reproduction studies have shown an adverse effect on the fetus, and there are no adequate and well-controlled studies in humans. However, potential benefits may warrant the use of the drug in pregnant women despite potential risks. OR There are no animal reproduction studies and no adequate and well-controlled studies in humans.

4) Category D: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans. However, potential benefits may warrant the use of the drug in pregnant women despite potential risks.

5) Category X: Studies in animals or humans have demonstrated fetal abnormalities, or there is evidence of fetal risk based on human experience, and the risks involved in using the drug in pregnant women clearly outweigh potential benefits. Such drugs are contraindicated in women who are or may become pregnant.

TGA Pregnancy Classification

The Therapeutic Goods Administration (TGA) in Australia uses its own classification system to categorize the potential risks of medicines during pregnancy. This system is different from the FDA’s and provides a unique perspective. Here’s a detailed look at the TGA pregnancy classification:

Category A : Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Category B1 : Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal damage.

Category B2: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

Category B3 : Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.

Category C : Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing

harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.

Category D : Drugs which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human fetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects. Accompanying texts should be consulted for further details.

Category X : Drugs which have such a high risk of causing permanent damage to the fetus that they should not be used in pregnancy or when there is a possibility of pregnancy.

This classification helps healthcare professionals make informed decisions about prescribing medications to pregnant women, ensuring the safety of both the mother and the unborn child.

Indications: The "indications" of a drug refer to the specific conditions or diseases for which the drug has been approved to treat. Indications are based on evidence from clinical trials that demonstrate the drug's efficacy and safety in treating a particular condition or set of conditions. In some cases, drugs might also be used for "off-label" indications, which means they are used in a manner not approved by regulatory agencies but supported by evidence or clinical experience. In this book dosage recommended in adults" provides guidance on how much of the drug should be taken, how often it should be taken, and the route of administration (for example oral, intravenous). Dosage can vary depending on multiple factors, including the specific indication or purpose for which the drug is being used, the patient's age, weight, and health status, the formulation of the drug (e.g., immediate-release vs. extended-release), the presence of other concurrent illnesses or conditions.

Off-label Uses: "Off-label" use refers to the practice of prescribing a drug for a condition, age group, dosage, or route of administration that hasn't been approved by regulatory authorities, such as the U.S. Food and Drug Administration (FDA). Even though a drug might only be approved for specific indications, over time, more information can emerge about other potential benefits of the medication. When there's compelling evidence, clinical experience, or both to support these non-approved uses, physicians might opt to prescribe the drug off-label.

Why Off-Label Prescribing Happens?

Evidence-based findings over time, clinical studies or case reports might suggest that a drug is effective for conditions other than those it's officially approved to treat. Lack of alternative treatments, If no approved treatments are effective for a patient, a doctor might consider an off-label medication that has shown promise. Special populations, some medications might not have been thoroughly tested in specific populations (like children or pregnant women), but they are sometimes prescribed off-label if believed beneficial.

Common areas for Off-Label use: psychiatric medications, some antipsychotics or antidepressants are prescribed for conditions other than what they were initially approved for, such as using SSRIs for generalized anxiety disorder or certain antipsychotics for treatment-resistant depression. Pain Management, drugs like anticonvulsants or antidepressants can sometimes be used for neuropathic pain, even if that's not their primary indication. Pediatric use, many drugs haven't been rigorously tested in children, but based on their known pharmacology and limited data, they might be used in pediatric settings.

Safety and efficacy: off-label prescribing is based on the best available evidence, but it's essential to recognize that this evidence might not be as robust as what's required for official drug approval. As such, there can be more uncertainty regarding the drug's safety and effectiveness for off-label uses.

It's typically considered essential for doctors to inform patients when they're receiving a medication off-label and discuss the rationale and potential risks and benefits.

It's crucial for healthcare providers to stay informed about the latest research and clinical guidelines, as the landscape of off-label drug use can change based on new evidence.

Contraindications

Contraindications refer to specific situations or conditions in which a medication should not be used because it may be harmful to the patient. Recognizing and understanding contraindications is crucial for ensuring patient

safety and optimizing therapeutic outcomes.

1) Absolute Contraindication: This is when a drug is not advised under any circumstances because the potential risks significantly outweigh any potential benefits. For instance, certain medications are absolutely contraindicated during pregnancy due to a high risk of fetal harm.

2) Relative Contraindication: This means that the drug should be used with caution. The benefits might outweigh the risks in certain situations. The healthcare provider will have to assess the individual patient's circumstances and make a judgment.

3) Categories of Contraindications

Medical Conditions: Some drugs shouldn't be used in patients with specific diseases. For example, certain types of painkillers might be contraindicated in patients with certain kidney diseases.

Drug Interactions: Some medications can interact harmfully with others. If a patient is already on a medication that can interact poorly with another, the second drug might be contraindicated.

Allergies: If a patient has had an allergic reaction to a particular drug or a drug class in the past, that drug (and often related ones) will be contraindicated.

Age: Some drugs are contraindicated in certain age groups, e.g., tetracycline antibiotics are typically contraindicated in children under 8 due to the potential for tooth discoloration.

Pregnancy & Breastfeeding: Many drugs are contraindicated during pregnancy due to potential fetal harm. Others might be contraindicated during breastfeeding if they pass into breast milk and could harm the infant.

Organ Impairment: Drugs that are metabolized by the liver might be contraindicated in patients with significant liver disease. Similarly, drugs excreted by the kidneys might be contraindicated in severe kidney disease.

It's crucial for patients to give a full medical history and a list of current medications to their healthcare provider to identify potential contraindications accurately. Patients should also report any allergies or adverse reactions they've had to medications in the past.

In essence, understanding and adhering to contraindications can significantly reduce the risk of adverse drug reactions or other negative health outcomes. It's an essential aspect of safe and effective patient care.

Cautions

Caution in the context of medication use, refer to the careful consideration or actions taken to avoid potential harm or risks associated with the use of a specific drug. While contraindications dictate situations where a drug should not be used, cautions highlight conditions or scenarios where the drug can be used but with extra care and vigilance.

Medical conditions:

Certain conditions may require dose adjustments, special monitoring, or additional tests. For instance, patients with a history of heart disease taking a medication that might affect heart rate would need regular cardiac monitoring.

In conditions like renal or hepatic impairment, drug metabolism and clearance can be altered, necessitating dose adjustments or more frequent monitoring.

Drug interactions:

Some drugs may have interactions that don't necessarily contraindicate their use together but require monitoring. For instance, two drugs that can both increase potassium levels in the body might be used together, but the patient's potassium levels would need regular checking.

Allergies:

Even if a patient hasn't had a full-blown allergic reaction to a drug, they might have had milder reactions or intolerances that would necessitate caution if the drug is to be used again.

Age-related precautions:

Elderly patients often metabolize drugs differently than younger adults. They might be more susceptible to side effects or adverse reactions, so they might need dose adjustments or additional monitoring.

Children and infants, due to differences in drug metabolism and organ maturity, often require special dosing considerations and monitoring.

Pregnancy and lactation:

If a drug isn't contraindicated during pregnancy or breastfeeding but has some associated risks, it would be used with caution. For instance, a drug that has shown some risk in animal studies but hasn't been studied in humans would be used cautiously during pregnancy, weighing the potential benefits against the risks.

Surgical or dental procedures:

Some medications, especially anticoagulants or antiplatelet agents, can increase the risk of bleeding during surgical or dental procedures. Such drugs might need to be temporarily stopped or adjusted before the procedure.

Diet and lifestyle:

Some drugs might require dietary cautions, like avoiding grapefruit juice, which can interact with several medications.

Lifestyle factors, such as smoking or alcohol consumption, might also influence drug efficacy or increase the risk of side effects, necessitating additional precautions.

Administration precautions:

Some medications have specific administration guidelines, like taking on an empty stomach or avoiding crushing/chewing. Adhering to these can be crucial for the drug's effectiveness and safety.

Monitoring and Follow-up:

Even in the absence of specific conditions, some drugs require regular monitoring to ensure they're working as intended and not causing harm. This can include blood tests, imaging studies, or other diagnostic procedures.

In essence, cautions are about optimizing drug therapy to ensure it's both effective and safe. It requires a partnership between healthcare providers and patients, with both parties staying informed and vigilant.

Dose Adjustments (Specific adjustments for renal or hepatic failure)

Dose adjustments for medications in patients with renal (kidney) or hepatic (liver) impairment are crucial to prevent drug toxicity, maintain therapeutic efficacy, and ensure patient safety. Both the liver and the kidneys play significant roles in drug metabolism and excretion, so when their function is compromised, drug pharmacokinetics can be significantly altered.

1) Renal (Kidney) Impairment

a. Mechanism of impact: Kidneys are primarily responsible for the elimination of many drugs and their metabolites from the body through urine. Impaired kidney function can lead to decreased drug clearance and increased drug concentrations in the blood.

b. Factors to consider:

- Glomerular Filtration Rate (GFR): This is a measure of kidney function and is used to stage the severity of kidney disease. Medications often have dosing recommendations based on GFR or creatinine clearance (another measure of kidney function).
- Drug Characteristics: Not all drugs are primarily excreted by the kidneys. For those that are, dose adjustments are more likely to be needed in kidney disease.

c. Dose adjustments:

- Reduce the Dose: For drugs primarily eliminated by the kidneys, reducing the dose can help prevent accumulation and potential toxicity.
- Increase the Dosing Interval: Instead of giving a drug every 6 hours, it might be given every 8 or 12 hours, for instance.
- Alternate Drug: In some cases, it may be safer to use a different drug altogether if the primary drug has significant renal elimination and potential for toxicity.

2) Hepatic (Liver) impairment

a. Mechanism of impact:

- The liver metabolizes many drugs into active or inactive metabolites, which are then excreted. Liver impairment can affect this metabolism, leading to increased drug concentrations or accumulation of potentially toxic metabolites.

b. Factors to consider:

- Severity of Liver Disease: There are various scoring systems, such as the Child-Pugh score, to assess the severity of liver disease and guide drug dosing.
- Drug Characteristics: Drugs with extensive liver metabolism, or those that can potentially exacerbate liver disease, require particular attention in patients with liver impairment.

c. Dose adjustments:

- Reduce the Dose: Especially for drugs primarily metabolized by the liver, reducing the dose can help prevent drug accumulation and adverse effects.
- Increase the Dosing Interval: Similar to renal adjustments, increasing the time between doses can help prevent drug accumulation.
- Avoidance: Some drugs may be too hepatotoxic or risky to use in significant liver disease and might be avoided altogether.

d. Monitoring:

- Regular monitoring of liver enzymes and other relevant parameters is crucial when administering drugs with potential hepatic impacts to patients with liver disease.

General considerations:

- Individualized Approach: Dose adjustments should be individualized based on the specific patient, the severity of organ impairment, the therapeutic index of the drug, and the potential risks and benefits of the medication.
- Drug Information Resources: Healthcare providers often use specialized drug information resources, which provide specific dosing recommendations for patients with renal or hepatic impairment.

- Regular Monitoring: It's essential to monitor patients closely, both for therapeutic efficacy and potential adverse effects or toxicities, especially when adjusting doses in the context of organ impairment.

In essence, dose adjustments for renal or hepatic failure are a complex and vital aspect of pharmacotherapy, en-

suring medications are used safely and effectively in vulnerable populations.

Pharmacokinetics

Pharmacokinetics is the study of how the body affects a drug after administration. It encompasses four main areas: Absorption, Distribution, Metabolism, and Elimination, often referred to by the acronym "ADME".

1) Absorption:

a. Bioavailability (F):

- Definition: It represents the fraction of an administered dose of a medication that reaches the systemic circulation unchanged. It's a measure of how effectively a drug is absorbed.
- Factors Affecting Bioavailability: Drug formulation (e.g., tablet vs. liquid), route of administration (e.g., oral vs. intravenous), first-pass metabolism in the liver, and drug-drug interactions.

b. Effect of Food on Absorption:

- Food Interactions: Some medications are affected by food, which can increase, decrease, or delay absorption.
- Examples: High-fat meals might increase the absorption of certain drugs, while other drugs might bind to components in certain foods, decreasing their absorption.

2) Distribution:

a. Volume of Distribution (V_d):

- Definition: It is a theoretical volume into which the total drug administered would have to be uniformly distributed to produce the observed blood concentration.
- Factors Influencing V_d: Drug's lipid solubility, degree of ionization, and its binding to plasma and tissue proteins.

b. Protein Binding:

- Definition: Many drugs bind to plasma proteins (like albumin) to varying degrees, only the unbound fraction of a drug is pharmacologically active and can be cleared from the body.
- Implications: Drugs that are highly protein-bound can be displaced by other drugs, potentially leading to increased free drug concentrations and adverse effects.

3) Metabolism:

- Definition: Refers to the biotransformation of drugs within the body, mainly in the liver, into more water-soluble compounds for easier elimination.
- Cytochrome P450 Enzyme System: A group of liver enzymes responsible for the metabolism of many drugs. Drug-drug interactions can occur when one drug inhibits or induces these enzymes, affecting the metabolism of another drug.
- Prodrugs: Some drugs are administered in an inactive form and require metabolic conversion in the body to become active.

4) Elimination:

a. Routes of Excretion:

- Kidneys: Most drugs are eliminated via the kidneys in urine. Kidney function (measured as glomerular filtration rate or GFR) can affect drug clearance.
- Other Routes: Some drugs or their metabolites might be eliminated via the bile into the feces, exhaled through the lungs, or excreted in breast milk.

b. Half-Life ($t_{1/2}$):

- Definition: The time it takes for the concentration of the drug in the plasma or the total amount in the body to be reduced by 50%.
- Clinical Implication: It informs dosing intervals. For instance, a drug with a long half-life might be dosed once daily, while one with a short half-life might need multiple doses a day.

Understanding pharmacokinetics is crucial for healthcare providers to ensure the safe and effective use of medications. It helps guide dosing, anticipate drug interactions, and monitor for therapeutic and adverse effects.

Major Drug Interactions

Drug-drug interactions can greatly influence the safety and efficacy of a drug. These interactions can either augment or diminish the effects of the treatment, potentially leading to therapeutic failure or unwanted side effects. Drug-drug interactions can be broadly categorized into:

1) Pharmacodynamic Interactions:

These are interactions where two or more drugs affect the same physiological system or receptor and thereby either potentiate or inhibit each other's effects. Examples include:

- Additive effects: Using two sedatives together, such as alcohol and benzodiazepines, can cause excessive sedation.
- Antagonistic effects: Using beta-blockers with beta-agonists (like those in asthma inhalers) can diminish the effects of the beta-agonists.
- Synergistic effects: The combination of alcohol and opioids can lead to profound respiratory depression.

2) Pharmacokinetic Interactions:

These are interactions where one drug affects the absorption, distribution, metabolism, or excretion of another drug. Examples include:

- Absorption: Antacids can reduce the absorption of tetracyclines.
- Distribution: Warfarin and aspirin both bind to plasma proteins. When given together, aspirin can displace warfarin from its binding sites, leading to increased free warfarin in the bloodstream and a heightened risk of bleeding.
- Metabolism: Many drugs are metabolized in the liver by the cytochrome P450 enzyme system. Drugs can either inhibit or induce these enzymes, affecting the metabolism of other drugs. For instance, grapefruit juice inhibits CYP3A4, increasing the levels of many drugs, including certain statins and calcium channel blockers.
- Excretion: Drugs like probenecid can reduce the renal excretion of penicillin, leading to higher penicillin levels in the bloodstream.

3) Chemical or Physical Interactions:

Some drugs, when mixed in the same solution, can bind to each other, precipitate, or degrade. This is particularly relevant in settings like i.v. admixture in hospitals.

4) Pharmaceutical Interactions:

Certain drugs, when taken together, might compete for the same drug transporter, leading to altered levels of one or both drugs.

Major Concerns with Drug-Drug Interactions:

- Polypharmacy: As patients take more medications, the risk of potential interactions increases.
- Age: Older adults are more susceptible to drug-drug interactions due to polypharmacy and altered pharmacokinetics.
- Comorbidities: Conditions like liver or kidney disease can amplify the effects of drug-drug interactions

as they affect drug metabolism and clearance.

Prevention and Management:

- Comprehensive Review: Regularly review all prescribed medications, over-the-counter drugs, and supplements.
- Drug Monitoring: Some drugs require regular monitoring, e.g., checking INR for patients on warfarin.
- Electronic Systems: Many electronic prescribing systems have built-in drug-drug interactions checkers.
- Patient Education: Inform patients about potential interactions, especially with over-the-counter drugs and supplements.

It's essential for healthcare providers to be aware of potential drug-drug interactions and to utilize drug guide 2023 to check for them. Patients should also be encouraged to inform all their healthcare providers about all the medications they are taking, including over-the-counter drugs and supplements.

Side Effects

Side effects, also known as adverse drug reactions (ADRs), can range from minor annoyances to severe, life-threatening conditions.

1) Common side effects (occur in more than 10% of users):

These are side effects that are frequently reported in clinical trials and post-marketing surveillance. Given their prevalence, clinicians often expect to encounter them when prescribing the medication.

- Example: Many antihypertensive medications can cause dizziness or lightheadedness, especially upon standing (orthostatic hypotension).

Implications:

- Anticipation: Since these side effects are common, patients can be pre-emptively counseled about them.
- Management: Depending on the side effect, dose reductions, or alternative medications may be considered. Often, however, these effects are mild and transient, resolving as the body becomes accustomed to the medication.

2) Less common side effects (occur in between 1% to 10% of users):

These are less frequently observed, but clinicians should still be aware of them as they can influence patient adherence to the medication regimen.

- Example: Certain cholesterol-lowering medications, like statins, can lead to muscle aches in some patients.

Implications:

- Vigilance: Given their less frequent occurrence, these side effects may not be immediately attributed to the medication. Monitoring and patient feedback are key.
- Evaluation: If a patient reports such a side effect, the benefit-to-risk ratio of the medication should be re-evaluated. It might be necessary to change the treatment strategy.

3) Rare but Serious Side Effects (occur in less than 1%):

While infrequent, the seriousness of these side effects means they can have severe consequences when they do occur. Thus, they are critical for clinicians to be aware of and for patients to be informed about.

- Example: Clozapine, an antipsychotic medication, has a rare side effect of agranulocytosis (a severe drop in white blood cells), which can be life-threatening.

Implications:

- Informed consent: Due to the severity of these side effects, it's essential that patients are well informed before starting the medication and provide informed consent.
- Monitoring: Drugs with known rare but serious side effects often require rigorous monitoring. For instance, patients on clozapine need regular blood tests to monitor white blood cell counts.
- Emergent management: If a rare but serious side effect is suspected, the medication is typically stopped immediately, and appropriate medical intervention is initiated.

In conclusion, understanding the side effect profile of a medication is essential to ensure safe and effective treatment. Always ensuring open communication channels between patients and healthcare providers can optimize treatment outcomes and minimize potential harm.

Patient Educations

Effective patient education is crucial for ensuring the safe and effective use of medications. It not only enhances adherence to medication regimens but also empowers patients to participate actively in their own healthcare. Below are detailed guidance notes:

1) Introduction to the Medication:

- Generic vs. Brand Name: Educate the patient about the drug's generic name and any common brand names.
- Purpose: Describe what the drug is used for, whether it's to treat symptoms, cure a condition, or prevent illness.

2) Administration:

- Dosage: Clarify the correct dose, including the amount and the number of times per day.
- Method: Explain how the drug should be taken (e.g., oral, topical, inhalation). For oral medications, specify if it should be taken with or without food.
- Duration: Indicate how long the medication should be taken. Is it short-term, or is it a long-term medication?

3) Storage:

- Describe how the medication should be stored. Some might require refrigeration, while others need a dry place away from sunlight.

4) Side Effects:

- Provide a list of common, less common, and rare but serious side effects.
- Educate on when to seek medical attention if certain side effects are experienced.

5) Interactions:

- Food and Drink: Explain if any foods or drinks should be avoided. For example, grapefruit juice can interact with several medications.
- Other Medications: Advise patients to always inform any healthcare provider about all the medications they're taking, including over-the-counter drugs, to avoid potential interactions.

6) Missed Dose:

- Offer guidance on what to do if a dose is missed. Generally, taking the missed dose as soon as remembered is advised unless it's close to the time for the next dose.

7) Overdose:

- Explain the signs of an overdose and advise on immediate steps. This typically involves seeking emergency medical attention.

8) Special Considerations:

- Pregnancy and Breastfeeding: Provide guidance on the drug's safety during pregnancy or while breastfeeding.
- Driving and Operating Machinery: Advise if the drug affects their ability to drive or operate machinery.

9) Adherence:

- Stress the importance of taking the medication exactly as prescribed, even if symptoms improve.

10) Review Technique:

- For medications requiring special techniques (e.g., inhalers, injections), it might be helpful to review the technique with the patient and offer a demonstration.

11) Follow-up and Monitoring:

- Some medications might require regular monitoring, like blood tests. Ensure the patient is aware of any necessary follow-up appointments.

12) Ending Medication:

- Advise on whether the medication can be stopped abruptly or needs to be tapered down. Always emphasize the importance of consulting with a healthcare provider before making any decisions.

Final Notes:

- Open Communication: Encourage patients to ask questions and report any concerns or unusual experiences while on the medication.
- Written Information: Consider providing patients with written information or pamphlets about their medication as a reference.

In essence, thorough patient education aims to provide all the necessary information for patients to use their medication safely and effectively while also fostering an open line of communication between the patient and the healthcare provider.

We hope this drug guide 2024-2025 proves beneficial for your needs. Should you have any queries, please reach out to the authors of drug guide for more detailed insights.

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Acknowledgment

Dr. Samer Noori Center (DSNC) extends its sincere thanks and appreciation to the scientific bureau and pharmaceutical companies that contributed to the support and publication of the Iraq Drug Guide 2024-2025 through their advertisements and continued support. This collaboration strengthens the development of medical and scientific content in Iraq

VITAL INFORMATION ON 572 DRUGS AVAILABLE IN IRAQ

Abemaciclib

ATC Code: L01EF03 Antineoplastic Agents (Cyclin-Dependent Kinase (CDK) Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid; breastfeeding discontinue 3 weeks after the last dose.

Dosage forms and trade names available in Iraq

Abemaciclib 150 mg tablet
Verzenio (Lilly USA)

Indications and Dosage

• Metastatic breast cancer in combination with an aromatase inhibitor or as monotherapy: 150mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to abemaciclib.

Cautions

Diarrhea; Pneumonitis; Venous thrombosis; Pulmonary embolism.
Dose adjustment in renal failure :Not required.
Dose adjustment in hepatic failure: in severe hepatic failure reduce frequency to once daily.

Pharmacokinetic parameters

Absorption F=45%, high fat food increase absorption.
Distribution Vd=690L, 95-98%protein bound.
Metabolism Hepatic metabolism mediated by CYP3A4.
Elimination Renal elimination is 3% with half-life of 18.3 hours.

Drug interactions

Carbamazepine: Carbamazepine will decrease the level or effect of abemaciclib by affecting hepatic and intestinal enzyme CYP3A4 metabolism.
Combined hormonal
Dexamethasone: Dexamethasone will decrease the level or effect of abemaciclib by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Arthralgia; Cough; Decreased appetite; Decreased WBC; Diarrhea; Dizziness; Dry mouth; Fatigue; Headache; Infection; Pyrexia; Stomatitis; Weight decreased.
Less common (1-10%) Abdominal pain; Anemia; Decreased neutrophils; Decreased platelets; Dehydration; Increased ALT; Increased AST; Infections; Leukopenia; Nausea; Neutropenia; Thrombocytopenia; Vomiting.
Rare but serious (less than 1%) Constipation; Decreased lymphocytes; Increased creatinine; Leukopenia.

Patient educations

A Patient education is not currently available for this monograph.

Abiraterone

ATC Code: L02BX03 Endocrine Therapy (Other Hormone Antagonists and Related Agents)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Metastatic, castration-resistant prostatic cancer in combination with prednisone: 1000mg once daily with prednisone 5mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to abiraterone.

Cautions

Adrenal insufficiency; Fluid retention; Heart failure; Hypokalemia; Recent myocardial infarction; Ventricular arrhythmia; Abiraterone increase risk of hyperglycemia, monitor blood sugar frequently.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In patients with baseline moderate hepatic impairment reduce the recommended dose of to 250mg once daily.

Dosage forms and trade names available in Iraq

ABIRATERONE acetate 250mg tablet

Zytiga (cilag Belgium).

Pharmacokinetic parameters

Absorption F less than 10%, food increase absorption.

Distribution Vd=19,669 ± 13,358 L, 99%protein bound.

Metabolism Metabolized by esterase to inactive compounds.

Elimination Renal elimination is 5% with half-life of 12 hours.

Drug interactions

Rifampicin: Avoid concomitant strong CYP3A4 inducer during abiraterone treatment.

Side effects

Common (more than 10%) Cough; Diarrhea; Dyspepsia; Dyspnea; Edema; Fatigue; Hot flush; Hyperglycemia; Hypernatremia; Hypertension; Hypertriglyceridemia; Hypokalemia; Hypophosphatemia; Increased ALT; Increased AST; Increased total bilirubin; Insomnia; Joint swelling; Lymphopenia; Muscle discomfort; Nasopharyngitis; Upper respiratory tract infection; Urinary tract infection.

Less common (1-10%) Arrhythmia; Cardiac failure; Chest pain; Falls; Fractures; Groin pain; Headache; Hematuria; Urinary frequency.

Rare but serious (less than 1%) Allergic alveolitis; Hyponatremia; Insomnia.

Patient educations

Must be taken on empty stomach; Sexually active men must wear condoms during treatment and for 1 week after treatment.

Aceclofenac

ATC Code: M01AB16 Antiinflammatory And Antirheumatic Products (Acetic Acid Derivatives And Related Substances).

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Avoid

Indications and Dosage

• Rheumatoid arthritis; Ankylosing spondylitis; Osteoarthritis: 100mg bid.

Off-label uses

Fever; Gout; Migraine; Myalgia.

Contraindications

Hypersensitivity to aceclofenac; Active peptic ulcer; Acute rhinitis; Asthma; Urticaria.

Cautions

Crohn's disease; Hematological abnormalities; History of cerebrovascular bleeding; Hypertension; Mild to moderate CHF; Ulcerative colitis.

Dose adjustment in renal failure: Use of aceclofenac in moderate to severe renal failure is contraindicated.

Dose adjustment in hepatic failure: Reduce initial dose to 100mg once daily; Use of aceclofenac in severe hepatic failure is contraindicated.

Dosage forms and trade names available in Iraq

ACECLOFENAC 100mg tablet

LOFLAM (Medpharma UAE)

Pharmacokinetic parameters

Absorption F=15%, rapidly and completely absorbed from GIT.

Distribution Vd=25L, 99%protein bound.

Metabolism Hepatic metabolism mediated by CYP2C9.

Elimination Renal elimination is 70-80% with half-life of 4 hours.

Drug interactions

Digoxin: Aceclofenac may increase serum concentration of digoxin.

Glibenclamide: Aceclofenac may increase hypoglycemic effects of glibenclamide.

Warfarin: Aceclofenac may enhance the effect of anticoagulants.

Side effects

Abdominal pain; Abnormal liver function; Agranulocytosis; Angioedema; Aplastic anemia; Asthma; Bronchospasm; Cardiac failure; Constipation; Diarrhea; Dizziness; Drowsiness; Dyspepsia; Dyspnea; Enuresis; Flatulence; Gastritis; Hematemesis; Headache; Hepatitis; Jaundice; Nausea; Nephritic syndrome; Nephritis; Neutropenia; Optic neuritis; Pancreatitis; Paresthesia; Pruritus; Purpura; Rash; Renal failure; Thrombocytopenia; Ulcerative stomatitis; Urticaria; Visual disturbance; Vomiting.

Patient educations

Advise the patient not to drive or operate machinery; Preserve in tight containers, store at room temperature not exceeding 30C.

Acetaminophen

ATC Code: N02BE01 Analgesics (Anilides)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- ACETAMINOPHEN 10mg/1ml IV Solution
- ACETAMINOPHEN 100mg/1ml drop
- ACETAMINOPHEN 120mg/5ml syrup
- ACETAMINOPHEN 120mg/5ml Suspension
- ACETAMINOPHEN 125mg/5ml syrup
- ACETAMINOPHEN 250mg/5ml Suspension
- ACETAMINOPHEN 500mg tab
- ACETAMINOPHEN 125mg suppository
- ACETAMINOPHEN 250mg suppository

Indications and Dosage

• Analgesia and antipyretic: 500mg-650mg every 4-6 hours or 1g tid, (max 3g daily). By rectal, 125mg-250mg every 4-6 hours, (max 6 doses daily). By i.v. infusion, 1000mg every 6 hours or 650mg every 4 hours, (max 3g daily).

Off-label uses

None.

Contraindications

Hypersensitivity to paracetamol; Severe active liver disease.

Cautions

Alcohol dependency; Active hepatic disease; Chronic malnutrition; Hypovolemia; G6PD deficiency; Limit dose to less than 4g/day.

Dose adjustment in renal failure: CrCl 10-50ml per minute increase interval to every 6 hours; CrCl less than 10ml per minute increase interval to every 8 hours.

Dose adjustment in hepatic failure: Use with caution; i.v. dosage form of paracetamol is contraindicated in severe hepatic failure.

Pharmacokinetic parameters

Absorption F=63-89%.

Distribution Vd= roughly 50 L-60 L= 0.7- 0.9kg, Protein binding is negligible, except under the conditions of overdose, when it may reach 15–21%

Metabolism Paracetamol metabolized by the liver via CYP2E1 enzyme system.

Elimination Paracetamol elimination half-life is 1-3 hours.

Drug interactions

Acyclovir: The metabolism of Acyclovir can be decreased when combined with Acetaminophen.

Enoxaparin: Paracetamol increases effects of enoxaparin by unknown mechanism.

Side effects

Common (more than 10%) generally well tolerated

Less Common (1-10%) Allergic reactions such as rash, itching, swelling, severe dizziness, or trouble breathing, Nausea-Vomiting-Loss of appetite-Mild stomach pain; Laryngeal edema;.

Rare but Serious (less than 1%) Hepatotoxicity, Persistent nausea/vomiting; Disorientation; severe abdominal pain-Agranulocytosis; Angioedema; Nephrotoxicity; Neutropenia; Pancytopenia; Gastrointestinal hemorrhage; Pneumonitis.

Patient educations

Do not take more than 4g/day; Avoid alcohol.

Acetylsalicylic Acid

ATC Code: B01AC06 Antithrombotic Agents (Platelet Aggregation Inhibitors Excl. Heparin)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding for occasional use and in low doses.

Indications and Dosage

• Prevention of transient ischemic attack, cerebral thromboembolism, myocardial infarction: 75mg-100mg once daily.
• Treatment of unstable angina, (NSTEMI), (STEMI), suspected transient ischemic attacks: 300 mg.
• Treatment of acute ischemic stroke: 300 mg once daily for 14 days, to be initiated within 48 hours of symptom onset in patients not receiving thrombolysis or 24 hours after thrombolysis.
• Mild to moderate pain, fever, joint pains: 300 – 900 mg qid.

Off-label uses

Prevention of preeclampsia; Pericarditis; Kawasaki's disease; Autoimmune disorders; Colorectal cancer, Secondary prevention of DVT or pulmonary embolism (in patients who refuse continued anticoagulation treatment): 75 - 150 mg daily.

Dosage forms and trade names available in Iraq

- ACETYLSALICYLIC ACID 75mg tablet
  ASPIREM (Remedica Cyprus).
- ACETYLSALICYLIC ACID 81mg tablet
  Aspin (SDI Iraq).
- Acetylsalicylic acid 100mg tablet
  ASPIN (SDI Iraq), **Duspirin** (Dubai Iraq).

Contraindications

Hypersensitivity to acetylsalicylic acid or NSAIDs; Asthma; Inherited or acquired bleeding disorders; Active peptic ulceration; Use in children younger than 16 years for viral infections. Do not use for at least 7 days after tonsillectomy or oral surgery.

Cautions

Bleeding disorders; Dehydration; Erosive gastritis; Peptic ulcer disease.
Dose adjustment in renal failure: In severe renal failure acetylsalicylic acid contraindicated.
Dose adjustment in hepatic failure: In severe hepatic failure acetylsalicylic acid contraindicated.

Pharmacokinetic parameters

Absorption F=80-100%, Absorption rapid and complete following oral administration.
Distribution Vd=0.16L/kg, 50-90%protein bound.
Metabolism Metabolized by liver via microsomal enzyme system.
Elimination Elimination Predominantly via the kidneys with half-life of 2-3 hours for low dose; more than 20 hours for high dose.

Drug interactions

ACE inhibitors: Coadministration may result in a significant decrease in renal function. Acetylsalicylic acid may diminish the antihypertensive effect of ACE inhibitors.

Side effects

Angioedema; Bronchospasm; Gastrointestinal ulceration; Hearing loss; Hepatotoxicity; Nausea; Premature hemolysis; Pulmonary edema; Rash; Renal damage; Tinnitus; Urticaria; Vomiting.

Patient educations

Avoid alcohol; Behavioral changes and persistent vomiting may be early signs of Reye's syndrome.
mechanical ventilation and preparation to the ICU and the in-hospital mortality rate in COVID-19.

Aciclovir

ATC Code: J05AB01 Antivirals for Systemic Use (Nucleosides and Nucleotides Excl. Reverse Transcriptase Inhibitors)
Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N
Lactation: Compatible with breastfeeding.

Indications and Dosage

• Genital herpes simplex: By i.v. infusion, 5mg-10mg/kg every 8hours for 3 days, followed with oral therapy 400mg tid or 200mg 5 times a day for 7-10 days.
• Herpes zoster, shingles, varicella: 800mg 5 times a day for 7-10 days.
• Herpes labialis, cold sores: Apply cream to affected area 5 times a day for 4 days.
• Acute herpetic keratitis: Apply eye ointment to affected eye 5 times a day (every 3 hours while awake) until healed.

Dosage forms and trade names available in Iraq

- Aciclovir 200mg tablet
- Aciclovir 400mg tablet
- Aciclovir 800mg tablet
- Aciclovir 200mg/5ml oral suspension
- Aciclovir 250mg vial
- Aciclovir 30mg/1g eye oint
- Aciclovir 5% (50mg/1g) cream

Off-label uses

Herpes zoster encephalitis; Varicella pneumonia.

Contraindications

Hypersensitivity to aciclovir.

Cautions

Preexisting serious neurologic, hepatic, pulmonary, or fluid and electrolyte abnormalities; Obesity.
Dose adjustment in renal failure: CrCl 10-25ml/min: increase interval to every 8 hours; CrCl less than 10ml/min: increase interval to every 12 hours.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=10-20%, food has no effect on absorption.
Distribution Vd=0.8L/kg, 9-33% protein bound.
Metabolism Metabolized by liver (in small amounts).
Elimination Renal elimination is 62-90% with a half-life of 2.5-3.3 hours.

Drug interactions

Amphotericin B: Aciclovir and amphotericin B both increase nephrotoxicity and ototoxicity. avoid or use alternate drugs.
Valproic acid: Aciclovir decreased absorption and lower plasma concentration of valproic acid, monitor and adjust dose if necessary.

Side effects

Common (more than 10%) Diarrhea; Dizziness; Fever; Headache; Itching; Photosensitivity.
Less common (1-10%) Hair loss.
Rare (less than 1%) Alopecia; severe skin reaction.

Patient educations

Maintain adequate hydration during therapy.

Adalimumab

ATC Code: L04AB04 Immunosuppressants (Tumor Necrosis Factor Alpha (TNF-α) Inhibitors)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Breastfeeding discontinue 5 months after the last dose.

Dosage forms and trade names available in Iraq

- ADALIMUMAB 40mg/0.4ml in a pre-filled syringe **HUMIRA** (AbbVie Germany).
- ADALIMUMAB 40mg/0.8ml in a pre-filled syringe **Amsparity** (Pfizer USA).

Indications and Dosage

• Plaque psoriasis, uveitis: Initially, 80mg then 40mg after 1 week, maintenance 40mg every 2 weeks.

• Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis: 40mg every 2 weeks, review treatment if no response within 12 weeks.

• Crohn's disease: Initially, 80mg then 40mg after 2 weeks.

• Ulcerative colitis: Initially, 160mg (dose can alternatively be given as divided injections over 2 days), then 80mg after 2 weeks, maintenance 40mg every 2 weeks.

Off-label uses

None.

Contraindications

Hypersensitivity to Adalimumab; Severe infections (such as sepsis, TB).

Cautions

Decreased left ventricular function; Diabetes; Elderly; Heart failure; History of malignancies; Indwelling catheters; Invasive fungal infections; Open wounds.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=64%.

Distribution Vd=4.7-6L.

Metabolism Not metabolized.

Elimination Adalimumab elimination half - life is 10-20 days.

Drug interactions

Azathioprine: Adalimumab and azathioprine both increase immunosuppressive effects; risk of infection. avoid or use alternate drug.

Abciximab: Thee risk or severity of adverse effects can be increased when adalimumab is combined with abciximab.

Influenza virus vaccine: Adalimumab decrease effects of vaccine by pharmacodynamic antagonism.

Side effects

Common (more than 10%) Headache; Injection site pain; Rash; Sinusitis; Upper respiratory tract infection.

Less common (1-10%) Abdominal pain; Flu-like syndrome; Hematuria; Hyperlipidemia; Hypertension; Nausea; Urinary tract infection.

Rare (less than 1%) Aplastic anemia; Leukopenia; Pancytopenia; Thrombocytopenia.

Adapalene

ATC Code: D10AD03 Anti-Acne Preparations (Retinoids for Topical Use in Acne)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Mild to moderate acne vulgaris: Apply once daily at bedtime after washing gently with non-medicated soap.

Off-label uses

Actinic keratosis; Alopecia areata; Rosacea and rosacea like perioral dermatitis.

Contraindications

Hypersensitivity to adapalene.

Cautions

Safety and efficacy have not been established in children less than 12 years of age; Not intended for application to broken, sunburnt or eczematous skin.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Adapalene 0.1% (1mg/1g) gel
Sure Cure (Jamjoom Pharma KSA).

Pharmacokinetic parameters

Absorption Adapalene absorption through the skin is low.
Distribution Trace amount found in plasma following topical application.
Metabolism Metabolized by liver.
Elimination Excreted primarily by biliary route with a half-life of 7-51 hours.

Drug interactions

Benzoyl peroxide: Application of adapalene and benzoyl peroxide to the same areas may cause excessive irritation or drying of the skin.
Isotretinoin: Using isotretinoin together with adapalene may increase skin irritation, concurrent use should generally be avoided.

Side effects

Common (more than 10%): Burning; Dryness; Erythema; Scaling; Stinging.
Less common (1-10%): Desquamation; Pruritus; Skin discomfort; Sunburn.
Rare (less than 1%): Acne flare; Conjunctivitis; Contact dermatitis; Eczema; Erythema; Eyelid edema; Rash; Skin discoloration.

Patient educations

A burning sensation, stinging, dryness, itching, or redness of the skin may occur, especially during the first month of use. Other skin products such as hair removal products, shaving creams with a large amount of alcohol, other acne medications, and certain soaps and cleansers may irritate the skin while using adapalene; Minimize sun exposure.

Adenosine

ATC Code: C01EB10 Cardiac Therapy (Other Cardiac Preparations)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

ADENOSINE 3mg/1ml
Emergcine (Pioneer Iraq).

Indications and Dosage

• Treatment of paroxysmal supraventricular tachycardia including patients associated with accessory bypass tracts (Wolff-Parkinson-White syndrome): By i.v. injection, initially 6mg, administer into central or large peripheral vein and give over 2 seconds (cardiac monitoring required) followed by 12mg after 1-2 min if required, then 12mg after 1-2 min if required, increments should not be given if high level AV block develops at any particular dose.

Off-label uses

Acute vasodilator testing in pulmonary artery hypertension.

Contraindications

Hypersensitivity to adenosine; Atrial fibrillation or flutter; Second or third degree AV block or sick sinus syndrome; Ventricular tachycardia.

Cautions

First degree AV block; Bundle branch block; Autonomic dysfunction; Pericarditis; Pleural effusion; Carotid stenosis; Uncorrected hypovolemia; Elderly; Bronchoconstriction.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Data regarding the absorption not readily available.
Distribution Undetermined.
Metabolism Rapidly converted to inosine and adenosine monophosphate.
Elimination Adenosine is predominantly eliminated in the urine as uric acid with half-life of 10 seconds.

Drug interactions

Dipyridamole: Dipyridamole increases levels of adenosine by decreasing metabolism.

Side effects

Common (more than 10%) Dyspnea; Flushing.
Less common (1-10%) Chest pressure; Dizziness; Lightheadedness; Nausea; Numbness; Tingling in arms.
Rare but serious (less than 1%) Apprehension; Blurred vision; Hyperventilation; Hypotension.

Patient educations

May induce feelings of impending doom, which resolves quickly; Report continued chest pain, head or neck pain, difficulty breathing.

Adrenaline

ATC Code: C01CA24 Cardiac Stimulants Excl. Cardiac Glycosides (Adrenergic and Dopaminergic Agents

Pregnancy category:

FDA A B **C** D X N

TGA **A** B1 B2 B3 C D X N

Lactation: It is not known if adrenaline is excreted in breast milk. However it is unlikely to affect the infant if used therapeutically.

Indications and Dosage

Dosages vary widely based on indication. For anaphylaxis, typical adult intramuscular dosage is 0.3 -0.5 mg.

Off-label uses

the temporary treatment of control bleeding.

Contraindications

In those with hypersensitivity to adrenaline or any of its excipients.

Cautions

In patients with heart diseases, hyperthyroidism, diabetes, and during pregnancy.

Dose adjustment in renal failure: No specific guidelines have been provided.

Dose adjustment in hepatic failure: No specific guidelines have been provided .

Dosage forms and trade names available in Iraq

ADRENALINE 1mg/1ml ampoule

Adrenaline Aguettant (AGUETTANT France).

Pharmacokinetic parameters

Absorption Rapid when injected intramuscularly or subcutaneously.

Distribution Not extensively protein bound.

Metabolism Rapidly metabolized in the liver and tissues by monoamine oxidase and catechol- O-methyltransferase.

Elimination Primarily by the kidneys, with half-life of about 2-3 minutes.

Drug interaction

Beta-blockers: May diminish the therapeutic effect of adrenaline.

Monoamine Oxidase Inhibitors (MAOIs): May enhance the hypertensive effect of adrenaline.

Side effects

Common (more than 10%) Anxiety, restlessness, headache, tremor.

Less common (1-10%) Palpitations, tachycardia, hypertension, sweating.

Rare but serious (less than 1%) Pulmonary edema, arrhythmias, myocardial infarction.

Patient Education

1. Adrenaline is used to treat severe allergic reactions and should be used immediately at the first sign of an allergic reaction.
2. Do not inject this medication into a vein or into the muscles of your buttocks, or it may not work as well.
3. Seek immediate medical attention after use, even if symptoms seem to be improving.

Aescin

ATC Code: C05CX03 Vasoprotectives (Other Capillary Stabilizing Agents)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available

Indications and Dosage

Used for the relief of symptoms of chronic venous insufficiency (CVI), such as swollen legs, leg heaviness, and leg pain. Dosage is typically 20mg twice or thrice daily, but may depend on the specific product formulation and manufacturer instructions.

Off-label uses

None

Contraindications

Hypersensitivity to aescin or any other component of the formulation.

Cautions

Use with caution in patients with liver or kidney disease. Aescin may increase bleeding risk so it should be used with caution in people with bleeding disorders or taking anticoagulant or antiplatelet medications.

Dose adjustment in renal failure: There are no specific guidelines

Dose adjustment in hepatic failure: There are no specific guidelines

Dosage forms and trade names available in Iraq

Aescin 20mg tablet
Reparil (Madaus Germany).

Pharmacokinetic parameters

Detailed pharmacokinetic data (**absorption, distribution, metabolism, elimination**) for aescin is not available as of my last update.

Drug interaction

Anticoagulants or Antiplatelets: Aescin may enhance the adverse/toxic effect of these drugs by increasing bleeding risk.

Medications with Antiplatelet Effects: The risk for bleeding may be increased.

Side effects

Common (more than 10%) Gastrointestinal discomfort
Less common (1-10%) Nausea, itching, rash
Rare but serious (less than 1%) Allergic reactions, kidney damage

Patient Education

1. Aescin is used to relieve symptoms of CVI such as swelling, heaviness, and pain in the legs.
2. If you are taking anticoagulants, inform your healthcare provider because of the increased risk of bleeding.
3. Notify your healthcare provider if you experience side effects such as gastrointestinal discomfort, nausea, itching, or rash.

Aflibercept

ATC Code: L01XX44 Antineoplastic Agents (Other Antineoplastic Agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: No data available

Indications and Dosage

• For Eylea: Indicated for wet age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy. Typical dosage is 2 mg (0.05 mL) via intravitreal injection monthly initially, followed by a maintenance dose every 1-2 months.

• For Zaltrap: Indicated for metastatic colorectal cancer, usually given as 4 mg per kg intravenously every 2 weeks in combination with chemotherapy.

Off-label uses

Treatment of other forms of choroidal neovascularization.

Contraindications

Ocular or periocular infections, active intraocular inflammation, known hypersensitivity to aflibercept or any of the excipients in Eylea.

Dosage forms and trade names available in Iraq

Aflibercept 40mg/ml vial
Eylea (Bayer Germany).

Cautions

Increased intraocular pressure and arterial thromboembolic events have been reported following use.
Dose adjustment in renal failure: No specific guidelines have been provided
Dose adjustment in hepatic failure: No specific guidelines have been provided

Pharmacokinetic parameters

Traditional pharmacokinetic parameters like absorption, distribution, metabolism, and elimination don‘t apply to aflibercept in the same way as it is given as an injection.

Drug interaction

no major interactions have been reported with aflibercept.

Side effects

Common (more than 10%) Conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters.
Less common (1-10%) Retinal pigment epithelial tear, endophthalmitis, retinal detachment, intraocular pressure increased.
Rare but serious (less than 1%) Arterial thromboembolic events.

Patient educations

• Aflibercept is used to treat certain eye conditions and certain types of cancer.
• The medication can cause side effects such as eye pain, blurred vision, or changes in vision - inform your doctor if these occur.
• If you are pregnant or breastfeeding, please consult your doctor before starting treatment.

Agalsidase Beta

ATC Code: A16AB04 Other Alimentary Tract and Metabolism Products (Enzymes)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation: Use during breast-feeding is not recommended

Indications and Dosage

For the treatment of Fabry disease in adults and children. The recommended dosage of agalsidase beta is 1 mg/kg body weight administered every two weeks as an intravenous infusion.

Off-label uses

None

Contraindications

Hypersensitivity to agalsidase beta or any of its excipients.

Cautions

Hypersensitivity and anaphylactic reactions.
Dose adjustment in renal failure: No specific guidelines have been provided
Dose adjustment in hepatic failure: No specific guidelines have been provided

Dosage forms and trade names available in Iraq

Agalsidase Beta 35mg vial
Fabrazyme (Genzyme Ireland).

Pharmacokinetic parameters

As agalsidase beta is an intravenous infusion, absorption is not applicable. Traditional pharmacokinetic parameters (distribution, metabolism, and elimination) are not available.

Drug interaction

no major interactions have been reported with agalsidase beta.

Side effects

Common (more than 10%) Infusion reactions (fever, chills, flushing), headache, nausea, fatigue. chest pain-abdominal discomfort-difficulty in breathing-swelling face-pallor-joint pain –itching-decreased blood pressure-abnormal tear secretion- chest discomfort-feeling weak-face oedema-tinnitus-exacerbated difficulty in breathing -nasal congestion-muscle tightness
Less common (1-10%) Dizziness, rapid heart rate, low or high blood pressure. – tremor-skin discomfort-red eyes-musculoskeletal pain - ear pain-rhinitis - throat pain-influenza - like illness - fast breathing - malaise-itchy rash-low heart rate due to conduction disturbances
Rare but serious (less than 1%) Severe allergic reactions including anaphylaxis.

Patient educations

You may experience side effects like fever, headache, and nausea during or after the infusion.

Albendazole

ATC Code: P02CA03 Anthelmintics (Benzimidazole Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Hydatid disease: 400mg bid with meals for 28 days.
• Hookworm infections: 400mg single dose.

Off-label uses

Ascaris lumbricoides (roundworm); Enterobius vermicularis (pinworm); Strongyloides stercoralis (threadworm); Trichuris trichiura (whipworm). Taenia saginata (beef tapeworm).

Contraindications

Hypersensitivity to albendazole.

Cautions

Cysticercosis involving the eye; Potential for bone marrow suppression and aplastic anemia; Reversible elevations of liver enzymes may occur.

Dosage forms and trade names available in Iraq

ADRENALINE 1mg/1ml ampoule
Adrenaline Aguettant (AGUETTANT France).

ALBENDAZOLE 200mg tablet
Alzental (Eipico Egypt).

Pharmacokinetic parameters

Absorption Less than 5% increase up to 4-5 times with a fatty meal.
Distribution Well inside hydatid cysts and CSF, 70% protein bound.
Metabolism Hepatic, extensive first-pass effect.
Elimination Urine; Feces, with half-life of 8-12 hr.

Drug interactions

Dexamethasone: Dexamethasone increases levels of albendazole by unspecified interaction mechanism.
Phenytoin: Phenytoin decreases levels of albendazole by increasing metabolism.
Grapefruit juice may increase in blood levels of albendazole when administered concurrently.

Side effects

Common (more than 10%) Headache.
Less common (1-10%) Abdominal pain; Alopecia; Dizziness; Fever; Increased intracranial pressure; Nausea; Vertigo; Vomiting.
Rare (less than 1%) Acute liver failure; Acute renal failure; Agranulocytosis; Aplastic anemia; Bone marrow suppression; Granulocytopenia; Hepatitis; Pancytopenia; Rash; Thrombocytopenia; Urticaria.

Patient educations

Liver function tests and CBC should be performed at the start of a 28-day cycle and every two weeks during therapy; Take with food; Adequate intake of fluids (2 L) to prevent deposits in kidneys which more likely to occur in dehydration.

Albumin

ATC Code: B05AA01 Blood

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: There are no data on the excretion of albumin into human milk.

Dosage forms and trade names available in Iraq

ALBUMIN (HUMAN) 200mg/1ml (100ml vial) **HUMAN ALBUMIN** (Baxter Austria).
ALBUMIN (HUMAN) 50mg/1ml 250ml vial **Biseko** (Biotest Germany).

Indications and Dosage

• Acute Liver Failure: 6-8 g i.v. for every 1000 ml of ascitic fluid removed.
• Adult Respiratory Distress Syndrome: 25 g i.v. over 30 minutes; repeat every 8 hours on need.
• Burns: Indicated after 24 hours post burn if severe albumin depletion.
• Hypoalbuminemia: 25-50 g administered i.v.
• Hemodialysis: 25 g administered i.v.
• Hypovolemia: Initial 25 g i.v.; adjust according to volume requirements.
• Ovarian Hyperstimulation Syndrome: 50-100 g i.v. infused over 4 hours; repeat every 4-12 hours on need.
• Post-operative heart and lung transplant.
• Major hepatic resection > 40% of liver.

Off-label uses

None.

Contraindications

Hypersensitivity to albumin products; Severe anemia; Heart failure.

Cautions

Albumin may cause fluid overload or pulmonary edema; Patients with bleeding disorders or those undergoing surgery; Renal impairment.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%
Distribution Vd=0.3-0.5 L/kg, 60% protein bound.
Metabolism ALBUMIN is metabolized in the liver.
Elimination Renal elimination with half-life of approximately 19 days.

Drug interactions

Anticoagulant: Albumin may interact with anticoagulants, increasing the risk of bleeding.
Diuretics: Albumin use with caution in patients taking diuretics that may affect fluid balance.

Side effects

Common (more than 10%) Dizziness; Headache; Nausea.
Less common (1-10%) Allergic reactions; Fever.
Rare but serious (less than 1%) Anaphylaxis; Fluid overload; Pulmonary edema.

Patient education

Albumin is administered intravenously. Monitoring of vital signs, including breathing, pulse, blood pressure, electrolyte levels, and kidney function, is done closely during the administration of albumin. Regular blood tests are also necessary throughout the treatment. It is important to maintain adequate hydration by drinking plenty of fluids while undergoing albumin treatment.

Alectinib

ATC Code: L01ED03 Antineoplastic Agents (Anaplastic Lymphoma Kinase (ALK) Inhibitors)

Pregnancy category:
FDA A B C D X **N**
TGA A B1 B2 B3 C **D** X N

Lactation: Not recommended during lactation.

Indications and Dosage

Typically used for the treatment of metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive, 600 mg PO BID with food until disease progression or unacceptable toxicity.

Off-label uses

None.

Contraindications

Hypersensitivity to alectinib or any component of the formulation.

Cautions

Caution is advised in patients with hepatic impairment, bradycardia, or other cardiac conditions.

Dose adjustment in renal failure:

• Mild (CrCl 60 to less than 90 mL/min) or moderate (30 to less than 60 mL/min renal impairment: No adjustment recommended.

• Severe renal impairment (CrCl less than 30 mL/min) or end-stage renal disease: Data not available.

• Grade 3 renal impairment: Temporarily withhold therapy until recovery to baseline or to 1.5 x ULN or less, then resume at reduced dose, while in Grade 4 renal impairment: Permanently discontinue therapy.

Dose adjustment in hepatic failure:

• Mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic dysfunction: No adjustment recommended.

• Severe hepatic dysfunction (Child-Pugh C): Reduce dose to 450 mg orally 2 times a day, And according to the AST and ALT levels.

Dosage forms and trade names available in Iraq

Alectinib 150mg tablet
Alecensa (Excella Germany)

Pharmacokinetic parameters

Absorption High oral bioavailability.
Distribution Protein bound (parent drug and M4 metabolite): >99%, Vd: 4016 L; 10,093 L.
Metabolism Primarily hepatic metabolism via CYP3A4.
Elimination Mostly excreted in feces; half-life is approximately 33 hours.

Drug interactions

• Strong CYP3A inhibitors may increase alectinib plasma concentrations.
• Strong CYP3A inducers may decrease alectinib plasma concentrations.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal distention; Abdominal pain; Acid regurgitation; Constipation; Dyspepsia; Flatulence; Gastritis; Muscle pain; Musculoskeletal pain; Nausea.
Rare (less than 1%) None.

Patient educations

• Follow the prescribed dosage and schedule closely.
• Report any new or worsening symptoms to your healthcare provider promptly.

Alendronic Acid

ATC Code: M05BA04 Drugs For Treatment Of Bone Diseases (Bisphosphonates)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Osteoporosis: 70mg once weekly.

Off-label uses

Osteoporosis caused by spinal injury; Vitamin D overdose.

Contraindications

Hypersensitivity to alendronic acid or other bisphosphonates; Esophageal abnormalities such as stricture or achalasia that delay esophageal emptying; Hypocalcemia; Inability to stand or sit upright for 30 min.

Cautions

Children; Esophageal disease; Gastritis; Gastrointestinal ulcers; Osteonecrosis of jaw.

Dose adjustment in renal failure: CrCl less than 35ml/min: avoid use.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- ALENDRONIC ACID 70mg caplet
  Alendomax (Joswe Jordan).
- ALENDRONIC ACID 70mg Effervescent tablet
  Binosto (labatec-pharma Switzerland).
- ALENDRONIC ACID 70mg tablet
  FOSAMAX (Merck Netherland).

Pharmacokinetic parameters

Absorption F=1%, food decrease absorption.

Distribution Vd=28L, 78% protein bound.

Metabolism Not metabolized.

Elimination Renal elimination is 50% with half-life in bone of 10 years.

Drug interactions

Calcium carbonate: Calcium carbonate decreases levels of alendronate by inhibition of GI absorption, separate by 2 hr.

Deferasirox: Combination may increase GI bleeding, ulceration and irritation.

Side effects

Common (more than 10%) None.

Less common (1-10%) Abdominal distention; Abdominal pain; Acid regurgitation; Constipation; Dyspepsia; Flatulence; Gastritis; Muscle pain; Musculoskeletal pain; Nausea.

Rare (less than 1%) None.

Patient educations

Give at least 30 minutes before first food, beverage, or medication of the day; Do not lie down for at least 30 minutes after taking medication; Supplemental calcium and vitamin D should be taken if dietary intake inadequate; Optimal duration of use not determined, for patients at low risk for fracture consider drug discontinuation after 3-5 years of use.

Alfacalcidol

ATC Code: A11CC03 Vitamins (Vitamin D and Analogues)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: It's not known whether Alfacalcidol passes into breast milk. Caution is advised.

Dosage forms and trade names available in Iraq

- Alphacalcidol 0.25µg soft gelatin capsule
  ONE - ALPHA (LEO Denmark).
- Alphacalcidol 1µg soft gelatin capsule
  ONE - ALPHA (LEO Denmark).
- Alphacalcidol 2mcg/ml drops
  ONE - ALPHA (LEO Denmark).

Indications and Dosage

Alfacalcidol is used to treat conditions where the amount of vitamin D needs to be increased, like certain bone conditions, such as osteomalacia and rickets. It's also used to manage hypocalcemia in patients undergoing chronic renal dialysis. The typical initial dosage for adults is 1 mcg daily, but it can range from 0.25 to 2 mcg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to alfacalcidol
In patients with hypercalcemia or evidence of vitamin D toxicity.

Cautions

In patients with kidney stones or heart disease. Regular monitoring of serum calcium is required.

Dose adjustment in renal failure: may be necessary, depending on the degree of impairment and the patient's response.

Dose adjustment in hepatic failure: No specific guidelines have been provided.

Pharmacokinetic parameters

As it's a prodrug, alfacalcidol is rapidly converted in the liver to calcitriol, the active form of vitamin D. Its metabolism and excretion then follow the pathways of endogenous vitamin D.

Drug interaction

Thiazide Diuretics: May increase the serum concentration of Alfacalcidol. This can lead to hypercalcemia.
Phosphate Binders: May decrease the absorption of Alfacalcidol.

Side effects

Common (more than 10%) Hypercalcemia, hypercalciuria.
Less common (1-10%) Nausea, headache, rash.
Rare but serious (less than 1%) Pancreatitis, cardiac arrhythmias.

Patient educations

• If you experience symptoms like persistent nausea, loss of appetite, or unusual tiredness, contact your healthcare provider.
• Regular blood tests will be needed to monitor your response, so keep all lab appointments.

Alfuzosin

ATC Code: G04CA01 Urologicals (Alpha-Adrenoreceptor Antagonists)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Alfuzosin is not indicated for use in female patients.

Indications and Dosage

• Benign prostatic hyperplasia: 2.5mg tid (max. 10mg daily); Elderly 2.5mg bid; Modified-release tablet 10mg once daily.

Off-label uses

Facilitates expulsion of ureteral stones.

Contraindications

Hypersensitivity to alfuzosin.

Cautions

Congenital or acquired QT interval prolongation.
Dose adjustment in renal failure: Initially 2.5mg bid then adjust dose according to response.
Dose adjustment in hepatic failure: Mild to moderate hepatic failure, initially 2.5mg daily may increase to 2.5mg bid according to response; In severe hepatic failure use of alfuzosin is contraindicated.

Dosage forms and trade names available in Iraq

- ALFUZOSIN 10mg tablet
  Xatral XL (Sanofi Aventis France).
- ALFUZOSIN 2.5mg tablet
  XATRAL (Sanofi Aventis France).
- ALFUZOSIN 5mg tablet
  XATRAL SR (Sanofi Aventis France).

Pharmacokinetic parameters

Absorption F=49%, food enhances absorption.
Distribution Vd=3.2 L/kg, 82-90%protein bound.
Metabolism Mostly metabolized by the liver (CYP3A4 enzyme system).
Elimination Renal elimination is 11% with half-life of 10 hours.

Drug interactions

Enzalutamide: Enzalutamide will decrease the level or effect of alfuzosin by affecting hepatic and intestinal enzyme CYP3A4 metabolism.
Ondansetron: alfuzosin and ondansetron both increase QTc interval, avoid with congenital long QT syndrome; ECG monitoring recommended with concomitant medications that prolong QT interval, electrolyte abnormalities, CHF, or bradyarrhythmias.
Sildenafil: Sildenafil is used to treat erectile dysfunction and sometimes high blood pressure using it with alfuzosin may lead to very low blood pressure, separate sildenafil more than 25mg from alpha blocker by 4hours.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Back pain; Bronchitis; Constipation; Dizziness; Dyspepsia; Fatigue; Headache; Impotence; Nausea; Pharyngitis; Sinusitis; Upper respiratory infection; Urinary tract infection.
Rare but serious (less than 1%) None.

Patient educations

Take after the same meal each day; Don't crush or chew alfuzosin tablets; Avoid tasks that require alertness, motor skills until response to drug is established.

Alglucosidase

ATC Code: A16AB07 Other Alimentary Tract and Metabolism Products (Enzymes)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Alglucosidase Alfa 50mg vial
Myozyme (Genzyme Netherland).

Indications and Dosage

• Pompe disease: By i.v. infusion, 1mg/kg/hour, may increase by 2mg/kg/hour every 30 minute if there is no sign of infusion associated reaction, not exceed 7mg/kg/hr.

Off-label uses

None.

Contraindications

None.

Cautions

Infusion associated reactions; Patients with compromised cardiac and respiratory function due to advanced Pompe disease; Pneumonia; Sepsis; Closely monitor patients who develop IgE to alglucosidase alfa; Regularly monitor IgG titers.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Administration i.v. results in complete bioavailability.

Distribution Vd=96±16ml/kg.

Metabolism Undetermined.

Elimination Renal elimination is 94-98% with half-life of 2.4±0.4 hours.

Drug interactions

No interactions studies have been performed because it is a recombinant human protein, alglucosidase alfa is an unlikely candidate for cytochrome P450 mediated drug-drug interactions.

Side effects

Common (more than 10%) Anemia; Bradycardia; Bronchiolitis; Catheter-related infection; Constipation; Cough; Diaper dermatitis; Diarrhea; Flushing; Gastroenteritis; GERD; Infusion reactions; Nasopharyngitis; O2 saturation decreased; Oral candidiasis; Otitis media; Pharyngitis; Pneumonia; Post-procedural pain; Pyrexia; Rash; Respiratory distress; Respiratory failure; Rhinorrhea; Tachycardia; Tachypnea; Urticaria; Vomiting.

Less common (1-10%) Bronchospasm; Blurred vision; Abdominal pain; Agitation; Dyspnea; Facial Erythema; Insomnia; Irritability; Pallor; Restlessness; Tremor; Vertigo; Coronary artery disease; Hypokalemia; Conjunctivitis.

Rare but serious (less than 1%) None.

Patient educations

Roll each vial gently do not shake.

Allopurinol

ATC Code: M04AA01 Antigout Preparations (Preparations Inhibiting Uric Acid Production)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- ALLOPURINOL 100mg tablet
  Hyporic (SDI Iraq), **Piloric** (Pioneer Iraq).
- ALLOPURINOL 300mg tablet
  Hyporic (SDI Iraq), **Piloric** (Pioneer Iraq).

Indications and Dosage

• Long term control „prophylaxis".
• Primary or secondary gout: Initially, 100mg once daily after food, maintenance dose according to plasma uric acid concentration, (max 900mg daily), started after control of acute attack.
• Recurrent uric acid and calcium oxalate calculi: 100mg once daily.
• Secondary hyperuricemia associated with cancer chemotherapy: 600mg-900mg daily in divided doses.

Off-label uses

Hematemesis caused by gastritis induced by nonsteroidal anti-inflammatory drugs; Pain from acute pancreatitis.

Contraindications

Hypersensitivity to allopurinol.

Cautions

Acute gout attack; Dehydration; Renal insufficiency; Thyroid disorders.
Dose adjustment in renal failure: CrCl 10-25ml/min: decrease dose to 200mg daily; CrCl less than 10ml/min: decrease dose to 100mg daily.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=80-90%, no effect of food on absorption.
Distribution Vd=1.6-2.4L/kg, less than 1% protein bound.
Metabolism Metabolized in liver (78%) and red blood cells.
Elimination Renal elimination is 80% with half-life of 2 hours, active metabolite (oxypurinol) has half-life of 15-25 hours.

Drug interactions

Captopril: Captopril increases toxicity of allopurinol by unspecified interaction mechanism.
Warfarin: Allopurinol may inhibits the metabolism of Warfarin, possibly enhances its anticoagulant effect.

Side effects

Common (more than 10%) None.
Less common (1-10%) Nausea; Rash; Renal failure; Vomiting.
Rare (less than 1%) Agranulocytosis; Aplastic anemia; Granulomatous hepatitis; Hepatotoxicity; Stevens Johnson syndrome; Thrombocytopenia; Toxic epidermal necrolysis.

Patient educations

May take 1 week or longer for full therapeutic effect; Maintain adequate hydration, drink 2500-3000 ml of fluid daily while taking drug; Avoid alcohol (may increase uric acid).

Note

Doses greater than 300mg should be given in divided doses.

Alprazolam

ATC Code: N05BA12 Psycholeptics (Benzodiazepine Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

• Anxiety: 0.25mg-0.5mg tid, (max 4mg daily in divided doses).
• Panic disorder: 0.5mg tid.

Off-label uses

Agoraphobia; Depression; Premenstrual syndrome.

Contraindications

Hypersensitivity to alprazolam; Narrow angle glaucoma; Labor and delivery; Myasthenia gravis; Sleep apnea; Chronic psychoses.

Cautions

History of attempted suicide or drug dependence; Elderly patients.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Reduce dose to 0.25mg daily.

Dosage forms and trade names available in Iraq

- ALPRAZOLAM 0.25mg tablet
  Xanax (Pfizer Belgium).
- ALPRAZOLAM 0.5mg tablet
  Xanax (Pfizer Belgium).
- ALPRAZOLAM 1mg tablet
  Xanax (Pfizer Belgium).

Pharmacokinetic parameters

Absorption F=80-90%, no effect of food on absorption.
Distribution Vd=0.9-1.2L/kg, 80% protein bound.
Metabolism Metabolized in the liver to alfa-hydroxyalprazolam.
Elimination Renal elimination is 80% with
full release 6 hours while extended release 11.3 hours.

Drug interactions

Clarithromycin: Clarithromycin will increase the level or effect of alprazolam by affecting hepatic and intestinal enzyme CYP3A4 metabolism, avoid or use alternate drug.
Oral contraceptive: Oral contraceptive reduce the clearance of alprazolam.

Side effects

Common (more than 10%) Ataxia; Lethargy; Somnolence; Weight gain; Change in appetite; Constipation; Fatigue; Decreased libido.
Less common (1-10%) Tachycardia; Palpitations; Nausea; Vomiting; Blurred vision; Confusion.
Rare (less than 1%) Seizures; Mania; Depression; Liver failure; Stevens Johnson syndrome.

Patient educations

Drowsiness usually disappears during continued therapy; Smoking reduces drug effectiveness; Sour hard candy, gum, sips of water may relieve dry mouth; Do not abruptly withdraw medication after long-term therapy; Avoid alcohol; Swelling of face, lips, tongue and throat may also occur.

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Date of issue	: 01.09.2023
Certificate period	: 3 years
Reissue date	: 02.09.2024
Certificate No	: KQ.2021.1861

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Date of first issue	: 03.09.2021
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Certificate period	: 3 years
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Certificate No	: IG.2023.1861

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Alprostadil

ATC Code: G04BE01 Urologicals (Drugs Used in Erectile Dysfunction)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Not relevant as it's not used in females.

Dosage forms and trade names available in Iraq

ALPROSTADIL 500µg (0.5mg/1ml ampoule)
PROSTINVR (Pfizer Belgium).

Indications and Dosage

•For erectile dysfunction, alprostadil is administered via intracavernosal injection or urethral suppository. Dose is individualized.

• For neonatal patent ductus arteriosus, it's given intravenously with the starting dose usually at 0.05-0.1 micrograms/kg/min.

Off-label uses

None

Contraindications

In men for whom sexual activity is inadvisable or contraindicated.
Men with sickle cell anemia.

Cautions

In individuals with underlying conditions that might be adversely affected by fluid overload or by an increase in blood pressure.
Dose adjustment in renal failure: No specific guidelines have been provided
Dose adjustment in hepatic failure: No specific guidelines have been provided

Pharmacokinetic parameters

Alprostadil is rapidly metabolized in the body, with an elimination half-life of less than 10 minutes.

Drug interaction

Antihypertensive Agents: May enhance the hypotensive effect of Alprostadil.
Vasodilators: Alprostadil may enhance the vasodilating effect of other vasodilators.

Side effects

Common (more than 10%) Penile pain, prolonged erection, or fibrosis at injection site (for erectile dysfunction use); fever, hypotension, apnea (for PDA use).
Less common (1-10%) Headache, dizziness, hematoma or rash at the injection site (for erectile dysfunction use); seizures, diarrhea, flushing (for PDA use).
Rare but serious (less than 1%) Penile curvature or hematoma, priapism (for erectile dysfunction use); bleeding or thrombocytopenia (for PDA use).

Patient educations

For men, it's important to report any unusual penile symptoms, prolonged erection, or pain.

Ambrisentan

ATC Code:C02KX02 ANTIHYPERTENSIVES (Antihypertensives for pulmonary arterial hypertension)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: It is not recommended during lactation.

Indications and Dosage

treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) Initiate treatment at 5 mg PO qDay, with or without tadalafil 20 mg PO qDay, At 4-week intervals, either ambrisentan or tadalafil dose can be increased, as needed and tolerated, not to exceed ambrisentan 10 mg/day or tadalafil 40 mg/day.

Off-label uses

No data available.

Contraindications

Hypersensitivity to ambrisentan or any component of the formulation, pregnancy, Idiopathic pulmonary fibrosis.

Cautions

patients with hepatic impairment, fluid retention, anemia, or hypotension, Decreased Sperm Counts, Coadministration with cyclosporine or CYP3A4 or CYP2C19 inhibitors.

Dose adjustment in renal failure: Caution is recommended.

Dose adjustment in hepatic failure: contraindicated in patients with moderate or severe hepatic impairment.

Dosage forms and trade names available in Iraq

Ambrisentan 5mg caplets

Ambritan (Sama Al Fayhaa Iraq)

Ambrisentan 10mg caplets

Ambritan (Sama Al Fayhaa Iraq)

Pharmacokinetic parameters

Absorption Well-absorbed after PO with approximately 65% bioavailability, Peak Plasma Time: 2 hr.

Distribution Extensively distributed; Ambrisentan is 99% plasma protein bound.

Metabolism Primarily hepatic metabolism via glucuronidation and oxidative pathways.

Elimination Mostly excreted in feces and urine; half-life is approximately 15 hours.

Drug interaction

- Coadministration with cyclosporine increases ambrisentan plasma concentrations.
- Coadministration with rifampin decreases ambrisentan plasma concentrations.

Side effects

Common (more than 10%): Peripheral edema, headache, nasal congestion, flushing.

Less common (1-10%): Anemia,dizziness, palpitations, Constipation, Abdominal pain.

Rare but serious (less than 1%): Hepatotoxicity, pulmonary edema, seizure.

Patient educations

- Report any new or worsening symptoms, especially swelling or difficulty breathing or eye disorders, to your healthcare provider promptly.
- Avoid pregnancy while taking ambrisentan and use effective contraception.

Amikacin

ATC Code: J01GB06 Antibacterials for Systemic Use (Other Aminoglycosides)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid; Breastfed infants should be monitored for amikacin associated colitis, diarrhea and candidiasis.

Dosage forms and trade names available in Iraq

AMIKACIN 100mg ampoule
AMIKACIN 500mg ampoule
KAMICIN (Pioneer Iraq).

Indications and Dosage

•Serious gram-negative bacterial infections resistant to gentamicin and other aminoglycosides: Administer by IM or IV infusion at a dose of 7.5mg/kg bid for up to 10 days (max. daily dose 1.5g).

• Acute prostatitis, acute pyelonephritis, urinary tract infection: Give by IV infusion, 15 mg/kg once daily (max. daily dose 1.5g).

Off-label uses

As part of 2nd line therapy from Mycobacterium avium complex lung disease.

Contraindications

Hypersensitivity to amikacin and other aminoglycosides.

Cautions

Preexisting renal impairment; Auditory or vestibular impairment; Hypocalcemia; Elderly; Patients with neuromuscular disorders; Dehydration; Concomitant use of neurotoxic or nephrotoxic medications.

Dose adjustment in renal failure: CrC1 10–50 ml per minute increase dosing intervals to every 24 hours; CrC1 less than 10 ml per minute increase dosing intervals to every 48–72 hours.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%.

Distribution Vd=0.25 L/kg, <11% protein bound.

Metabolism The structure of amikacin has been modified to reduce enzymatic deactivation, reducing bacterial resistance.

Elimination Renal elimination accounts for 90% of the drug, with half-life of 2-4 hours.

Drug interactions

Furosemide: Coadministration of furosemide and amikacin increased risk of ototoxicity and nephrotoxicity.

Side effects

Common (more than 10%) None.

Less common (1-10%) Nephrotoxicity; Neurotoxicity; Ototoxicity.

Rare but serious (less than 1%) Arthralgia; Drug fever; Eosinophilia; Headache; Hypotension; Nausea; Paresthesia; Rash; Tremor; Vomiting; Weakness.

Patient educations

Complete the full-course of amikacin treatment; space the doses evenly; IM injection may cause discomfort; report any hearing, visual, balance, urinary problems, even after treatment completion.

Aminophylline

ATC Code: R03DA05 Drugs for Obstructive Airway Diseases (Xanthines)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

AMINOPHYLLINE 225mg tablet

AMINOPHYLLINE 250mg/10ml ampoule

Indications and Dosage

• Acute bronchospasm: Loading i.v. injection in patients not currently taking aminophylline, 5mg-7mg/kg, not to exceed 25mg/min; Loading i.v. injection in patients currently taking aminophylline, 6mg-7mg/kg infused over 20 min; Maintenance i.v. injection 0.4mg-0.6mg/kg/hr or orally 225mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to xanthine compounds or ethylenediamine; Seizure disorders.

Cautions

Cardiac arrhythmia; Acute pulmonary edema; Peptic ulcer; Hypothyroidism; Glaucoma; Diabetes; Hypertension; Severe hypoxemia; History of seizure; Active influenza infection.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: After loading dose, 0.39mg/kg/hour i.v. for next 12 hours, then 0.08mg-0.16mg/kg/hour.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=0.3 to 0.7L/kg, 60% protein bound.

Metabolism Hepatic via demethylation (CYP1A2) and hydroxylation (CYP2E1 and CYP3A4).

Elimination Renal elimination is 10% with half-life of 8 hours for nonsmoker, and 4-5 hours for smoker. Differences in the half-life are important because the toxic dose is close to the therapeutic dose.

Drug interactions

Allopurinol: Allopurinol increases levels of aminophylline by decreasing metabolism.

Smoking: Smoking can

Side effects

Diarrhea; Exfoliative dermatitis; Flutter; Headache; Hypercalcemia; Insomnia; Irritability; Nausea; Restlessness; Seizure; Skeletal muscle tremors; Tachycardia; Urinary retention; Vomiting.

Patient educations

Drink plenty of fluids to decrease the thickness of lung secretions; Avoid excessive use of caffeinated products, such as chocolate, cocoa, cola, coffee, and tea; Smoking and a high protein, low carbohydrate diet may decrease the theophylline level.

Amiodarone

ATC Code: C01BD01 Cardiac Therapy (Antiarrhythmics, Class III)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Ventricular arrhythmia: 800mg-1600mg daily for 1-3 weeks, titrate down to 600mg-800mg daily for 1 month, then maintenance 400mg-600mg daily give as single dose or bid.

Off-label uses

Atrial fibrillation; Paroxysmal supraventricular tachycardia.

Contraindications

Hypersensitivity to amiodarone; Bradycardia induced syncope; second and third degree AV block; severe sinus node dysfunction; Sinus bradycardia; Cardiogenic shock.

Cautions

Amiodarone may prolong QT interval; Thyroid disease; Electrolyte imbalance; Hypotension; Left ventricular dysfunction; Pulmonary disease; Patients taking warfarin; surgical patients.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Should be considered.

Dosage forms and trade names available in Iraq

AMIODARONE 50mg/ml (3ml ampoule)
Amiocord (Pioneer Iraq).

AMIODARONE 200mg tablet
Amiocord (Pioneer Iraq).

Pharmacokinetic parameters

Absorption F=50%, food increase rate and extent of absorption.

Distribution Vd=66L/kg, 96% protein bound.

Metabolism Metabolized in the liver.

Elimination Renal elimination with a half-life of 40-55 days.

Drug interactions

Fingolimod: Fingolimod increases effects of amiodarone by pharmacodynamic synergism, increased risk of bradycardia, AV block, and torsade de pointes, concomitant use is contraindicated.

Side effects

Common (more than 10%): Hypotension; Dizziness; Headache; Malaise; Fatigue; Impaired memory; Involuntary movement; Sleep disturbances; Photosensitivity; Hypothyroidism; Constipation; Anorexia.

Less common (1-10%): CHF; Bradycardia; Sinus arrest; AV block; SA node dysfunction; Hyperthyroidism; Hepatitis; Cirrhosis; Visual disturbances; Optic neuritis.

Rare (less than 1%): None.

Patient educations

Protect against photosensitivity reaction on skin exposed to sunlight, bluish skin discoloration gradually disappears when drug is discontinued; Do not abruptly discontinue medication; Restrict salt, alcohol intake. Recommend ophthalmic exams every 6 months.

Amisulpride

ATC Code: N05AL05 Psycholeptics (Anesthetics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

- Amisulpride 200mg tablet
  Percepta (UPM Jordan).
- Amisulpride 50mg tablet
  Percepta (UPM Jordan).

Indications and Dosage

• Acute and chronic schizophrenic disorders, characterized by positive symptoms with delusions, hallucinations and negative symptoms (deficit syndrome) with blunted affect, emotional and social withdrawal: 200mg-400mg bid and not exceed 1200mg daily.
• Acute psychotic episodes: 200mg-400mg bid (max 1200mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to amisulpride.

Cautions

Epilepsy; Parkinson‘s disease.
Dose adjustment in renal failure: CrCl 30-60ml per minute use half of the usual dose.; CrCl less than 10-29ml per minute use one-third of the usual dose.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=48%.
Distribution Vd=5.8 L/kg, 25-30%protein bound.
Metabolism Amisulpride undergoes minimal metabolism.
Elimination Renal elimination is 74% with half-life of 12 hours.

Drug interactions

Amitriptyline: The risk or severity of QTc prolongation can be increased when amitriptyline is combined with amisulpride.
Cyproheptadine: Amisulpride may increase the central nervous system depressant activities of cyproheptadine.
Digoxin: The risk or severity of QTc prolongation can be increased when digoxin is combined with amisulpride.
Duloxetine: The risk or severity of adverse effects can be increased when duloxetine is combined with amisulpride.
Haloperidol: Haloperidol may increase the antipsychotic activities of amisulpride.

Side effects

Common (more than 10%) None.
Less common (1-10%) Increased blood prolactin; Chills; Hypokalemia; Procedural hypotension; Abdominal distension; Infusion site pain.
Rare but serious (less than 1%) None.
in dose of about 5mg, also indicated for the treatment of postoperative nausea and vomiting in dose of about 10mg.

Amitriptyline

ATC Code: N06AA09 Psychoanaleptics (Non-Selective Monoamine Reuptake Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding in doses up to 150mg/day.

Indications and Dosage

•Depression: 25mg–50mg at bedtime may increase to 100mg-300mg daily in divided doses, elderly 10mg tid and 25mg at bedtime.

Off-label uses

Agoraphobia; Depression; Premenstrual syndrome.

Contraindications

Hypersensitivity to amitriptyline; Acute recovery period after myocardial infarction.

Cautions

Bipolar disorder; Cardiovascular disease; Closed angle glaucoma; Elderly patients; Hyperthyroidism; Increased intraocular pressure; Paranoia; Prostatic hypertrophy; Schizophrenia; Seizures; Urinary retention.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Start with low initial dose and increase as needed and tolerated.

Dosage forms and trade names available in Iraq

- Amitriptyline 10mg tablet
  APO-Amitriptyline (Apotex Canada).
- Amitriptyline 25mg tablet
  APO-Amitriptyline (Apotex Canada).
- Amitriptyline 50mg tablet
  APO-Amitriptyline (Apotex Canada).

Pharmacokinetic parameters

Absorption F=100%, food has no effect on absorption.
Distribution Vd is highly variable.
Metabolism Extensive hepatic metabolized.
Elimination Renal elimination is minimal with a half-life of 9-27 hr.

Drug interactions

Indapamide: Amitriptyline and indapamide both increase QT interval, contraindicated.
Selegiline: Selegiline and amitriptyline both increase serotonin levels, concurrent use or use within 14 days of selegiline treatment is contraindicated.

Side effects

Agitation; Agranulocytosis; Alopecia; Anorexia; Anxiety; Blurred vision; Constipation; Diarrhea; Dizziness; Dry mouth; ECG changes; Extrapyramidal symptoms; Fatigue; Hypertension; Insomnia; Ocular pressure increased; Orthostatic hypotension; Palpitation; Paresthesia; Photosensitivity; Rash; Sexual dysfunction; Stomatitis; Vomiting; Weakness; Weight gain.

Patient educations

Tolerance to postural hypotension, sedative and anticholinergic effects usually develops during early therapy; Maximum therapeutic effect may be noted in 2–4 weeks; Sensitivity to sun may occur; Report visual disturbances; Do not sudden discontinue medication; Avoid alcohol; Sips of water may relieve dry mouth.

Amlodipine

ATC Code: C08CA01 Calcium Channel Blockers (Dihydropyridine Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

•Hypertension, Stable angina, Vasospastic angina (previously referred to as Prinzmetal or variant angina): 5mg single dose daily, (max 10mg daily), elderly 2.5mg once daily.

Off-label uses

Diabetic nephropathy; Left ventricular hypertrophy; Raynaud's phenomenon; Silent myocardial ischemia.

Contraindications

Hypersensitivity to amlodipine.

Cautions

Aortic stenosis; Children; Elderly patients; Heart failure.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Reduce dose to 2.5mg daily.

Dosage forms and trade names available in Iraq

- AMLODIPINE 2.5mg tablet
- AMLODIPINE 10mg tablet
- AMLODIPINE 5mg capsule
  AMLONEER (Pioneer Iraq), **DUACTIN** (Pharma International Jordan).
- AMLODIPINE 5mg tablet
  Amlodepen (AL-Kindi Iraq), **SAMADIPINE** (SDI Iraq).

Pharmacokinetic parameters

Absorption F=64-90%, food has no effect on absorption.
Distribution Vd=21L/kg, ~93% protein bound.
Metabolism Hepatic metabolism ~90%.
Elimination Renal elimination is 10% with half-life of 30-50 hr.

Drug interactions

Carbamazepine: Coadministration may significantly decrease the plasma concentrations and pharmacologic effects of amlodipine. Rifampin: Rifampin may decrease effect of amlodipine.
Simvastatin: Amlodipine may increase level of simvastatin and may increase the risk of myopathy or rhabdomyolysis; simvastatin dose should not exceed 20 mg/day if coadministered with amlodipine. Clopidogrel: amlodipine may result in decreased antiplatelet effect of clopidogrel. Clarithromycin: may decrease the plasma concentration of amlodipine.

Side effects

Common (more than 10%) Edema.
Less common (1-10%) palpitations; Flushing; Headache; Fatigue; Dizziness; Male sexual disorder; Pruritus; Skin rash; Nausea; Abdominal pain; Muscle cramps; weakness; dyspnea.
Rare (less than 1%) Arrhythmia; Paresthesia; Tremor; Vertigo; Anorexia; Constipation; Dysphagia; Arthralgia; Dyspnea; Epistaxis; Angioedema; Dry mouth; Hyperglycemia; Leukopenia; Purpura; Thrombocytopenia.

Patient educations

Do not abruptly discontinue medication; Compliance with therapy regimen is essential to control hypertension; Avoid tasks that require alertness, motor skills until response to drug is established.

Amoxicillin

ATC Code: J01CA04 Antibacterials for Systemic Use (Penicillins with Extended Spectrum)

Pregnancy category:

FDA A **B** C D X N

TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding

Dosage forms and trade names available in Iraq

- Amoxicillin 125mg/5ml susp
- Amoxicillin 250mg/5ml susp
- Amoxicillin 250mg cap
- Amoxicillin 500mg cap
- Amoxicillin 250mg vial
- Amoxicillin 500mg vial
- Amoxicillin sodium 1g vial

Indications and Dosage

• Acute oral infection: 250mg-500mg tid for 5 days, or as prescribed by the dentist.
• Acute otitis media: 500mg-1g bid for 10 days.
• Ear, nose, and throat infection, infection of skin and subcutaneous tissue, infection of genitourinary system: 500mg-1g bid for 10 days.
• H. pylori gastrointestinal tract infection: 1 g bid with PPI.
• Lower respiratory tract infection: 1g tid for 10 days.
• Pharyngitis, tonsillitis: 250mg-500mg tid for 10 days.

Off-label uses

Chlamydia trachomatis infection in pregnant; Prophylaxis of bacterial endocarditis.

Contraindications

Hypersensitivity to penicillin.

Cautions

History of allergy to cephalosporins; Infectious mononucleosis; Asthma.

Dose adjustment in renal failure: CrCl 10-30ml/min: 250mg-500mg bid; CrCl less than 10ml/min: 250mg-500mg once daily.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=85%, food has no effect on absorption.
Distribution Protein bound 17-20%.
Metabolism Partially metabolized in the liver.
Elimination Renal elimination is 50-70% with a half-life of 1-2 hr.

Drug interactions

Allopurinol: Amoxicillin may increase incidence of allopurinol rash.
Methotrexate: Amoxicillin may increase blood levels and side effects of methotrexate.
Tetracycline: Tetracycline is a bacteriostatic antibiotic that can interfere with amoxicillin.

Side effects

Common (more than 10%) Diarrhea; Nausea.
Less common (1-10%) Skin rash; Vomiting; Headache.
Rare but serious (less than 1%) Severe hypersensitivity; Renal failure; Hepatic failure; Pancytopenia.

Patient educations

Continue antibiotic for the full length of treatment; Take with meals if gastrointestinal upset occurs.

Note

Amoxicillin may be used as a prophylactic measure or as a therapeutic measure.

Amphotericin B

ATC Code: J02AA01 Antimycotics for Systemic Use (Antibiotics)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X **N**

Lactation: No data available.

Dosage forms and trade names available in Iraq

Amphotericin B 50mg vial
Am Bisome (Gilead Ireland).
Amphotericin B 100mg vial
Abelcet (Sigma-Tau USA).

Indications and Dosage

• Treatment of systemic mycoses caused by aspergillus, blastomyces or any type of invasive fungal infections; Empiric treatment of fungal infection in febrile neutropenic patients; Treatment of cryptococcal meningitis in HIV-infected patients; Treatment of visceral leishmaniasis: 3mg-5mg/kg/day (max 6mg/kg/day).

Off-label uses

Serious candida infections; Treatment of systemic histoplasmosis infection.

Contraindications

Hypersensitivity to amphotericin B.

Cautions

Concomitant use with other nephrotoxic drugs; Avoid rapid infusion (risk of arrhythmias);Renal impairment.
Dose adjustment in renal failure: Dosage modification is necessary only in extreme renal dysfunction.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Widely distributed to all tissues except the CNS, 90%protein bound.
Metabolism Elimination is mainly via slow hepatic metabolism.
Elimination Renal elimination is very prolonged, detectable in urine up to 7 weeks after discontinuation with half-life of 15 days.

Drug interactions

Amikacin: Amikacin and amphotericin B both increase nephrotoxicity and ototoxicity.

Side effects

Common (more than 10%) Abdominal pain; Anemia; Anorexia; Anxiety; Back pain; Bilirubinemia; Blood transfusion reaction; Chest pain; Chills; Constipation; Cough; Diarrhea; Dyspnea; Headache; Hyperglycemia; Hypertension; Hypotension; Infusion reaction; Insomnia; Leukopenia; Nausea; Peripheral edema; Phlebitis; Tachycardia; Thrombocytopenia; Vomiting; Weakness.
Less common (1-10%) Abnormal thinking; Acidosis; Agitation; Alopecia; Arthralgia; Dizziness; Mucositis; Petechia; Rash; Seizure; Stomatitis.
Rare but serious (less than 1%) None.

Patient educations

Prolonged therapy (weeks or months) is usually necessary; Fever reaction may decrease with continued therapy; Muscle weakness may be noted during therapy (due to hypokalemia).

Ampicillin

ATC Code: J01CA01 Antibacterials for Systemic Use (Penicillins with Extended Spectrum)

Pregnancy category:

FDA A **B** C D X N

TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Susceptible infections: Orally, 500mg-1g qid; By i.m. or i.v. injection, 500mg qid.

• Endocarditis: i.v. infusion, 2g qid.

Off-label uses

Surgical prophylaxis for orthopedic surgeries.

Contraindications

Hypersensitivity to ampicillin or any penicillin; Infections caused by penicillinase producing organisms.

Cautions

Acute and chronic Lymphocytic leukaemia.

Dose adjustment in renal failure: CrCl 10-50ml per minute increase interval to every 6-12 hours; CrCl less than 10ml per minute increase interval to every 12-24 hours.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Ampicillin 125mg/5ml suspension

Epicocillin (Eipico Egypt).

Ampicillin 250mg/5ml suspension

Acampin (ACAI Iraq).

Ampicillin 250mg capsule

Apcillin (Ajanta India), Etc.

Ampicillin 500mg capsule

Acampin (ACAI Iraq).

Ampicillin 250mg vial

Acampin (ACAI Iraq), **Ampicillin** (SDI Iraq).

Ampicillin 500mg vial

Ampicillin Panpharma (Panpharma France)

Pharmacokinetic parameters

Absorption F=30–40%.

Distribution protein binding is 15-20%, with enhanced penetration through blood-brain barrier and adequate CSF concentration is achieved due to inflamed meningitis.

Metabolism Variably metabolized by the liver.

Elimination Renal elimination is about 85% with half-life of 1-2 hours.

Drug interactions

Aspirin: Ampicillin and aspirin increases levels of the other by plasma protein binding competition.

Esomeprazole: Esomeprazole will decrease the level or effect of ampicillin by increasing gastric pH.

Spironolactone: Ampicillin increases effects of spironolactone by unspecified interaction mechanism.

Warfarin: Ampicillin potentially alters the anticoagulant effect of Warfarin, monitoring INR is advisable.

Side effects

Agranulocytosis; Anaphylaxis; Anemia; Aspartate aminotransferase increased; Black hairy tongue; Diarrhea; Enterocolitis; Eosinophilia; Erythema multiforme; Exfoliative dermatitis; Fever; Glossitis; Hemolytic anemia; Interstitial nephritis; Laryngeal stridor; Leukopenia; Nausea; Oral candidiasis; Pseudomembranous colitis; Rash; Seizure; Serum sickness-like reaction; Stomatitis; Thrombocytopenia purpura; Urticaria; Vomiting.

Patient educations

Continue antibiotic for full length of treatment; Space doses evenly; More effective if taken 1 hour before or 2 hours after food; Discomfort may occur with i.m. injection.

Anastrozole

ATC Code: L02BG03 Endocrine Therapy (Aromatase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

•Advanced breast cancer in postmenopausal women: 1mg once daily.

Off-label uses

Recurrent or metastatic endometrial or uterine cancers; Ovarian cancer.

Contraindications

Hypersensitivity to anastrozole.

Cautions

Preexisting ischemic cardiac disease; Osteopenia; Hyperlipidemia. May increase fall risk with fractures during therapy in patients with history of osteoporosis.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Anastrozole 1mg tab
Arimidex (ASTRAZENECA USA).

Pharmacokinetic parameters

Absorption F=80%, minimal food effect on absorption.
Distribution Vd=300-500L, 40% protein bound.
Metabolism Metabolized in liver 85%.
Elimination Renal elimination is 10% with a half-life of 50 hr.

Drug interactions

Estradiol: Estradiol decreases effects of anastrozole by antagonism.
Tamoxifen: Tamoxifen reduce blood level of anastrozole without increasing treatment benefit, these drugs should not be taken together.

Side effects

Common (more than 10%): Edema; Hypertension; Vasodilation; Nausea; Vomiting; Arthralgia; Arthritis; Osteoporosis; Hot flashes; Depression; GI tract disorder; Mood disturbance; Pain.
Less common (1-10%): Angina; Chest pain; Thrombophlebitis; Alopecia; Pruritus; Rash; Weight gain; Hyperlipidemia; Xerostomia; Thromboembolic events; Ischemic cardiovascular disease; Diarrhea; Elevated serum cholesterol; Anxiety; Cataract; Cyst; Deep vein thrombosis.
Rare (less than 1%): Myocardial infarction; Endometrial cancer; Cerebrovascular accident.

Patient educations

Better take before food; Notify physician if nausea and hot flashes become unmanageable; Use a condom or other non-hormonal contraceptive while taking anastrozole; Patients may need routine bone density tests while taking anastrozole.

DUBAI

Dubai Pharmaceutical Industries

Your Pathway to Wellness

شركة دبي للصناعات الدوائية هي شركة أدوية مؤسسة بشكل وثيق ومدارة باحتراف، وتقوم بتصنيع أشكال صيدلانية عديدة بجرعات مختلفة. سجلت شركة دبي نمواً ممتازاً لتصل إلى مكانتها الحالية كشركة رائدة في مجال الصناعة الدوائية. تتمتع الشركة بخبرة تصنيع غنية مدتها 11 سنة.وتحرص شركة دبي على تطبيق مواصفات هيئة الغذاء والدواء الأمريكية والأوروبية وكذلك اتباع معايير وممارسات التصنيع الجيدة (cGMP). تهدف شركة دبي الى تلبية توقعات العملاء للحصول على الأدوية الفعالة والآمنة وعالية الجودة وبأسعار مناسبة. تمتلك الشركة وحدات تصنيع لأشكال صيدلانية متعددة (حبوب ، سوائل)، تحضيرات شبه صلب (مرهم ، كريم)ومعلقات جافة. وتسعى الشركة الى اضافة خطوط انتاج متعددة ومتنوعة لتغطي نسبة كبيرة من متطلبات سوق العراق الدوائي .جميع انشطة الشركة في موقعها الرئيسي الذي يقع في المنطقة الصناعية ، سامراء - صلاح الدين - العراق.

Dubai Pharmaceutical Industries is a closely established and professionally managed pharmaceutical company, manufacturing many pharmaceutical forms in various dosages. Dubai pharma has recorded excellent growth to reach its current position as a leader in the pharmaceutical industry. The company has 11 years of rich manufacturing experience. Dubai pharma is keen to apply the specifications of the US and European Food and Drug Administration as well as follow good manufacturing standards and practises (cGMP). Dubai pharma aims to meet customer expectations for effective, safe and high quality medicines at reasonable prices. The company has manufacturing units for multiple pharmaceutical forms (tablets, liquids), semi-solid preparations (ointment, cream) and dry suspensions. The company seeks to add multiple and varied production lines to cover a large proportion of the requirements of the Iraqi pharmaceutical market. All the company's activities are in its main location, which is located in the industrial zone, Samarra - Salah al-Din - Iraq.

Apixaban

ATC Code: B01AF02 Antithrombotic Agents (Direct Factor Xa Inhibitors)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 **C** D X N

Lactation: No data available.

Indications and Dosage

• Prevention of stroke and systemic embolism in patients with nonvalvular AF: 5mg bid.

Off-label uses

Prophylaxis of DVT following hip or knee replacement surgery (orally 2.5mg 12-24 hours after surgery).

Contraindications

Hypersensitivity to apixaban; Active pathologic bleeding.

Cautions

Prosthetic heart valve, Rheumatic heart disease.
Dose adjustment in renal failure: Serum creatinine 1.5mg/dL or greater, age 80 years or older, body weight 60 kg or less: reduce dose to 2.5 mg bid.
Dose adjustment in hepatic failure: Severe impairment: Not recommended.

Dosage forms and trade names available in Iraq

- APIXABAN 2.5mg tablet
  Eliquis (Pfizer Ireland).
- APIXABAN 5mg tablet
  Eliquis (Pfizer Ireland).

Pharmacokinetic parameters

Absorption F=50%, food has no effect on absorption.
Distribution Vd=21L, 87% protein bound.
Metabolism Metabolized in the liver.
Elimination Renal elimination is 27% with a half-life of 9-14 hours.

Drug interactions

NSAIDs: NSAIDs increased antiplatelet activity of apixaban, monitor for bleeding.
Warfarin: increased anticoagulant effects, avoid concurrent administration.

Side effects

Common (more than 10%) Bleeding.
Less common (1-10%) Nausea.
Rare (less than 1%) Allergic reaction; Hypotension.

Patient educations

Avoid alcohol, aspirin, NSAIDs; Consult physician before surgery, dental work; Use electric razor, soft toothbrush to prevent bleeding; Report blood tinged mucus from coughing, heavy menstrual bleeding, headache, vision problems, weakness, abdominal pain, frequent bruising, bloody urine or stool, joint pain or swelling.

Notes

If elective surgery or invasive procedures with moderate or high risk for bleeding, discontinue apixaban at least 24-48hr prior to procedure.

Aprepitant

ATC Code: A04AD12 Antiemetics and Antinauseants (Other Antiemetics)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Enters breast milk/not recommended

Dosage forms and trade names available in Iraq

Aprepitant 125mg hard capsule
Emend (MSD Ireland).

Indications and Dosage

• Prevention of chemotherapy-induced nausea and vomiting: Oral: 125 mg on Day 1, then 80 mg on Days 2-3

• Prevention of postoperative nausea and vomiting: Oral: 40 mg within 3 hours prior to induction of anesthesia

Off-label uses

Treatment of chronic nausea in palliative care patients.

Contraindications

Hypersensitivity to aprepitant or any component of the formulation.

Cautions

In patients with severe hepatic impairment. Monitor for adverse reactions if used with strong CYP3A4 inhibitors or inducers.

Dose adjustment in renal failure: No dose adjustment is necessary.

Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption Well absorbed from the gastrointestinal tract.

Distribution Highly protein-bound (approximately 95%).

Metabolism Metabolized primarily by CYP3A4.

Elimination Primarily fecal, with a half - life of approximately 9-13 hours.

Drug interaction

CYP3A4 inducers (e.g., rifampin): Can significantly decrease aprepitant exposure, reducing its efficacy.

CYP3A4 substrates (e.g., midazolam): Aprepitant can increase plasma concentrations of these drugs, potentially leading to toxicity.

Side effects

Common (more than 10%): Fatigue, diarrhea, dyspepsia

Less common (1-10%): Constipation, hiccups, loss of appetite

Rare but serious (less than 1%): Serious allergic reactions, including anaphylaxis and Stevens-Johnson syndrome

Patient education

Report any serious side effects such as rash or severe abdominal pain to your doctor immediately.

Aripiprazole

ATC Code: N05AX12 Psycholeptics (Other Antipsychotics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Excretion in milk unknown/use caution

Dosage forms and trade names available in Iraq

- Aripiprazole 10mg tablet
  Arpenia (Tabuk KSA).
- Aripiprazole 15mg tablet
  Arpenia (Tabuk KSA).

Indications and Dosage

• Schizophrenia: Oral: Initial: 10-15 mg/day; can increase based on response and tolerability up to 30 mg/day

• Bipolar disorder: Oral: Initial: 15 mg/day as monotherapy or 10 mg/day as adjunctive therapy; can increase based on response and tolerability up to 30 mg/day

Off-label uses

Depression (as adjunctive therapy), agitation associated with autism, Tourette syndrome.

Contraindications

Hypersensitivity to aripiprazole

Cautions

In patients with Parkinson disease, a history of seizures, cardiac disease, or risk factors for stroke; In patients at risk of pneumonia or predisposed to hypotension.

Dose adjustment in renal failure: No adjustment is necessary.

Dose adjustment in hepatic failure: Use with caution, initial dose 10 mg/day; maximum: 30 mg/day.

Pharmacokinetic parameters

Absorption Well absorbed with peak plasma concentrations occurring within 3-5 hours; the absolute oral bioavailability is 87%

Distribution Volume of distribution (Vd) is 4.9 L/kg, with 99% protein bound

Metabolism Primarily hepatic, via CYP2D6 and CYP3A4

Elimination Excreted in urine (27%) and feces (60%), with a half-life of 75 hours.

Drug interaction

Strong CYP2D6 inhibitors (e.g., fluoxetine, quinidine): Can increase aripiprazole concentrations.

Strong CYP3A4 inducers (e.g., carbamazepine): Can decrease aripiprazole concentrations.

Side effects

Common (more than 10%): Akathisia; headache; anxiety; insomnia; constipation; nausea and vomiting; and increasing weight.

Less common (1-10%): Dizziness; restlessness; tremor; rash; fatigue; xerostomia; rhinitis; myalgia; blurred vision; and abdominal discomfort.

Rare but serious (less than 1%): Neuroleptic malignant syndrome; tardive dyskinesia; stroke; seizure; and dysphagia.

Patient education

• Do not abruptly discontinue, withdrawal symptoms may occur.

• Immediately report uncontrolled movements of the face, tongue, or other parts of body.

Arsenic Trioxide

ATC Code: L01XX27 Antineoplastic Agents (Other Antineoplastic Agents)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not known whether this drug is excreted in human milk, use is not recommended.

Indications and Dosage

• Acute promyelocytic leukemia (APL), relapsed or refractory: IV: 0.15 mg/kg/day until bone marrow remission; do not exceed 60 doses

Off-label uses

None

Contraindications

Hypersensitivity to arsenic trioxide or any component of the formulation.

Cautions

Closely monitor electrolyte levels, QTc interval, and for symptoms of differentiation syndrome and leukocytosis.

Dose adjustment in renal failure: No specific guidelines; use with caution.

Dose adjustment in hepatic failure: Use with caution; monitor hepatic function tests.

Dosage forms and trade names available in Iraq

Arsenic Trioxid 10mg/10ml ampoule
Leusenox (Kocak Farma Turkey).

Pharmacokinetic parameters

Absorption Complete
Distribution Widely distributed, enters cells via aquaglyceroporins.
Metabolism Partially by hepatic methyltransferases, also in other tissues
Elimination Predominantly in urine, with a half-life of 10-14 hours.

Drug interactions

Other QTc-prolonging agents (like amiodarone, sotalol): May increase the risk of serious arrhythmias.
Drugs that may affect electrolyte balance (like diuretics): May increase the risk of electrolyte abnormalities.

Side effects

Common (more than 10%): Fatigue, nausea, diarrhea, QTc prolongation
Less common (1-10%): Headache, peripheral edema, dyspnea
Rare but serious (less than 1%): Differentiation syndrome, serious cardiac arrhythmias

Patient education

• Report any signs of cardiac abnormalities, like chest pain or palpitations.
• Report any signs of differentiation syndrome, such as fever, difficulty breathing, weight gain, or swelling.

Asparaginase

ATC Code: L01XX02 Antineoplastic Agents (Other Antineoplastic Agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Not known whether asparaginase is excreted in human milk, caution advised.

Dosage forms and trade names available in Iraq

L-Asparaginase 10000 IU inj.
Asparaginase (Medac Germany),

Indications and Dosage

Asparaginase is indicated for use as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL). Typical dosage is 6000 IU/m2 IM or IV three times a week after induction of remission.

Off-label uses

Treatment of non-Hodgkin's lymphoma, but these uses are not standard or universally accepted.

Contraindications

Known hypersensitivity to asparaginase or any of its components history of pancreatitis, severe hepatic impairment, severe thrombosis.

Cautions

thrombosis, hemorrhage, hyperglycemia, and pancreatitis. It also has potential for severe allergic reactions.

Dose adjustment in renal failure: No guidelines available; use with caution.

Dose adjustment in hepatic failure: Use is contraindicated in severe hepatic impairment; monitor liver function regularly.

Pharmacokinetic parameters

Information regarding specific pharmacokinetic parameters such as bioavailability, volume of **distribution**, **metabolism**, **elimination**, and half-life is not readily available due to the drug's complex biochemical nature.

Drug interaction

Methotrexate: Asparaginase may decrease the effect of methotrexate by reducing its cellular uptake. Monitor therapy.

Vincristine: Concurrent use can potentiate the neurotoxicity of Vincristine. Monitor closely for symptoms of neuropathy.

Side effects

Common (more than 10%): Allergic reactions, hyperglycemia, elevated liver enzymes, coagulopathy.

Less common (1-10%): Pancreatitis, CNS thrombosis, seizures, hepatotoxicity.

Rare but serious (less than 1%): Severe allergic reactions, severe pancreatitis, severe thrombotic events, hemorrhage.

Patient education

Inform your doctor immediately if you experience signs of an allergic reaction, severe nausea, or unusual bleeding/bruising.

2. This medication may affect blood sugar control. Monitor your blood sugar regularly if you have diabetes.
3. Always keep your scheduled lab and doctor appointments to monitor your condition.

Atenolol

ATC Code: C07AB03 Beta Blocking Agents (Beta Blocking Agents, Selective)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Clinically significant bradycardia has occurred in breastfed infants.

Indications and Dosage

- Hypertension: 25-50mg once daily.
- Angina: 50mg twice daily.
- Arrhythmias: 50-100mg once daily.
- Migraine prophylaxis: 50-200mg daily in divided doses.

Off-label uses

Arrhythmia; Thyrotoxicosis.

Contraindications

Hypersensitivity to atenolol; Cardiogenic shock; Uncompensated heart failure; Second or third degree heart block; Sinus bradycardia; Sinus node dysfunction; Pulmonary edema.

Cautions

Elderly; Peripheral vascular disease; Diabetes; Thyroid disease; Bronchospastic disease; Myasthenia gravis; Psychiatric disease.

Dose adjustment in renal failure: CrCl 15-35ml/min: max dose 50mg once daily; CrCl less than 15ml/min: max dose 50mg once daily.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- ATENOLOL 25mg tablet
  TENORDIN (SDI Iraq).
- ATENOLOL 50mg tablet
  TENORMIN (AstraZeneca UK).
- ATENOLOL 100mg tablet
  TENORMIN (AstraZeneca UK).

Pharmacokinetic parameters

Absorption F=50%, food decreases AUC by 20%.
Distribution Vd=50-75L, less than 5% protein bound.
Metabolism Not metabolized.
Elimination Renal elimination is 40-50% and 50% in feces as unchanged drug with a half-life of 6-7 hr.

Drug interactions

Furosemide: Furosemide may increase hypotensive effect of atenolol.
Lisinopril: Lisinopril may increase hypotensive effect of atenolol.
NSAIDs: NSAIDs may decrease anti-hypertensive effect of atenolol.

Side effects

Common (more than 10%): Bradyarrhythmias; Cold extremities; Dizziness; Fatigue; Hypotension; Depression.
Less common (1-10%): Bronchospasm; Dyspnea; Somnolence; Sexual dysfunction.
Rare (less than 1%): Heart failure; Pulmonary embolism.

Patient education

Do not abruptly discontinue medication; Monitor blood glucose carefully in diabetic patients (may mask signs of hypoglycemia); Therapeutic antihypertensive effect noted in 1–2 weeks; Restrict salt, alcohol intake.

Atezolizumab

ATC Code: L01FF05 ANTINEOPLASTIC AGENTS (MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 C **D** X

Lactation: Contraindicated And Avoid For At Least 5 Months After The Last Dose.

Dosage forms and trade names available in Iraq

Atezolizumab 1200mg/ 20ml Vial

Tecentriq (Roche Germany)

Indications and Dosage

•Non-Small Cell Lung Cancer: 1200 mg IV q3Weeks. Small Cell Lung Cancer: 1200 mg IV on Day 1 q3Weeks.

•Hepatocellular Carcinoma: Indicated in combination with bevacizumab for unresectable or metastatic(HCC), Atezolizumab 1200 mg IV on Day 1 (administered before bevacizumab), plus Bevacizumab 15 mg/kg IV on Day 1 , Repeat every 3 weeks.

•Alveolar Soft Part Sarcoma: Indicated as a single agent, for unresectable or metastatic alveolar soft part sarcoma (ASPS) 1,200 mg IV q3Weeks.

Note: all dosages above will continue until disease progression or unacceptable toxicity

Off-label uses

No data available.

Contraindications

Hypersensitivity to atezolizumab or any component of the formulation.

Cautions

Patients with immune-related disorders, history of organ transplant, or prior severe adverse reactions to immunotherapy, Tumor spread to the brain.

Dose adjustment in renal failure: Mild or moderate (eGFR 30-89 mL/min/1.73 m2): No dose adjustment is recommended, Severe (eGFR <20 mL/min/1.73 m2): Not studied.

Dose adjustment in hepatic failure: Mild: No dose adjustment is recommended, Moderate-to-severe: Not studied.

Pharmacokinetic parameters

Absorption: Peak plasma concentration: 1.91-fold, and Minimum plasma concentration: 1.46-fold, AUC: 2.75-fold, Systemic accumulation over 2-3 cycles of repeated dosing.

Distribution: Vd: 6.9 L; protein bound information is not readily available.

Metabolism: Metabolized via proteolytic degradation.

Elimination: Mostly in feces and urine; half-life is approximately 27 days, Clearance: 0.2 L/day.

Drug interaction

• Concurrent use with immunosuppressive agents may interfere with the therapeutic effects of atezolizumab.

Side effects

Common (more than 10%): Fatigue, decreased appetite, nausea, diarrhea, rash, hair loss.

Less common (1-10%): cough, dyspnea, fever, headache, Abdominal pain, Neutropenia.

Rare but serious (less than 1%): Immune-related adverse reactions such as pneumonitis,

Patient education

A Patient education is not currently available for this monograph.

Atomoxetine

ATC Code: N06BA09 Psychoanaleptics (Centrally Acting Sympathomimetics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: No data available.

Indications and Dosage

•Attention Deficit Hyperactivity Disorder (ADHD): Adults, initially, 40mg once daily, may increase after at least 3 days to 80mg once daily or in two divided doses (max 100mg daily); Children 6 years and older weighing less than 70 kg: initially, 0.5mg/kg/day, may increase after at least 3 days to 1.2mg/kg/day (max. 1.4mg/kg/day or 100 mg, whichever is less).

Off-label uses

Mood disorders; Eating disorders; Cognitive dysfunction; Treatment of addictions.

Contraindications

Hypersensitivity to atomoxetine; Narrow angle glaucoma; Pheochromocytoma; Severe cardiovascular disease; The concomitant or recent use (within two weeks) of MAOI.

Dosage forms and trade names available in Iraq

- ATOMOXETINE 10mg capsule
  Strattera (UPM Jordan).
- ATOMOXETINE 18mg capsule
  Strattera (LILLY Spain).
- ATOMOXETINE 25mg capsule
  Strattera (LILLY Spain).
- ATOMOXETINE 40mg capsule
  Strattera (LILLY Spain).

Cautions

Bipolar disorders; Hypertension; Tachycardia; Cardiovascular disease; Urinary retention; Suicidal ideation.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In moderate hepatic impairment: initial and target dose should be reduced by 50% of normal dose; In severe hepatic impairment: initial and target dose should be reduced by 75% of normal dose.

Pharmacokinetic parameters

Absorption F=63%, food has no effect on absorption.

Distribution Vd=0.85L/kg, 98% protein bound.

Metabolism Metabolism in liver by CYP2D6.

Elimination Renal elimination is 80% and 17% in feces, with a half-life of 5.2-21.6 hours.

Drug interactions

Selegiline: Selegiline increases effects of atomoxetine by pharmacodynamic synergism.

Side effects

Common (more than 10%) Abdominal pain; Headache; Insomnia; Loss of appetite; Nausea; Xerostomia.

Less common (1-10%)

Agitation; Anxiety; Decreased growth and development; Dysmenorrhea; Erectile dysfunction; Increased blood pressure; Mood swing; Orthostatic; Hypotension; Rash; Somnolence; Syncope; Tachycardia; Urinary retention; Vomiting; Weight loss.

Rare (less than 1%) Dyskinesia; Mania; Prolonged QT interval, Seizure; Suicidal thoughts; Sudden cardiac death; Hepatotoxicity.

Atorvastatin

ATC Code: C10AA05 Lipid Modifying Agents (HMG CoA Reductase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Hyperlipidemias, prevention of cardiovascular disease by reduction of heart risk in those with elevated cholesterol: 10mg-80mg once daily.

Off-label uses

Secondary prevention in patients who have experienced an acute coronary syndrome event.

Contraindications

Hypersensitivity to atorvastatin.

Cautions

Anticoagulant therapy; Substantial alcohol consumption; Patient with prior stroke or TIA; Elderly.
Dose adjustment in renal failure: Avoid.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- ATORVASTATIN 10mg tablet
  Lipitor (Pfizer Germany).
- ATORVASTATIN 20mg tablet
  Atorvasam (SDI Iraq), **LIPONEER** (Pioneer Iraq), **Kivas** (AL-Kindi Iraq).
- ATORVASTATIN 40mg tablet
  LIPONEER (Pioneer Iraq).
- ATORVASTATIN 80mg tablet
  Lipitor (Pfizer Germany).

Pharmacokinetic parameters

Absorption F=14%, food slows rate of absorption.
Distribution Vd=381L, 98% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 1-2% with a half-life of 7-14 hr.

Drug interactions

Cyclosporine: Cyclosporine increases toxicity of atorvastatin by inhibit OATP1B1 enzyme this may increase risk of myopathy: Contraindicated.
Fenofibrate: Fenofibrate and atorvastatin increases effects of the other by pharmacodynamic synergism, also fenofibrate may further increase risk for rhabdomyolysis when added to optimal statin regimen to further decrease TG and increase HDL, avoid or use alternate drug.
Itraconazole: Itraconazole will increase the level or effect of atorvastatin by affecting hepatic and intestinal enzyme CYP3A4 metabolism, avoid or use alternate drug, limit atorvastatin dose to 20mg daily.

Side effects

Common (more than 10%) Arthralgia; Diarrhea; Headache.
Less common (1-10%) Increased liver enzymes; Indigestion; Insomnia; Musculoskeletal pain; Myalgia; Nasopharyngitis; Nausea; Increased hemoglobin A1c.
Rare (less than 1%) Rhabdomyolysis; Tendon rupture.

Patient educations

Follow special diet (important part of treatment); Periodic lab tests are essential part of therapy; Report dark urine, muscle fatigue, bone pain.

Atosiban

ATC Code: G02CX01 Genito Urinary System And Sex Hormones (Gynecologicals)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding; Atosiban can cross the placenta barrier.

Indications and Dosage

• Inhibit uncomplicated premature labor: Initially i.v. injection, 6.75 mg bolus by slow injection over 1 min, immediately followed by continuous infusion of 300mcg/minute for 3 hours, then decrease infusion rate to 100mcg/minute for up to 45 hours, prefer to be diluted with 0.9% N/S or G/W 5% or ringer lactate solution.

Off-label uses

None.

Contraindications

Hypersensitivity to Atosiban; Gestational age less than 24 or more than 33 weeks; Premature rupture of membranes before 30 weeks of gestation; uterine hemorrhage requiring immediate delivery; Eclampsia; Severe pre-eclampsia; Intra-uterine growth retardation with abnormal fetal heart rate; Intra-uterine fetal death; Suspected intra-uterine infection.

Dosage forms and trade names available in Iraq

ATOSIBAN 7.5 mg /ml (37.5mg/5ml vial)
Tractocile (Ferring Switzerland).

Cautions

Patient with abnormal placental site; Intra-uterine growth restriction; Multiple pregnancy.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=97%.
Distribution Vd= 18.3 ± 6.8L, 46-48% protein bound.
Metabolism Atosiban gives two main metabolites, M1 and M3, identified in plasma and urine samples of nonpregnant and pregnant women.
Elimination Small amounts of atosiban are found in the urine with half-life of 102±18 minutes.

Drug interactions

Salbutamol: The risk or severity of adverse effects can be increased when salbutamol is combined with atosiban.

Side effects

Common (more than 10%) Nausea.
Less common (1-10%) Hot flush; Hypotension; Tachycardia; Dizziness; Headache; Hyperglycemia; Vomiting; Injection site reaction.
Rare (less than 1%) Atrial fibrillation; Dyspnea; Insomnia; Fever; Pruritus; Pulmonary edema; Rash; Uterine atony; Uterine hemorrhage.

Patient educations

A Patient educations is not currently available for this monograph.

Atracurium Besilate

ATC CODE: M03AC04 Muscle Relaxants (Anti-Inflammatory And Antirheumatic Products, Non-Steroids)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Avoid.

Dosage forms and trade names available in Iraq

ATRACURIUM 10mg/ml solution ampoule

ATRANEER (Pioneer Iraq).

Indications and Dosage

• Skeletal muscle relaxation during surgery: i.v. injection, 0.4mg-0.5mg/kg over 1 min, then 0.05mg-0.10mg/kg/min, block usually maintained at rate of 0.011mg-0.013mg/kg/min.

Off-label uses

None.

Contraindications

Hypersensitivity to atracurium.

Cautions

Burn injury; Asthma; Respiratory alkalosis; Hypercalcemia; Demyelinating lesions; Peripheral neuropathies; Denervation; Muscle trauma; Electrolyte abnormalities; Neuromuscular diseases; Metabolic acidosis; Respiratory acidosis; Eaton-Lambert syndrome; Myasthenia gravis.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Administration i.v. results in complete bioavailability.

Distribution Vd= 120-188mL/kg, 80%protein bound.

Metabolism Converted to laudanosine and other metabolites by degradation via Hofmann elimination, undergoes ester hydrolysis by non-specific plasma esterase.

Elimination Atracurium elimination half-life is 20 minutes.

Drug interactions

Amikacin: Amikacin increases effects of atracurium by pharmacodynamic synergism, amikacin increase risk of apnea.

Fentanyl: Coadministration atracurium with skeletal muscle relaxant (fentanyl) may cause respiratory depression, hypotension, profound sedation, coma, and death. Consider dose reduction of either or both agents to avoid serious adverse effects.

Side effects

Common (more than 10%) None.

Less common (1-10%) Skin flush.

Rare but serious (less than 1%) Erythema; Increased bronchial secretions; Pruritus; Urticaria; Wheezing.

Patient educations

A Patient educations is not currently available for this monograph.

Atropine

ATC Code: S01FA01 Ophthalmologicals (Anticholinergics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- ATROPINE (10mg/1ml) 1% eye drops
  Piotropin (Pioneer Iraq).
- **ATROPINE** (5mg/1ml) 0.5% eye drop
  Isopto Atropine (Alcon Belgium).
- ATROPINE 1mg/1ml ampoule
  Piotropin (Pioneer Iraq).
- ATROPINE 600mg/1ml ampoule
  Piotropin (Pioneer Iraq).

Indications and Dosage

• Preanesthetic: By i.v. or i.m. injection, 0.4mg-0.6mg 30-60 min preoperative.
• Bradycardia: By i.v. injection, 0.5mg-1mg every 5 min, not to exceed total of 3mg or 0.04mg/kg.
• Mydriasis; Cycloplegia: 1-drops, cycloplegia 1 hour before refraction and mydriasis 7-14 days.
• Uveitis: 1-2 drops qid.

Off-label uses

None.

Contraindications

Hypersensitivity to atropine; pyloric stenosis; prostatic hypertrophy; Narrow angle glaucoma.

Cautions

Autonomic neuropathy; Paralytic ileus; Intestinal atony; Severe ulcerative colitis; Toxic Megacolon; Myocardial ischemia; Hyperthyroidism; Hypertension; Tachyarrhythmias; Heart failure; Coronary artery disease; Esophageal reflux; Hiatal hernia associated with reflux esophagitis; Biliary tract disease; Chronic pulmonary disease.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=25%-50%, rapidly and well absorbed after i.m injection.
Distribution Vd= 1-6 L/kg, 14-22%protein bound.
Metabolism Mostly metabolized by the liver.
Elimination Renal elimination is 30–50% with half-life of 2-4 hours.

Drug interactions

Amitriptyline: Atropine and amitriptyline both decrease cholinergic effects.

Side effects

Anhidrosis; Ataxia; Blurred vision; Constipation; Cycloplegia; Dermatitis; Drowsiness; Dry eyes; Dry mouth; Dry skin; Dyspnea; Edema; Exudate; Fever; Follicular conjunctivitis; Headache; Hyperemia; Increased intraocular pressure; Insomnia; Local irritation; Nasal dryness; Palpitation; Paralytic ileus; Photophobia; Physostigmine; Pulmonary edema; Urinary hesitancy; Urticaria; Vascular congestion; Xerophthalmia.

Patient educations

For preoperative use, explain that warm flushing feeling may occur.

Azacitidine

ATC Code: L01BC07 Antineoplastic Agents (Pyrimidine Analogues).

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C D **X** N

Lactation: Discontinue breastfeeding during treatment and for 1 week after the last dose.

Dosage forms and trade names available in Iraq

Azacitidine 100mg vial
Azacitidine **Neapolis** (Neapolis Tunisia)

Indications and Dosage

• **Myelodysplastic Syndromes:** Each cycle is 4 weeks, 75 mg/m2 IV or SC qDay for 7 days; repeat cycle every 4 weeks, may increase to 100 mg/m2 if no benefit observed after 2 treatment cycles and if no toxicity other than nausea and vomiting, Treat for minimum of 4-6 cycles, Continue treatment as long as patient continues to benefit.

• **Acute Myeloid Leukemia:** Each cycle is 28 days, 300 mg PO qDay on Days 1-14, Continue until disease progression or unacceptable toxicity.

Off-label uses

None.

Contraindications

• Known hypersensitivity to azacitidine or mannitol.
• Advanced malignant hepatic tumors.

Cautions

Patients with renal or hepatic impairment, and Monitor for hematologic toxicity and infectious complications.
Dose adjustment in renal failure: No specific dose adjustment guidelines; monitor for potential toxicity.
Dose adjustment in hepatic failure: No specific dose adjustment guidelines; use with caution and monitor for potential toxicity.

Pharmacokinetic parameters

Absorption SC: ~89% relative to IV.
Distribution Vd: IV: 76 L , PO: 881 L; Protein bound: ~6-12% (PO),Blood-to-plasma ratio: ~0.3 (PO)
Metabolism Primarily hepatic.
Elimination IV: 85% (urine); <1% (feces), SC: 50% (urine). Clearance: 167 L/hr (SC)

Drug interactions

• Interactions with nephrotoxic drugs may increase the risk of renal toxicity.
• Concurrent use with drugs affecting bone marrow function may increase the risk of myelosuppression.
• **Methotrexate**: coadministration will increase The risk or severity of adverse effects of azacitidine.
• **Cedazuridine**: coadministration will increase The serum concentration of azacitidine.

Side effects

Common (more than 10%): Nausea, vomiting, fatigue, anemia, Dyspnea.
Less common (1-10%): Thrombocytopenia (Gingival bleeding), neutropenia, constipation, Hypertension.
Rare but serious (less than 1%): Bone marrow suppression, hepatotoxicity, renal toxicity.

Patient educations

• Avoid crowded places; Avoid people with infectious diseases and avoid contact with people who have recently received live vaccines (such as influenza vaccine inhaled through the nose).
• This medicine may make you dizzy. Do not drive, use machinery, or do anything that requires alertness until you are sure how the medicine has affected you.

Azathioprine

ATC Code: L04AX01 Immunosuppressants (Other Immunosuppressants)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid; Breastfeeding discontinue 4 hours after the last dose.

Dosage forms and trade names available in Iraq

Azathioprine 50mg tablets
Imuran (Aspen Ireland).

Indications and Dosage

•Severe acute Crohn's disease and acute ulcerative colitis: PO for Adult 2–2.5 mg/kg daily, some patients may respond to lower doses.
•Rheumatoid Arthritis: PO for Adults initially, 1 mg/kg/day as a single dose or in 2 divided doses. May increase by 0.5 mg/kg/day after 6–8 wk at 4-wk intervals up to a maximum of 2.5 mg/kg/day.
•Polymyositis in cases of corticosteroid resistance: PO for Adult initially up to 2.5 mg/kg daily in divided doses.
•Suppression of transplant rejection: Adult:1–2.5 mg/kg daily, adjusted according to response, oral administration preferable.

Off-label uses

Treatment of dermatomyositis; Polymyositis; Lupus nephritis.

Contraindications

Hypersensitivity to azathioprine.

Cautions

Immunosuppressed patients; Active infection, Reduce dose in elderly; reduced thiopurine methyltransferase activity.
Dose adjustment in renal failure: CrCl 10-50ml per minute reduce dosage to 75% of normal dose; CrCl less than 10ml per minute reduce dosage to 50% of normal dose.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=88%.
Distribution Vd= Undetermined, 20-30%protein bound.
Metabolism Metabolized to mercaptopurine.
Elimination Renal elimination is 98% with half-life of 3 hours.

Drug interactions

Allopurinol: Allopurinol may increase serum concentrations of the active metabolites of azathioprine.

Side effects

Common (more than 10%) Bone marrow depression (dose-related); increased risk of infection; pancreatitis.
Less common (1-10%): Anaemia; hepatic disorders; hypersensitivity.
Rare but serious (less than 1%): Agranulocytosis; alopecia; bone marrow disorders.

Patient educations

Therapeutic response in rheumatoid arthritis may take up to 12 weeks.

Azelaic Acid

ATC Code: D10AX03 Anti-Acne Preparations (Other Anti-Acne Preparations for Topical Use)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Dosage forms and trade names available in Iraq

AZELAIC ACID 20g/100g (20%) cream

Indications and dosage

• Mild to moderate inflammatory and comedonal acne vulgaris: Apply a thin layer onto the affected areas on the face twice daily.
• Papulopustular rosacea: Apply a thin layer onto the affected areas on the face twice daily.

Off-label uses

Treatment of hyperpigmentary disorders such as melasma and post-inflammatory hyperpigmentation.

Contraindications

Hypersensitivity to azelaic acid.

Cautions

Avoid use on broken or eczematous (sensitive) skin; Avoid occlusive dressings; Avoid contact with eyes, nose, or mouth.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=4%.
Distribution Undetermined.
Metabolism Undergoes some β-oxidation to shorter chain dicarboxylic acids.
Elimination Azelaic acid is mainly excreted unchanged in the urine with a half-life of 12 hours.

Drug interactions

Isotretinoin; concomitant use may increase local skin irritation.

Side effects

Common (more than 10%): None.
Less common (1-10%): Burning; itching; redness; scaling; irritation; dry skin.
Rare but serious (less than 1%): Contact dermatitis; Edema.

Patient education

For external use only; Apply a thin layer and massage gently onto clean, dry affected areas usually twice daily; Avoid contact with eyes, nose, and mouth.

Azelastine

ATC Code: R01AC03 Nasal Preparations (Antiallergic Agents, Excl. Corticosteroids)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Seasonal allergic conjunctivitis, perennial conjunctivitis: Apply bid.

Off-label uses

None.

Contraindications

Hypersensitivity to azelastine.

Cautions

Concurrent use of alcohol.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Extremely low systemic absorption.
Distribution Vd=14.5L/kg, 78-95% protein bound.
Metabolism Hepatic metabolism 90%.
Elimination Fecal elimination is 75% with a half-life of 22-25 hours.

Dosage forms and trade names available in Iraq

AZELASTINE (0.5mg/ml) 0.05% eye drops **Allergodil** (MEDA Germany).

AZELASTINE 0.14ml (1dose) = 0.14mg Nasal spray **Allergodil** (MEDA Germany).

Drug interactions

Acetazolamide: Acetazolamide may increase the central nervous system depressant activities of azelastine.
Acyclovir: The metabolism of azelastine can be decreased when combined with Acyclovir.
Atropine: Azelastine may increase the central nervous system depressant activities of atropine.
Betaxolol: The metabolism of betaxolol can be decreased when combined with azelastine.
Chlorpheniramine: Chlorpheniramine may increase the central nervous system depressant activities of azelastine.

Side effects

Common (more than 10%) Bitter taste in mouth; Headache; Somnolence.
Less common (1-10%) Fatigue; Epistaxis; Pharyngitis; Rhinitis; Sneezing.
Rare (less than 1%) None.

Patient educations

Do not wear contact lenses if eyes are red, wait 10 minutes after azelastine to insert contact lenses.

Azilsartan

ATC Code: C09CA09 Agents Acting on The Renin-Angiotensin System (Angiotensin II Receptor Blockers (ARBs), Plain).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Not recommended and a decision should be made to discontinue breastfeeding.

Indications and Dosage

Indicated for hypertension, either alone or in combination with other antihypertensives, 80 mg PO qDay, Coadministration with high-dose diuretics: 40 mg PO qDay.

Off-label uses

not reported.

Contraindications

Hypersensitivity to azilsartan or any component of the formulation, history of angioedema related to previous use of angiotensin II receptor blockers (ARBs), and pregnancy (Black Box Warnings).

Cautions

patients with renal artery stenosis, severe congestive heart failure, hepatic impairment, and electrolyte imbalances, aged 75 or older, Coadministration with NSAIDs.

Dose adjustment in renal failure: No dose adjustment is required.

Dose adjustment in hepatic failure: not necessary with mild-to-moderate hepatic impairment; monitor in severe impairment (data not available).

Dosage forms and trade names available in Iraq

- Azilsartan 40 mg tablet
  Edarbi (APM JORDAN)
- Azilsartan 80 mg tablet
  Edarbi (APM JORDAN)

Pharmacokinetic parameters

Absorption Absorption: Azilsartan is well-absorbed after PO, Bioavailability: 60%, Peak Plasma Time: 1.5-3 hr

Distribution Vd: 16 L, Protein Bound: >99% (mainly albumin)

Metabolism Azilsartan undergoes hepatic metabolism via glucuronidation.

Elimination Half-Life: 11 hr, Clearance: 0.14 L/hr, Excretion: feces (55%), urine (42%)

Drug interactions

• Azilsartan may interact with potassium-sparing diuretics, potassium supplements, or potassium-containing salt substitutes, potentially leading to hyperkalemia.

• Sparsentan, Azilsartan. Either increases toxicity of the other by pharmacodynamic synergism and is Contraindicated.

Side effects

• **Common (more than 10%):** Diarrhea, headache.

• **Less common (1-10%):** Dizziness, fatigue, hypotension.

• **Rare but serious (less than 1%):** Angioedema, renal impairment.

Patient educations

• The patient is advised to avoid drinking alcohol while using the medication; The risk of low blood pressure is increased, it also may cause dizziness; Avoid driving or using heavy machinery.

• Inform your healthcare provider of any new or worsening symptoms, especially swelling of the face, lips, tongue, or throat; Avoid potassium supplements or salt substitutes containing potassium.

Azithromycin

ATC Code: J01FA10 Antibacterials for Systemic Use (Macrolides)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Avoid; Breastfeeding discontinues 2 days after the last dose.

Dosage forms and trade names available in Iraq

- AZITHROMYCIN 200mg/5ml suspension
  Zithromax (Pfizer UK).
- AZITHROMYCIN 250mg capsule
  ZITRONEER (Pioneer Iraq).
- AZITHROMYCIN 250mg tablet
  Azithrosam (SDI Iraq).
- AZITHROMYCIN 500 mg tablet
  ZITRONEER (Pioneer Iraq), Azithrosam (SDI Iraq).

Indications and Dosage

• Skin or soft tissue infection: 500mg once daily for 3 days or 500mg 1 dose then 250mg daily for 5 days.
• Bacterial sinusitis: 500mg once daily for 3 days.
• Community acquired pneumonia: 500mg once daily for 3 days.
• Streptococcal pharyngitis: 500mg 1 dose then 250mg daily for 2-5 days.

Off-label uses

Uncomplicated gonococcal infections of cervix, urethra, rectum, and pharynx; Traveler's diarrhea.

Contraindications

Hypersensitivity to azithromycin.

Cautions

Myasthenia gravis; Cholestatic hepatitis; Hepatic necrosis; Azithromycin may prolong QT interval.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=38%, food has no effect on absorption.
Distribution Protein bound 51%.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 6% with a half-life of 68 hr.

Drug interactions

Digoxin: Azithromycin will increase the level or effect of digoxin by altering intestinal flora, avoid or use alternate drug.
Escitalopram: Escitalopram increases toxicity of azithromycin by QT interval, avoid or use alternate drug.
Hydroxychloroquine sulfate: Hydroxychloroquine sulfate and azithromycin both increase QT interval, avoid or use alternate drug.

Side effects

Common (more than 10%) Abdominal pain; Appetite decreased; Arthralgia; Diarrhea; Dizziness; Eye discomfort; Headache; Hearing impairment; Nausea; Pancreatitis; Sensation abnormal; Skin reactions; Sleep disorders; Metallic taste; Vasodilation; Vision disorders; Vomiting.
Less common (1-10%) Headache; Elevated liver enzymes; Flatulence.
Rare (less than 1%) Stevens Johnson syndrome; Chest pain; Myasthenia gravis; QT prolongation; Torsades de pointes; Hepatitis.

Patient educations

Avoid concurrent administration of aluminum or magnesium containing antacids; Do not wear contact lenses during period of treatment; Avoid alcohol.

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المركز التسويقي 009647902368053 - 009647710048363

Baclofen

ATC Code: M03BX01 Muscle Relaxants (Other Centrally Acting Agents)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Baclofen 10mg tablet
  APO-Baclofen (APOTEX Canada),
- Baclofen 25mg tablet
  Baclocalm (Labatec Switzerland).

Indications and Dosage

• **Spasticity:** Start with 5mg tid, after meals, gradually increased if necessary, up to 80mg daily. Some patients may require up to 120mg daily.
• **Hiccups (off-label use):** Initial: 5 to 10 mg 3 times daily; may increase based on response and tolerability; usual maximum dose: 45 mg/day.
• Muscle spasm and/or musculoskeletal pain (off-label use): Initial: 5 to 10 mg 3 times daily as needed.

Off-label uses

Alcoholic liver disease; Alcohol related anxiety; Trigeminal neuralgia; Gastroesophageal reflux disease; Hiccups.

Contraindications

Hypersensitivity to baclofen; Psychological disorders (like schizophrenia); Patients with CrCl <30 mL/minute; Systemic or local infection with intrathecal use; Active peptic ulceration with oral use.

Cautions

Seizure disorder; Elderly; Elderly; cerebrovascular disease; diabetes; Autonomic dysreflexia; Reduced GI motility; GI or urinary obstruction; Peptic ulcer; Renal impairment; Hepatic impairment

Pharmacokinetic parameters

Absorption F=100%, food has no effect on absorption.
Distribution Vd=1.16L/Kg in pediatrics, 30% protein bound.
Metabolism Limited hepatic metabolism.
Elimination Over 70% via urine unchanged, stool; half-life: 3.75+/-0.96 (tablets), 5-6hrs (suspension), 1.5 hrs (intrathecal).

Drug interactions

Alprazolam: Baclofen and alprazolam both increase sedation, use together with caution.
NSAID: NSAID may decrease the excretion rate of baclofen which could result in a higher serum level.
Penicillin: Baclofen may decrease the excretion rate of penicillin which could result in a higher serum level.
Tramadol: Baclofen and tramadol both increase sedation, use together with caution.

Side effects

Common (more than 10%) Drowsiness; Dizziness; Weakness; Nausea; Confusion; Hypotonia; Somnolence.
Less common (1-10%) Hypotension; Headache; Insomnia; Fatigue; Constipation; Urinary frequency.
Rare (less than 1%) Pneumonia; GI hemorrhage.

Patient educations

Take with food or milk; Drowsiness usually diminishes with continued therapy; Do not abruptly withdraw medication after long term therapy (may result in muscle rigidity, rebound spasticity, high fever, altered mental status); Avoid alcohol and CNS depressants.

Barium Sulfate

ATC Code: V08BA02 Contrast Media (X-Ray Contrast Media, Non-Iodinated)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Data regarding its use during lactation is limited.

Dosage forms and trade names available in Iraq

Barium sulfate 100g/100ml suspension
Barium Sulphate Suspension (Safa Iraq).

Indications and Dosage

Barium sulfate is primarily used as a contrast agent for imaging studies, particularly in radiographic examinations of the gastrointestinal tract. Dosage varies based on the specific procedure and patient characteristics; administered orally or rectally.

Off-label uses

No data available.

Contraindications

Hypersensitivity to barium sulfate or any component of the formulation, suspected bowel perforation or obstruction, conditions predisposing to aspiration.

Cautions

Use caution in patients with impaired renal function, compromised gag reflex, or risk factors for aspiration, Blockages, ulcers, or holes in the esophagus, stomach, or intestines. Rectal cancer. Having any type of surgery, Intracranial hypertension.

Dose adjustment in renal failure: No specific dose adjustment is typically required in renal failure.

Dose adjustment in hepatic failure: No specific dose adjustment is typically required in hepatic failure.

Pharmacokinetic parameters

Absorption Barium sulfate is minimally absorbed from the gastrointestinal tract.

Distribution Not applicable.

Metabolism Barium sulfate is not metabolized.

Elimination Mostly excreted unchanged in feces; elimination half-life is not applicable.

Drug interactions

• No significant drug interactions have been reported with barium sulfate.

• However, caution is advised when used concomitantly with other medications, particularly those that may affect gastrointestinal motility or interfere with radiographic imaging.

Side effects

Common (more than 10%): Nausea, abdominal discomfort, constipation.

Less common (1-10%): Diarrhea, vomiting, transient taste alteration.

Rare but serious (less than 1%): Allergic reactions, aspiration pneumonia (in cases of aspiration).

Patient educations

• Report any adverse reactions or discomfort experienced during or after the procedure to your healthcare provider.

• The patient is advised to drink clear liquids only during certain times before the examination. The doctor may also ask you to avoid eating or drinking for a specific time after the examination. You may be asked to use laxatives; or enemas before the test or use laxatives to remove barium sulfate from your body after the test.

BCG

ATC Code: L03AX03 Antineoplastic and Immunomodulating Agents (Other Immunostimulants)
Pregnancy category:
FDA A B **C** D X N
TGA A B1 **B2** B3 C D X N
Lactation: No data available.

Indications and Dosage

• BCG is used to treat bladder cancer. The dosage can vary, but a common dosage is 50-75 mg weekly for 6 weeks intravesically.
• BCG is also used as a vaccine against tuberculosis in some countries, typically administered as a single intradermal injection.

Off-label uses

None

Contraindications

Hypersensitivity to BCG; immunodeficiency (congenital or acquired); active tuberculosis; febrile illness; pregnancy; concurrent systemic antiviral therapy.

Dosage forms and trade names available in Iraq

Bacillus Calmette-Guérin (derived from bacteria seed) vial
BCG-medac (Medac Gesellschaft Germany).
BCG from MyCobacterium bovis (30mg/vial)
VesiCulture (AJ Vaccines Denmark).

Cautions

Can cause serious side effects, including severe bladder symptoms and systemic BCG infection. It should be used with caution in patients with a weakened immune system.
Dose adjustment in renal failure: Not required as BCG is not metabolized in the kidneys.
Dose adjustment in hepatic failure: Not required as BCG is not metabolized in the liver.

Pharmacokinetic parameters

BCG is a live, attenuated bacteria and does not have traditional pharmacokinetic parameters such as absorption, distribution, metabolism, and elimination.

Drug interaction

Immunosuppressants: May diminish the therapeutic effect of BCG. Consider therapy modification.
Antibiotics: May diminish the therapeutic effect of BCG. Consider therapy modification.

Side effects

Common (more than 10%): Urinary frequency, urinary urgency, dysuria.
Less common (1-10%): Hematuria, urinary tract infection, malaise.
Rare but serious (less than 1%): Systemic BCG infection, sepsis.

Patient education

1. Report any severe bladder symptoms or signs of infection (fever, fatigue, cough, weight loss) immediately.
2. Do not father a child or become pregnant while receiving this treatment.
3. Follow specific instructions about care of the urinary opening, especially after treatment.

Beclomethasone

ATC Code: R03BA01 Drugs for Obstructive Airway Diseases (Glucocorticoids)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- BECLOMETHASONE 250µg/dose
  Cortis (BERG Tunisia).
- BECLOMETHASONE 50 µg/dose
  BECLOMETHASONE (LABORATORIO ALDO-UNION Spain).

Indications and Dosage

• Asthma: For patients not previously receiving inhaled corticosteroid, initial dose 40mcg-80mcg via oral inhalation bid; For patients switching from another inhaled corticosteroid, initial dose selection should be based on the previous inhaled corticosteroid strength, 40mcg-320mcg via oral inhalation bid.
• Allergic rhinitis; Nasal polyps: 1-2 sprays per nostril bid.

Off-label uses

Prevention of seasonal rhinitis.

Contraindications

Hypersensitivity to beclomethasone; Status asthmaticus.

Cautions

Cardiovascular disease; Cataracts; Diabetes; Elderly; Glaucoma; Myasthenia gravis; Osteoporosis; Peptic ulcer disease; Seizure disorder; Thyroid disease; Ulcerative colitis; Acute myocardial infarction; Avoid use in patients with untreated viral, fungal, or bacterial systemic infections.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=20%.
Distribution Vd=20L, 94-96%protein bound.
Metabolism Undergoes rapid hydrolysis mediated by esterase CYP3A.
Elimination Renal elimination is 10% with half-life of 2.8 hours.

Drug interactions

Natalizumab: Beclomethasone increases toxicity of natalizumab by immunosuppressive effects, before initiating natalizumab, taper of steroids patients receiving chronic corticosteroids.

Side effects

Common (more than 10%) Headache; Pharyngitis; Upper respiratory tract infection.
Less common (1-10%) Cough; Headache; Increased asthma symptoms; Nasopharyngitis; Oral candidiasis; Oropharyngeal pain; Pharyngitis; Pyrexia; Sinusitis; Vomiting.
Rare but serious (less than 1%) Oropharyngeal pain.

Patient educations

Do not change dose schedule or stop taking drug, must taper off gradually under medical supervision; Rinse mouth with water immediately after inhalation (prevents mouth and throat dryness, fungal infection of mouth); Report symptoms that do not improve; or if sneezing, nasal irritation occurs; Clear nasal passages prior to use; Improvement may take days to several weeks.

Bemiparin

ATC Code: B01AB12 Antithrombotic Agents (Heparin Group)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X **N**

Lactation: No data available.

Indications and Dosage

Bemiparin is indicated for the prevention and treatment of deep vein thrombosis and pulmonary embolism. The typical dosage for thromboprophylaxis in general surgery is 3500 IU once daily, starting 2 hours before surgery and continuing for 7-10 days.

Off-label uses

None

Contraindications

Hypersensitivity to bemiparin or heparin; Patients with a history of heparin-induced thrombocytopenia with or without disseminated intravascular coagulation; acute bleeding or risk of bleeding; injury or surgery of the central nervous system, eyes or ears; severe liver or pancreas impairment; and acute or subacute bacterial endocarditis, and is contraindicated in patients with hypersensitivity.

Dosage forms and trade names available in Iraq

- Bemiparin 2500 IU anti-Xa/ 0.2ml Pre-Filled Syringes
  Hibor (Hikma Jordan).
- Bemiparin 3500 IU anti-Xa/ 0.2ml Pre-Filled Syringes
  Hibor (Hikma Jordan).
- Bemiparin 5000 IU anti-Xa/ 0.2ml Pre-Filled Syringes
  Hibor (Hikma Jordan).

Cautions

Caution in patients with renal or hepatic impairment, history of heparin-induced thrombocytopenia, peptic ulcer disease, hypertension, diabetic retinopathy, or recent CNS surgery.
Dose adjustment in renal failure: Dose adjustments may be necessary
Dose adjustment in hepatic failure: Use with caution; dose adjustments may be necessary.

Pharmacokinetic parameters

Absorption: Rapidly absorbed following SC inj. Bioavailability: Approx 96%. Time to peak plasma concentration: 2-4 hours.
Excretion: Elimination half-life: 5-6 hours.

Drug interaction

- **Antiplatelet drugs:** Increased risk of bleeding. Monitor therapy closely.
- **Other anticoagulants:** Increased risk of bleeding. Monitor therapy closely.

Side effects

Common (more than 10%): Bleeding, hematoma at injection site.
Less common (1-10%): Thrombocytopenia, allergic reactions.
Rare but serious (less than 1%): Serious bleeding, heparin-induced thrombocytopenia.

Patient education

- Report any signs of bleeding or allergic reaction to your healthcare provider.
- This medication should be injected subcutaneously, not into a muscle.
- Do not take other anticoagulants or antiplatelet drugs without consulting your healthcare provider.

Bendamustine

ATC Code: L01AA09 Antineoplastic Agents (Nitrogen Mustard Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Chronic lymphocytic leukemia: 100mg/m2 by i.v. infusion over 30 minutes on days 1 and 2 of 28 days cycle for up to six cycles.
• Indolent non-Hodgkin's lymphomas: 120mg/m2 by i.v. infusion over 60 minutes on day 1 and 2 of a 28-day cycle for up to 6 cycles.

Dosage forms and trade names available in Iraq

BENDAMUSTINE 100mg vial
Ribomustin (Oncotec pharma Germany).

Off-label uses

Refractory mantle cell lymphoma; Multiple myeloma; Follicular lymphoma; Waldenströms macroglobulinemia.

Contraindications

Hypersensitivity to bendamustine.

Cautions

Cardiac disorders; Myelosuppression; Infections (it should not be used in serious infections); Secondary malignancies; Serious skin reactions.

Dose adjustment in renal failure: CrCl less than 30ml per minute, use of bendamustine not recommended.

Dose adjustment in hepatic failure: Mild hepatic failure, use of bendamustine with caution; Moderate to severe hepatic failure, use of bendamustine not recommended.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=20-25L, 94-96%protein bound.

Metabolism Primarily metabolized via hydrolysis to monohydroxy and dihydroxy bendamustine metabolites.

Elimination Renal elimination is 50% and hepatic elimination is 25% with half-life of 40 minutes.

Drug interactions

Myelosuppression is increased when bendamustine is used with other drugs that suppress bone marrow. Inhibitors and inducers of the P-450 enzyme system can increase and decrease concentration, respectively.

Side effects

Alopecia; Menorrhea; Anemia; Angina pectoris; Appetite decreased; Arrhythmias; Cardiac disorder; Chills; Constipation; Decreased leucocytes; Dehydration; Diarrhea; Dizziness; Fatigue; Fever; Hemorrhage; Headache; Hepatitis B reactivation; Hypertension; Hypokalemia; Hypotension; Increased risk of infection: Insomnia; Mucositis; Nausea; Neutropenia; Pain; Palpitations; Respiratory disorders; Skin reactions; Thrombocytopenia; Tumor lysis syndrome; Vomiting.

Patient educations

Avoid contact with those with known infection; Do not have immunizations without physician's approval (drug lowers body resistance); Monitor liver and kidney functions tests prior to and during bendamustine therapy; If bendamustine contacts the skin, wash the skin immediately with soap and water.

Benzoyl Peroxide

ATC Code: D10AE01 Anti-Acne Preparations (Peroxides)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Acne vulgaris: Apply 5%-10% gel sparingly to affected areas once daily after thoroughly washing skin, may gradually increase to bid or tid if needed.

Off-label uses

Decubitus ulcers; Dermal ulcers; Folliculitis including gram-negative folliculitis; Inflammatory forms of rosacea; Non-infectious folliculitis, and drug-induced folliculitis (acneiform eruptions); Perforating diseases; Pitted keratolysis; Progressive macular hypomelanosis; Pseudo-folliculitis barbae; Seborrheic dermatitis; Surgical wounds; Tinea pedis; Tinea versicolor.

Contraindications

Hypersensitivity to benzoyl peroxide.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=1%.

Distribution Undetermined.

Metabolism Converted to benzoic acid in skin

Elimination Absorbed benzoic acid eliminated in the urine.

Drug interactions

Adapalene: Adapalene is light-stable, resistant to oxidation by benzoyl peroxide and can be used with it as an acceptable combination product.

Isotretinoin: Using isotretinoin together with benzoyl peroxide may increase skin irritation, concurrent use should generally be avoided.

Tretinoin: Patients should avoid concurrent application of topical benzoyl peroxide with topical tretinoin as it results in decreased efficacy of tretinoin and make it less stable and thus should not be used at the same time. It is better to use benzoyl peroxide in the morning and tretinoin at night. There are newer formulations of tretinoin (micronized tretinoin gel, tretinoin gel microsphere) that are not affected by benzoyl peroxide and thus can be used in combination.

Side effects

Contact dermatitis; Erythema; Peeling; Skin dryness.

Patient educations

Avoid contact with eyes, eyelids, mouth, lips, and other mucous membranes, or broken skin; Avoid deliberate or prolonged exposure to sunlight or UV radiation, use sunscreen and wear protective clothing; May bleach hair and colored fabrics, avoid contact with hair, clothing, furniture or carpeting.

Dosage forms and trade names available in Iraq

BENZOYL PEROXIDE (10g/100g) 10% gel
Ben-oxide (Domina Syria).

BENZOYL PEROXIDE (5g/100g) 5% gel
Acnezoyl (Jamjoom KSA).

Benzyl Benzoate

ATC Code: P03AX03 Ectoparasiticides, Incl. Scabicides, Insecticides and Repellents (Other Ectoparasiticides, Incl. Scabicides)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• **Scabies:** Apply thoroughly to the entire body at night from the soles of the feet, omitting the head and neck, use just one time; For severe cases treatment may be repeated after 24 hours once any time within 5 days.

• **Pediculosis:** Apply to affected area and allow to remain on for 24 hours, then wash thoroughly. In severe cases treatment may be repeated 2 or 3 times after 24 hours.

Dosage forms and trade names available in Iraq

BENZYL BENZOATE 25g/100g Emulsion

Domizyle (Domina Syria).

Off-label uses

None.

Contraindications

Hypersensitivity to benzyl benzoate.

Cautions

Avoid contact with eyes and mucous membranes; Do not use on broken or secondarily infected skin.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Undetermined.

Distribution Undetermined.

Metabolism Rapidly hydrolyzed to benzoic acid and benzyl alcohol, which is further oxidized to benzoic acid. The benzoic acid is conjugated with glycine to form hippuric acid.

Elimination Undetermined.

Drug interactions

None reported.

Side effects

Benzyl benzoate when used as a topical scabicide, it can irritate the skin. An allergic reaction to an overdose might cause blisters or a rash. In higher concentrations than those employed in the therapeutic dose will cause loss of consciousness and jerking movements.

Patient educations

Thorough bathing with a complete change of clothing and bedding should follow each application. All contacting clothes and bedding should be washed and/or cleaned.

Note

Benzyl benzoate 25% can cause skin irritation and burning therefore to reduce irritation should be diluted to 12.5% for children and 6.25% for infants; However, it has been shown that dilution reduces its efficacy.

Alternative medications

Topical permethrin 5%.

Beractant

ATC Code: R07AA02 Other Respiratory System Products (Lung Surfactants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Not applicable, as it's used in neonates.

Dosage forms and trade names available in Iraq

Beractant 25mg/ml intratracheal suspension 4ml vial **Survanta** (AbbVie USA).

Indications and Dosage

Beractant is indicated for prevention and treatment of respiratory distress syndrome (RDS) in infants. For prevention, the dosage is 4 mL/kg birth weight as soon as possible, preferably within 15 minutes of birth. For treatment, the dosage is 4 mL/kg birth weight as soon as RDS is diagnosed.

Off-label uses

None

Contraindications

Hypersensitivity to beractant or any of its components.

Cautions

In infants with compromised cardiovascular function or infection, as well as those receiving high frequency oscillatory ventilation due to risk of airway obstruction.
Dose adjustment in renal failure: Not applicable, as it's used in neonates and not metabolized by the kidneys.
Dose adjustment in hepatic failure: Not applicable, as it's used in neonates and not metabolized by the liver.

Pharmacokinetic parameters

Pharmacokinetic studies in neonates have not been conducted. Beractant is not absorbed systemically; its effects are localized to the lungs.

Drug interaction

None known.

Side effects

Common (more than 10%): Bradycardia, oxygen desaturation, endotracheal tube reflux, pallor.
Less common (1-10%): Intraventricular hemorrhage, patent ductus arteriosus, pneumothorax.
Rare but serious (less than 1%): Severe hypersensitivity reactions.

Patient education

Please consult your healthcare provider for the most recent and precise information.

Besifloxacin

ATC Code: S01AE08 Ophthalmologicals (Fluoroquinolones)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: It is not known; caution should be exercised

Dosage forms and trade names available in Iraq

Besifloxacin (6mg/1ml) ophthalmic suspension
Besivance (Bausch & Lomb USA).

Indications and Dosage

Besifloxacin ophthalmic suspension is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates. The typical dosage is one drop in the affected eye(s) every 12 hours for 7 days.

Off-label uses

None

Contraindications

Hypersensitivity to besifloxacin or any component of the formulation.

Cautions

Prolonged use may result in overgrowth of non-susceptible bacteria and fungi. If superinfection occurs, discontinue use and institute alternative therapy.
Dose adjustment in renal failure: Not required
Dose adjustment in hepatic failure: Not required

Pharmacokinetic parameters

Minimal systemic absorption occurs following topical ocular administration.

Drug interaction

None known.

Side effects

Common (more than 10%) Conjunctival redness, blurred vision, eye pain.
Less common (1-10%) Eye pruritus, eye irritation, dry eye.
Rare but serious (less than 1%) Corneal erosion, hypersensitivity reaction.

Patient education

- Do not touch dropper tip to any surface, as this may contaminate the contents.
- If you wear contact lenses, remove them before using besifloxacin eye drops.
- Do not use other eye medications unless your doctor tells you to.

Betahistine

ATC Code: N07CA01 Other Nervous System Drugs (Antivertigo Preparations)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Ménière's syndrome (symptoms of which may include vertigo, tinnitus, hearing loss and nausea): 8mg-16mg tid.

Off-label uses

None.

Contraindication

Hypersensitivity to betahistine; Pheochromocytoma.

Cautions

Bronchial asthma; Peptic ulcer disease.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- BETAHISTINE 16mg tablet
  BETASERC (ABBOTT Netherlands).
- BETAHISTINE 8mg tablet
  BETASERC (ABBOTT Netherlands).

Pharmacokinetic parameters

Absorption When given orally, betahistine is rapidly and almost completely absorbed from the gastrointestinal tract; Delayed absorption with food.
Distribution Vd= Undetermined, less than 5%protein bound.
Metabolism Betahistine is metabolized primarily into the inactive metabolite 2-pyridylacetic acid.
Elimination Renal elimination is 85-91% with half-life of 3-4 hours.

Drug interactions

Amitriptyline: The therapeutic efficacy of betahistine can be decreased when used in combination with amitriptyline.
Cetirizine: The therapeutic efficacy of betahistine can be decreased when used in combination with Cetirizine.
Famotidine: The therapeutic efficacy of betahistine can be decreased when used in combination with famotidine.
Imipramine: The therapeutic efficacy of betahistine can be decreased when used in combination with imipramine.
Ketotifen: The therapeutic efficacy of betahistine can be decreased when used in combination with ketotifen.

Side effects

Abdominal distension or pain; Fatigue; Ploating; Bronchospasm; Rash; Convulsions; Dizziness; Dyspepsia; Hallucination; Dyspnea; Headache; Hypotension; Malaise; Urticaria; Orthostatic hypotension; Pruritus; Vasodilation; Somnolence; Confusion; Tachycardia; Nausea; Vomiting.

Patient educations

A Patient education is not currently available for this monograph.

Betamethasone

ATC Code: D07XC01 Corticosteroids, Dermatological Preparations (Corticosteroids, Potent, Other Combinations)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Anti-inflammation, immunosuppression, corticosteroid replacement therapy: 0.5mg-9mg daily in 2 divided doses.

• Inflamed and pruritic dermatoses: Apply to the affected areas once daily or bid.

• Plaque psoriasis: Apply to affected areas bid for up to 4 weeks.

• Topical treatment of inflammatory non-infected conditions of the eye, ear or nose: Initially 1-2 drops to be instilled into the affected eye(s) every two hr; 1-2 drops to be instilled into the affected ear(s) every 3-4 hr; 2-3 drops to be instilled into each nostril bid.

• Sore mouth ulcers and oral lichen planus: Swirl mouthwash for 5 minutes up to 4 times daily.

Off-label uses

Accelerate fetal lung maturation in patients with preterm labor.

Dosage forms and trade names available in Iraq

BETAMETHASONE 0.1% topical/scalp solution

Novacil-H (P.D. France).

BETAMETHASONE 0.1% cream

Betnosam (SDI Iraq), **Betacon** (AL-Kindi Iraq), **Betason** (Dubai Iraq),**Betnosadain** (Wadi Al-Rafidain Iraq).

BETAMETHASONE 0.1% ointment

Betnosam (SDI Iraq), **Betason** (Dubai Iraq), **Betnosadain** (Wadi Al-Rafidain Iraq).

BETAMETHASONE 0.5mg tablet

Betacon (AL-Kindi Iraq).

BETAMETHASONE 2mg/1ml (2ml ampoule)

Diprofos (MSD Belgium).

Contraindications

Hypersensitivity to betamethasone; IM. administration in idiopathic thrombocytopenia purpura.

Cautions

Hypothyroidism; Cardiovascular disease; Diabetes; Glaucoma; Cataracts; Myasthenia gravis; Osteoporosis; Seizures; Acute myocardial infarction; Elderly; Systemic fungal infections; Oral Burning or thrush

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption Undetermined.

Distribution Vd=94,584±23,539 ml.

Metabolism Hepatic metabolism of betamethasone yields 6 metabolites.

Elimination Betamethasone eliminated predominantly in the urine with half-life of 10.2±2.5 hours.

Drug interactions

• **Bumetanide:** The risk or severity of myopathy, rhabdomyolysis, and myoglobinuria can be increased when betamethasone is combined with bumetanide.

• Aminoglutethimide; Amphotericin B; Antibiotics, especially macrolide; Anticholinesterases; Oral anticoagulants; Antidiabetic drugs; Anti-tuberculosis drugs; Cholestyramine.

Side effects

Common (more than 10%) Blurred vision; Increased appetite; slow wound healing.

Less common (1-10%) Itching; folliculitis.

Rare but serious (less than 1%) None.

Patient educations

Betamethasone tablet taken with food, milk; Take single daily dose in the morning; Do not stop abruptly.

AL MAMORAH
GROUP

مجموعة المعمورة الدوائية

Abbott

ABDiIBRAHIM

acino

AMGEN

Bayer HealthCare
Women Healthcare

hikma.

hovid

جمجوم فارما
Jamjoom Pharma
An ISO Certified Company

LEO

Lagap

medpharma
The science of better health

MERZ

MERZ AESTHETICS

OPALIA
Pharma

Pharma Bavaria
International

PHARMALINE
Improves Quality of Life

So.Se. PHARM
INDUSTRIA FARMACEUTICA

xellia

https://almamorah.iq

Beta-Sitosterol

ATC Code:

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: No data available.

Dosage forms and trade names available in Iraq

- B-sitosterol 0.25% w/w ointment 15gm
  MEBO – CARE (SDI).

Indications and Dosage

• **Burns:** A thin layer of ointment is applied 3-4 times daily, and it is preferable to leave the area exposed unless the doctor gives instructions to the contrary in cases of third-degree wounds.
• **Ulcers:** The ulcer cavity should be filled with the treatment and a thin layer should be formed covering the adjacent area; this is repeated twice daily.
• **Treating surgical areas to hide the location of the surgical sutures:** A thick layer of ointment must be applied to prevent scar formation, and this must be continued; It is recommended to cover the area with sterile gauze twice daily.
• **Treating skin cracks, such as cracked nipples:** Apply a thin layer of ointment 3-4 times daily.

Off-label uses

None.

Contraindications

Hypersensitivity to B-sitosterol.

Cautions

None.
Dose adjustment in renal failure: No dose adjustment required.
Dose adjustment in hepatic failure: Mild: No dose adjustment required.

Pharmacokinetic parameters

Absorption no data available
Distribution no data available
Metabolism no data available
Elimination no data available

Drug interactions

No major drug interactions have been reported with B-sitosterol.

Side effects

No reported side effects when the drug is used topically.

Patient educations

• B-sitosterol treatment is a relatively safe treatment that can be used on the face without fear of any side effects unless you are allergic to its active ingredients.
• If you forget to apply b-sitosterol; It is recommended to administer the dose as soon as possible. If it is almost time for the next dose; Skip the missed dose and take the treatment at the regularly scheduled time. The quantity should not be doubled to make up for the missed dose.
• You must continue using the treatment until the scar disappears or there is a complete improvement in the area affected by burns or cracks.

Betaxolol

B

ATC Code: S01ED02 Ophthalmologicals (Beta Blocking Agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Breastfed infants should be monitored for the signs and symptoms of bradycardia, respiratory distress and hypoglycemia.

Dosage forms and trade names available in Iraq

BETAXOLOL (5mg/1ml) 0.5% eye drop
Bertocil (Edol Portugal).

Indications and Dosage

• Chronic open-angle glaucoma and ocular hypertension: 1 drop twice daily.

Off-label uses

Treatment of angle-closure glaucoma during or after iridectomy; Malignant glaucoma; Secondary glaucoma.

Contraindications

Hypersensitivity to Betaxolol; Severe asthma or severe COPD; Chronic heart failure; Second or third-degree heart block or sinus bradycardia.

Cautions:

Corneal disease and dry eye.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=4%.
Distribution Vd=Undetermined, 50% protein bound.
Metabolism Primarily hepatic metabolism.
Elimination Renal elimination is 15%, with a half-life of 14-22 hours.

Drug interactions

Timolol; increased risk of adverse effects and bradycardia when used with Betaxolol.

Side effects

Blurred vision; Corneal punctate keratitis; Inflammation; Itching and foreign body sensation erythema; Ocular dryness; Ocular pain and discharge; Photophobia; Short-term discomfort.

Patient education

Do not use Betaxolol if you have a serious heart condition or slow heartbeats. Contact your doctor immediately if you experience trouble breathing, heart problems, or an allergic reaction.

Note

Betaxolol can be used alone or in combination with other antiglaucoma medications. Primarily used for normal or low-pressure glaucoma due to its calcium channel-blocking activity, increasing optic nerve blood flow in addition to its pressure-lowering activity.

Bevacizumab

ATC Code: L01FG01 Antineoplastic Agents (Vascular Endothelial Growth Factor inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Discontinue breast-feeding.

Indications and Dosage

• Metastatic colorectal cancer: 5mg/kg every 2 weeks.
• Metastatic renal cell carcinoma; Brain cancer (Glioblastoma); Ovarian cancer: 10mg/kg every 2 weeks.
• Non-small cell lung cancer; Cervical cancer: 15mg/kg every 3weeks.

Dosage forms and trade names available in Iraq

BEVACIZUMAB 400mg/16ml vial
Avastin (Roche Switzerland).

Off-label uses

ARMD (Age-related macular degeneration); Breast cancer; Prostate cancer (needs further studies).

Contraindications

Hypersensitivity to bevacizumab; GI perforation; Hypertensive crisis; Nephrotic syndrome; Fistula; Serious bleeding; Wound dehiscence requiring medical intervention.

Cautions

Cardiovascular disease; Thrombocytopenia; Acquired coagulopathy; Hypertension; Do not administer within 28 days of major surgery or active bleeding.
Dose adjustment in renal failure: Avastin cause renal toxicity and proteinuria, withhold avastin until proteinuria less than 2 grams per 24 hours
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=2.39-3.29L, 97%protein bound.
Metabolism Non-specific clearance.
Elimination Catabolism or excretion are the primary processes of elimination with a half-life of 20 days.

Drug interactions

Sunitinib: Coadministration of bevacizumab and sunitinib is not recommended, cases of microangiopathic hemolytic anemia have been reported.

Side effects

Arterial thromboembolic events ESPECIALLY cardiovascular cerebral ischemia; Dysphonia; Gallbladder perforation; Gastrointestinal ulcer; Hypertension; Intestinal necrosis; Intraocular inflammation; Mesenteric venous occlusion; Nasal septum perforation; Permanent loss of vision; Pulmonary hypertension; Renal thrombotic microangiopathy; Retinal detachment; Vitreous floaters.

Patient educations

Do not receive immunizations without physician's approval; Avoid crowds, those with infection; Female patients should take measures to avoid pregnancy during treatment.

Bicalutamide

ATC Code: L02BB03 Endocrine Therapy (Anti-Androgens)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Prostatic carcinoma: 150mg once daily or 50mg bid.

Off-label uses

Monotherapy for locally advanced prostate cancer.

Contraindications

Hypersensitivity to bicalutamide.

Cautions

Diabetes.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=Undetermined, food has no effect on absorption.

Distribution Vd= Undetermined, 96%protein bound.

Metabolism Mostly metabolized by the liver.

Elimination Elimination half-life is 5.8 days.

Dosage forms and trade names available in Iraq

- BICALUTAMIDE 150mg tablet
  CASODEX (AstraZeneca UK).
- BICALUTAMIDE 50mg tablet
  CASODEX (AstraZeneca UK).

Drug interactions

Bosutinib: Bicalutamide increases levels of bosutinib by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Fentanyl: Bicalutamide will increase the level or effect of fentanyl by affecting hepatic and intestinal enzyme CYP3A4 metabolism; If coadministration of CYP3A4 inhibitors with fentanyl is necessary, monitor patients for respiratory depression and sedation at frequent intervals and consider fentanyl dose adjustments until stable drug effects are achieved.

Ifosfamide: Bicalutamide will decrease the level or effect of ifosfamide by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Abdominal pain; Anemia; Constipation; Diarrhea; Dyspnea; Edema; General pain; Hematuria; Hot flashes; Infection; Nausea; Nocturia; Pelvic pain; Peripheral edema.

Less common (1-10%) Anorexia; Anxiety; Arthritis; Breast pain; Chest pain; Flu like symptoms; Gynecomastia; Headache; Hypertension; Rash; UTI; Vomiting; Weight loss.

Rare but serious (less than 1%) None.

Patient educations

Instruct patient to take drug at same time each day, it is usually taken with or without food; Tell patient that any drug-related hair loss should reverse once therapy ends.

Bilastine

ATC Code: R06AX29 Antihistamines for Systemic Use (Other Antihistamines for Systemic Use)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Not recommended for use during breastfeeding

Indications and Dosage

Bilastine is an antihistamine used to relieve symptoms of seasonal and perennial allergic rhinitis and urticaria. The typical oral dose is 20 mg once daily.

Off-label uses

None

Contraindications

Hypersensitivity to bilastine or any component of the formulation.

Cautions

Bilastine may cause drowsiness and impair physical or mental abilities.

Patients should be cautioned about operating machinery, including automobiles, until they are reasonably certain that therapy does not affect them adversely.

Dose adjustment in renal failure: Not recommended in severe renal impairment.

Dose adjustment in hepatic failure: Not required

Dosage forms and trade names available in Iraq

Bilastine 20mg tablet

Alerbix (Faes Farma Pottugal).

Pharmacokinetic parameters

Absorption Oral bioavailability is about 61%.

Distribution Vd= ~1.29 L/kg; Approximately 84-90% protein bound.

Metabolism Not significantly metabolized.

Elimination Excreted in feces (66.5%) and urine (33.5%). The elimination half-life is about 14.5 hours.

Drug interaction

Food: Consumption of food or fruit juice prior to taking bilastine can reduce its absorption and effectiveness. It should be taken at least 1 hour before or 2 hours after a meal or consumption of fruit juice.

P-glycoprotein (P-gp) inhibitors: P-gp inhibitors (e.g., cyclosporine, verapamil) may increase the levels of bilastine.

Side effects

Common (more than 10%) Headache, drowsiness.

Less common (1-10%) Fatigue, abdominal discomfort.

Rare but serious (less than 1%) Allergic reactions including angioedema, rash, pruritus.

Patient education

• Take this medication on an empty stomach, 1 hour before or 2 hours after meals.

• This medication may cause drowsiness. Do not drive or operate heavy machinery until you know how bilastine affects you.

• Avoid drinking grapefruit, apple, or orange juice within 1 hour of taking this medication as it may decrease the effectiveness of the drug.

Bisacodyl

ATC Code: A06AB02 Drugs for Constipation (Contact Laxatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Treatment of constipation: 5mg-15mg as needed, (max 30mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to bisacodyl; Abdominal pain; Appendicitis; Intestinal obstruction; Nausea; Undiagnosed rectal bleeding; Vomiting.

Cautions

Long term use may lead to laxative dependence; Loss of normal bowel function.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Bisacodyl 5mg tab.
DULCOLAX (Boehringer Inglheim Greece).
Bisacodyl 5 mg supp.
Laxocodyl (Julphar UAE).
Bisacodyl 10 mg supp.
Safalax (SAFA Iraq).

Pharmacokinetic parameters

Absorption F=16%, absorption is minimal, action is local in the colon.
Distribution Vd=181-289L.
Metabolism Small amounts absorbed are metabolized by the liver.
Elimination Fecal elimination is 14-17% with half-life of 7-10 hours.

Drug interactions

Antacids: Antacids may diminish the therapeutic effect of bisacodyl; Antacids may cause the delayed -release bisacodyl tablets to release drug prior to reaching the large intestine. Gastric irritation and cramps may occur; Antacids should not be used within 1 hour before bisacodyl administration.
Atropine: The therapeutic efficacy of bisacodyl can be decreased when used in combination with atropine.
Calcium carbonate: The therapeutic efficacy of bisacodyl can be decreased when used in combination with calcium carbonate.
Potassium chloride: Bisacodyl decreases levels of potassium chloride by inhibition of gastrointestinal absorption.

Side effects

Abdominal cramping; Electrolyte and fluid imbalance; Excessive diarrhea; Rectal burning; Vertigo; Vomiting.

Patient educations

Institute measures to promote defecation: increase fluid intake, exercise, high fiber diet; Do not take antacids, milk, or other medication within 1 hour of taking bisacodyl (decreased effectiveness); Report unrelieved constipation, rectal bleeding, muscle pain or cramps, dizziness, weakness; Do not chew, crush, dissolve, or divide tablets.

Bismuth Subsalicylate

ATC Code: A02BX12 Drugs for Acid Related Disorders (Drugs for Peptic Ulcer and Gastro-Oesophageal Reflux Disease)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Salicylates enter breast milk; use with caution.

Indications and Dosage

• **Acute Nonspecific Diarrhea and Travelers' Diarrhea & Dyspepsia:** PO (525) mg every 30–60 minutes or 1.05 g every hour as needed, not to exceed 4.2 g in a 24-hour period. Use until diarrhea stops, but not >2 days.

• **Helicobacter pylori Infection and Duodenal Ulcer Disease:** PO (525) mg of bismuth subsalicylate in conjunction with the other antibiotic for H.pylori.

Off-label uses

None.

Contraindications

Hypersensitivity to bismuth subsalicylate, salicylates, or any component of the formulation; children or teenagers recovering from chickenpox or flu-like symptoms should not use it due to the risk of Reye's syndrome, von Willebrand disease, hemorrhage.

Dosage forms and trade names available in Iraq

Bismuth Subsalicylate 17.5mg/1ml Suspension

Cautions

patients with aspirin sensitivity, bleeding disorders, or renal impairment, Cases of neurotoxicity. .

Dose adjustment in renal failure: bismuth salts are contraindicated in patients with renal impairment.

Dose adjustment in hepatic failure: bismuth salts are contraindicated in patients with hepatic impairment.

Pharmacokinetic parameters

Absorption Bioavailability: Bismuth, <1%; salicylate, 80%, Peak plasma time: Bismuth, 1.8-5 hr, Onset: 4 hr.

Distribution Protein bound: Bismuth, 90%; salicylate, >90%, Vd: Bismuth, 170 mL/kg.

Metabolism hydrolyzed in the stomach to release salicylic acid and bismuth salts.

Elimination Half-life: Bismuth, 21-72 days; salicylate, 2.5 hr, Excretion: Bismuth, feces (99%) and urine (0.003%); salicylate, urine (95%), Clearance: Bismuth, 50 mL/min.

Drug interactions

• Concurrent use with anticoagulants (e.g., warfarin) may increase the risk of bleeding due to the salicylate component.

• Concurrent use with tetracycline antibiotics may decrease the absorption of both medications.

Side effects

Common (more than 10%): Darkening of the tongue or stool, constipation.

Less common (1-10%): Temporary discoloration of the tongue, tinnitus, mild stomach upset, Upper respiratory tract infection.

Rare but serious (less than 1%): salicylate toxicity (especially in children or with prolonged use), Myoclonic encephalopathy, azotemia, metabolic acidosis.

Patient educations

• Be aware of the signs of salicylate toxicity, such as ringing in the ears, dizziness, nausea, vomiting, and seek medical attention if they occur.

Bisoprolol

ATC Code: C07AB07 Beta Blocking Agents (Beta Blocking Agents, Selective)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Breastfed infants should be monitored for the signs and symptoms of bradycardia, respiratory distress and hypoglycemia.

Indications and Dosage

• Hypertension: 2.5mg-5mg daily, (max 20mg daily).

Off-label uses

Angina; Atrial fibrillation; Heart failure.

Contraindications

Hypersensitivity to bisoprolol; Cardiogenic shock; Sinus bradycardia; Heart failure; Second or third degree heart block.

Cautions

Hyperthyroidism; Diabetes; Bronchospastic disease; Myasthenia gravis; Psychiatric disease; Peripheral vascular disease; Raynaud's disease.

Dose adjustment in renal failure: Initially 2.5mg daily (max. 10mg daily).

Dose adjustment in hepatic failure: Initially 2.5mg daily (max. 10mg daily).

Dosage forms and trade names available in Iraq

- BISOPROLOL 2.5mg tablet
  Concor (Merck Germany).
- BISOPROLOL 5mg tablet
  Biscor (Pharma International Jordan).
- BISOPROLOL 10mg tablet
  Biscor (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F= >90%, food has no effect on absorption.
Distribution Protein bound 30%.
Metabolism Extensive hepatic metabolism.
Elimination Bisoprolol elimination 50% unchanged in urine with a half-life of 10-12 hours.

Drug interactions

Furosemide: Bisoprolol increases and furosemide decreases serum potassium, also furosemide may increase hypotensive effect of bisoprolol; Effect of interaction is not clear, use together with caution.

Side effects

Common (more than 10%) None.
Less common (1-10%) Arthralgia; Brady arrhythmia; Cough; Diarrhea; Dizziness; Dyspnea; Insomnia; Nausea; Pharyngitis; Rhinitis; Sinusitis; Upper respiratory infection; Vomiting.
Rare (less than 1%) Bronchospasm; Cold extremities; Depression; Dyspepsia; Hypotension.

Patient educations

Compliance with therapy regimen is essential to control hypertension; If dizziness occurs, sit or lie down immediately; Take pulse properly before each dose and report excessively slow pulse rate (less than 60 beats/min); Report numbness of extremities, dizziness; Do not use nasal decongestants; Restrict salt, alcohol intake.

Bortezomib

ATC Code: L01XG01 Antineoplastic Agents (Proteasome Inhibitors)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: No data available.

Dosage forms and trade names available in Iraq

BORTEZOMIB 3.5mg vial
VELCADE (Janssen cilag Belgium).

Indications and Dosage

• Mantle cell lymphoma: 1.3mg/m2 on days 1, 4, 8, 11 of a 21 days' cycle for 6 cycles.
• Multiple myeloma: 1.3mg/m2 on days 1, 4, 8, 11, 22, 25, 29, 32 of a 42 days' cycle for 4 cycles, then 1.3mg/m2 on days 1, 8, 22, 29 of a 42 days' cycle for 5 cycles.

Off-label uses

Treatment of Waldenströms macroglobulinemia; Peripheral or cutaneous T-cell lymphoma; Systemic light chain amyloidosis.

Contraindications

Hypersensitivity to bortezomib, boron or mannitol; Intrathecal administration.

Cautions

History of syncope; Dehydration; Diabetes; Cardiac disease; Neuropathy.

Dose adjustment in renal failure: Dose adjustments may be necessary.

Dose adjustment in hepatic failure: Moderate hepatic failure (bilirubin greater than 1.5-3 times upper limit of normal) to severe (bilirubin greater than 3 times upper limit of normal), decrease initial dose to 0.7mg/m2 (based on tolerance may increase to 1mg/m2 or decrease to 0.5mg/m2).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=498-1884L/m2, 83%protein bound.
Metabolism Mostly metabolized by the liver (P450 enzymes).
Elimination Excretion is unknown with half-life of 9-15 hours.

Drug interactions

Enzalutamide: Enzalutamide will decrease the level or effect of bortezomib by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Anemia; Anorexia; Arthralgia; Asthenia; Constipation; Cough; Dehydration; Diarrhea; Dizziness; Dyspnea; Edema; Headache; Insomnia; Limb pain; Neutropenia; Paresthesia; Peripheral neuropathy; Pyrexia; Rash; Thrombocytopenia; URI; Vomiting.
Less common (1-10%) None.
Rare but serious (less than 1%) None.

Patient educations

Report new and worsening vomiting, bleeding, breathing difficulties; Increase fluid intake; Avoid tasks that require mental alertness, motor skills until response to drug is established.

Bosentan

ATC CODE: C02KX01 Antihypertensives (Antihypertensives For Pulmonary Arterial Hypertension)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Pulmonary arterial hypertension: 62.5mg bid for 4 weeks; then increase to maintenance dose of 125mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to bosentan; Pregnancy.

Cautions

Pulmonary edema.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In moderate and severe hepatic failure use of bosentan is contraindicated.

Dosage forms and trade names available in Iraq

- BOSENTAN 125mg tablet
  Tracleer (Actelion Switzerland).
- BOSENTAN 62.5mg tablet
  Gonista (The United Jordan).

Pharmacokinetic parameters

Absorption F=50%, food has no effect on absorption.

Distribution Vd=18L, 98%protein bound.

Metabolism Bosentan metabolism in the liver by CYP2C9 and CYP3A4.

Elimination Biliary excretion following metabolism in the liver with half-life of 5 hours.

Drug interactions

Cyclosporine: Cyclosporine will increase the level or effect of bosentan.

Abemaciclib: Bosentan will decrease the level or effect of abemaciclib by affecting hepatic and intestinal enzyme CYP3A4 metabolism, coadministration of abemaciclib with strong CYP3A4 inducers reduces plasma concentration of abemaciclib and its metabolites.

Side effects

Common (more than 10%) Edema; Flushing; Headache; Hypotension; Nasopharyngitis; Respiratory tract infection.

Less common (1-10%) Abnormal AST and ALT; Anemia; Arthralgia; Chest pain; Diarrhea; Flushing; Hypotension; Palpitations; Red skin; Sinusitis; Syncope.

Rare but serious (less than 1%) Angioedema.

Patient educations

Tell patient to take drug with or without food in morning and evening; Because of the potential for adverse effects in the breastfeeding infant, a decision should be made to discontinue breastfeeding or discontinue drug, taking into account the importance of drug to the mother; Inform patient that he'll undergo CBC measurement and liver function testing regularly during therapy.

Bosutinib

ATC Code: L01EA04 Antineoplastic Agents (BCR-ABL Tyrosine Kinase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Chronic myelogenous leukemia: 500mg once daily. If complete hematologic response not achieved by week 8 or complete cytogenetic response not achieved by week 12, may increase to 600mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to bosutinib.

Cautions

Anemia; Thrombocytopenia; Neutropenia; Recent diarrhea; Pulmonary edema; Heart failure; Fluid retention; Pancreatitis.

Dose adjustment in renal failure: CrCl 30-50ml per minute reduce dose of bosutinib to 400mg once daily; CrCl less than 30ml per minute reduce dose of bosutinib to 300mg once daily.

Dose adjustment in hepatic failure: Reduce dose of bosutinib to 200mg once daily.

Dosage forms and trade names available in Iraq

- Bosutinib 100mg tablet
  Bosulif (Pfizer Belgium).
- Bosutinib 400mg tablet
  Bosulif (Pfizer Belgium).
- Bosutinib 500mg tablet
  Bosulif (Pfizer Belgium).

Pharmacokinetic parameters

Absorption F=34%, high fat food increase absorption.
Distribution Vd=1230 L, 94%protein bound.
Metabolism Metabolized in the liver by CYP3A4.
Elimination Renal elimination is 3% with half-life of 22-27 hours.

Drug interactions

Dexamethasone: Dexamethasone decreases levels of bosutinib by affecting hepatic and intestinal enzyme CYP3A4 metabolism, dexamethasone decreased bosutinib plasma concentration by 85%.

Side effects

Common (more than 10%) Abdominal pain; Calcium decreased; Creatinine increased; Diarrhea; Headache; Hemoglobin decreased; Lymphocyte count decreased; Phosphorus decreased; Platelet count decreased; Vomiting.
Less common (1-10%) Acute kidney injury; Bronchitis; Dehydration; Gastritis; Hypothyroidism; Myalgia; Pancreatitis; Pulmonary hypertension; Tinnitus.
Rare but serious (less than 1%) Erythema multiforme; Febrile neutropenia; Hyperthyroidism; Pericarditis; Pulmonary edema.

Patient educations

Take with meals; Drink plenty of fluids (diarrhea may result in dehydration); Avoid alcohol; Separate antacid dosing by more than 2 hours before and after medication, lansoprazole, pantoprazole may reduce absorption of bosutinib.

Brimonidine

B

ATC Code: S01EA05 Ophthalmologicals (Sympathomimetics in Glaucoma Therapy)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Ocular hypertension, open angle glaucoma: 1 drop in affected eye tid.

Off-label uses

None.

Contraindications

Hypersensitivity to brimonidine or any of its ingredients.

Cautions

Should be used with great caution in young children, in whom severe central nervous system (CNS), depression and hypotension been reported.

Pharmacokinetic parameters

Absorption Minor systemic absorption following ophthalmic use.
Distribution Effective penetration of brimonidine into aqueous humor.
Metabolism Metabolized 24% by unknown enzymes.
Elimination Renal elimination is 74% with a half-life of 3 hours.

Dosage forms and trade names available in Iraq

BRIMONIDINE 0.2% Sterile ophthalmic drops
Brimogan (Cooper Greece)

Drug interactions

Selegiline: Coadministration of selegiline and brimonidine is contraindicated.
Valsartan: Brimonidine increases effects of valsartan by pharmacodynamic synergism, use together with caution.
Monoamine oxidase inhibitor antidepressants: due to the risk of hypertensive crisis.

Side effects

Allergic conjunctivitis; Blepharitis; Conjunctival hyperemia; Dizziness; Dyspepsia; Eye discharge; Eye pruritus; Fatigue; Headache; Oral dryness; Photophobia; Rash.

Patient educations

Wash your hands and remove contact lenses before using brimonidine, for administration, lie down or tilt head back, with index finger, pull down the lower lid of eye to form a pocket, hold the dropper close to eye with the other hand, drop into the pocket made between lower lid and eyeball, gently close eyes, place index finger over the inner corner of eye for 1 minute, do not rinse or wipe the dropper or allow it to touch anything, including eye, put the cap on bottle right away, reinsert contacts after 15 minutes, separate administration of other ophthalmic drug by 5 minutes.

Bromfenac

ATC Code: S01BC11 Ophthalmologicals (Antiinflammatory Agents, Non-Steroids)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: It is not yet known

Indications and Dosage

Bromfenac ophthalmic solution is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. The recommended dose is one drop in the affected eye(s) twice daily, starting the day after surgery and continuing for the first 2 weeks post-op.

Off-label uses

None

Contraindications

Hypersensitivity to any ingredient in the formulation.

Cautions

The use of topical NSAIDs may result in keratitis. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs.
Dose adjustment in renal failure: Not required
Dose adjustment in hepatic failure: Not required

Dosage forms and trade names available in Iraq

Bromfenac Sodium 0.9mg Sterile ophthalmic solution
Brofix (Jamjoom KSA).

Pharmacokinetic parameters

As bromfenac is used topically, systemic absorption is minimal and pharmacokinetic parameters are not typically discussed or considered in treatment.

Drug interaction

No known major drug interactions.

Side effects

Common (more than 10%): Abnormal sensation in eye, conjunctival hyperemia.
Less common (1-10%): Eye pain and stinging, visual disturbances.
Rare but serious (less than 1%): Corneal erosion, ulcers or perforation, acute renal failure, severe hepatic reaction.

Patient education

1. Do not touch dropper tip to any surface, as this may contaminate the contents.
2. If you wear contact lenses, remove them before using bromfenac eye drops.
3. If you experience any signs of eye pain, changes in vision, or persistent redness or irritation of the eye, stop using bromfenac and contact your healthcare provider immediately.

Bromhexine

ATC Code: R05CB02 Cough and Cold Preparations (Mucolytics)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X N

Lactation: Bromhexine is excreted in breast milk. Although unfavorable effects on breastfed infants would not be expected, bromhexine is not recommended for use in breastfeeding mothers.

Dosage forms and trade names available in Iraq

BROMHEXINE 4mg/5ml syrup
Mucosolve (Pioneer Iraq), **Solvodad** (Wadi Al-Rafidain Iraq), **Solvodin** (SDI Iraq), **Solvohexin** (Dubai Iraq), **Solvocough** (AL-Kindi Iraq), **MucoAway** (AL-mansour Iraq).

BROMHEXINE 8mg tablet
Solvodin (SDI Iraq).

Indications and Dosage

• As a mucolytic in the treatment of viscid mucoid secretions associated with bronchitis or sinusitis: 8mg-16mg tid; Maximum daily dose 48mg in 3 divided doses; Children 6-11 years (only on the advice of a physician) 24 mg in 3 divided doses; Do not use in children under 6 years of age. Or Inhalation: Solution for nebulization (2 mg/mL): Children 2 to <6 years: 1.3 mg (10 drops) twice daily; Children 6 to <12 years: 2 mg (1 mL) twice daily; Children ≥12 years and Adolescents: 4 mg (2 mL) twice daily; Adults: 8 mg (4 mL) twice daily.

Off-label uses

None.

Contraindications

Hypersensitivity to bromhexine.

Cautions

Asthma; Peptic ulcer disease.
Dose adjustment in renal failure: Safety and efficacy has not been established.
Dose adjustment in hepatic failure: Safety and efficacy has not been established.

Pharmacokinetic parameters

Absorption F=22-27%, bromhexine undergoes extensive first pass effect in the range of 75-80%.
Distribution Vd=19L/kg, 95%protein bound.
Metabolism Bromhexine is completely metabolized to a variety of hydroxylated metabolites in addition to dibromanthranilic acid.
Elimination Renal elimination is 97% with half-life of 6.6-31.4 hours.

Drug interactions

Amoxycillin: Following the administration of bromhexine, the antibiotic concentrations of amoxycillin in the sputum and bronchopulmonary secretions are increased.
Erythromycin: Following the administration of bromhexine, the antibiotic concentrations of erythromycin in the sputum and bronchopulmonary secretions are increased.

Side effects

Angioedema; Bronchospasm; Diarrhea; Dizziness; Headache; Nausea; Pruritus; Rash; Stevens Johnson syndrome; Sweating; Toxic epidermal necrolysis; Upper abdominal pain; Urticaria; Vomiting.

Patient educations

Bromhexine may be taken with or without food.

Bromocriptine

ATC Code: N04BC01 Anti-Parkinson Drugs (Dopamine Agonists)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Bromocriptine inhibits lactation.

Indications and Dosage

• Hyperprolactinemia: Initially, 1.25mg-2.5mg daily, may increase by 2.5mg/day at 3-7 days' intervals.
• Parkinson disease: Initially, 1.25mg bid, may increase by 2.5mg/day every 14-28 days.
• Acromegaly: Initially, 1.25mg-2.5mg, may increase at 3-7 days' intervals, usual dose 20mg-30mg daily.

Off-label uses

Hyperprolactinemia associated with pituitary adenomas; Neuroleptic malignant syndrome.

Contraindications

Hypersensitivity to bromocriptine; Peripheral vascular disease; Severe ischemic heart disease; Uncontrolled hypertension.

Dosage forms and trade names available in Iraq

BROMOCRIPTINE 2.5mg tablet
CRIPTIKIN (AL-Kindi Iraq).

Cautions

Parkinsonian syndrome who manifest mild degrees of dementia; Myocardial infarction; Nodal or ventricular arrhythmia; History of psychosis; Peptic ulcer.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=28%.
Distribution Vd= Undetermined, 90-96%protein bound.
Metabolism Completely metabolized by the liver.
Elimination Renal elimination is 6% with half-life of 2-8 hours.

Drug interactions

Cabergoline: The concomitant use of bromocriptine with cabergoline may potentially lead to cabergoline toxicity, therefore the combination should be avoided.

Side effects

Common (more than 10%) Asthenia; Constipation; Dizziness; Fatigue; Headache; Nausea; Rhinitis.
Less common (1-10%) Abdominal cramps; Amblyopia; Anorexia; Diarrhea; Dry mouth and nasal stuffiness; Dyspepsia; Flu syndrome; Gastrointestinal bleeding; Indigestion; Infection; Nasal congestion; Postural orthostatic hypotension; Sinusitis; Syncope; Vomiting.
Rare but serious (less than 1%) None.

Patient educations

Instruct patient to take bromocriptine within 2 hours of waking in the morning and with food.

Budesonide

ATC Code: R03BA02 Drugs for Obstructive Airway Diseases (Glucocorticoids)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Budesonide 0.5 mg/ml Nebulising suspension
Pulmicort (Astra Zenca Sweden).

Budesonide 200 mcg/ dose turbuhaler
Pulmicort (Astra Zenca Sweden).

Budesonide 64 mcg / dose nasal spray
RHINOCORT AQUA (Astra Zenca Sweden).

Indications and Dosage

• Asthma: 180mcg-360mcg bid via metered dose inhaler.
• Allergic rhinitis, Nasal polyps: 64mcg bid, dose to be administered to each nostril, reduce dose when control achieved.

Off-label uses

None.

Contraindications

Hypersensitivity to budesonide; Not for relief of acute bronchospasms.

Cautions

Thyroid disease; Cardiovascular disease; Diabetes; Glaucoma; Cataracts; Myasthenia gravis; Patients at risk for osteoporosis; Seizures; Post-acute myocardial infarction; Elderly.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=6%.

Distribution Vd=3L/kg, 85-90% protein bound.

Metabolism Extensive hepatic metabolism.

Elimination Renal elimination is 60% and fecal elimination 15-29% with a half-life of 2-3 hr.

Drug interactions

Clarithromycin: Clarithromycin will increase the level or effect of budesonide.

Everolimus: Budesonide will decrease the level or effect of everolimus.

Itraconazole: Itraconazole may increase concentration of budesonide.

Rifampin: Rifampin will decrease the level or effect of budesonide.

Side effects

Common (more than 10%) Respiratory infection; Rhinitis; Otitis media.

Less common (1-10%) Bronchospasm; Cough; Epistaxis; Nasal congestion; Nasal irritation; Nasopharyngitis; Oral candidiasis; Viral gastroenteritis; Viral upper respiratory tract infection.

Rare (less than 1%) Cataracts; Decreased body growth; Decreased bone mineral density.

Patient educations

Improvement noted in 24hours but full effect may take 3-7 days; Rinse mouth following treatment.

Bumetanide

ATC Code: C03CA02 Diuretics (Sulfonamides, Plain)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Bumetanide may inhibit lactation

Indications and Dosage

• Edema: 0.5mg-2mg as a single dose in the morning, may repeat every 4-5 hours.
• Hypertension: Initially, 0.5mg once daily, range 1mg-4mg daily, (max 5mg daily).

Off-label uses

Treatment of hypercalcemia.

Contraindications

Hypersensitivity to bumetanide; Anuria; Hepatic coma; Severe electrolyte depletion.

Cautions

Hypotension.
Dose adjustment in renal failure: Contraindicated in anuria.
Dose adjustment in hepatic failure: Contraindicated hepatic coma.

Dosage forms and trade names available in Iraq

Bumetanide 1mg tab
Burinex (Karo pharma Sweden).

Pharmacokinetic parameters

Absorption F=80%, food has no effect on absorption.
Distribution Vd= Undetermined, 72-96%protein bound.
Metabolism Partially metabolized by liver.
Elimination Renal elimination is 50% with half-life of 60-90 minutes.

Drug interactions

Amikacin: bumetanide and amikacin both increases toxicity of the other, increased risk of ototoxicity and nephrotoxicity.
Gentamicin: bumetanide and gentamicin both increases toxicity of the other, increased risk of ototoxicity and nephrotoxicity.
Streptomycin: bumetanide and streptomycin both increases toxicity of the other, increased risk of ototoxicity and nephrotoxicity.

Side effects

Common (more than 10%) Azotemia; Hyperuricemia; Hypochloremia; Hypokalemia.
Less common (1-10%) Dizziness; Hyperglycemia; Increased serum creatinine; Muscle cramps; Ototoxicity.
Rare but serious (less than 1%) Asterixis; Dehydration; Hypotension; Orthostatic hypotension; Pruritus; Rash; Renal failure; Vertigo; Vomiting.

Patient educations

Expect increased urinary frequency and volume; Report auditory abnormalities (e.g., sense of fullness in ears, tinnitus); Eat foods high in potassium such as whole grains, meat, bananas, apricots, orange juice, potatoes; Rise slowly from sitting or lying position.

Bupivacaine

ATC Code: N01BB01 Anesthetics (Amides)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N
Lactation: It is not yet known

Dosage forms and trade names available in Iraq

Bupivacaine hydrochloride anhydrous 0.5% injection
Marcaine spinal (Aspen pharma Ireland).

Indications and Dosage

Bupivacaine is used for local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures. Dosage varies widely depending on the procedure, location, and individual patient factors.

Off-label uses

For chronic pain management.

Contraindications

Hypersensitivity to bupivacaine or other amide-type local anesthetics.

Cautions

In patients with heart block, severe hepatic disease, or severe renal impairment. It should also be used cautiously in people with hypovolemia or hypotension.
Dose adjustment in renal failure: Use with caution
Dose adjustment in hepatic failure: Hepatic disease can reduce the clearance of bupivacaine, leading to increased risks of toxicity. Use with caution in patients with severe hepatic disease.

Pharmacokinetic parameters

Absorption Systemic absorption of local anesthetics produces effects on the cardiovascular and central nervous systems.
Distribution After injection, bupivacaine is rapidly absorbed and distributed throughout the body.
Metabolism Bupivacaine is metabolized primarily in the liver.
Elimination Metabolites and unchanged drug are excreted by the kidneys. The elimination half-life is about 2.7 hours.

Drug interaction

Other local anesthetics or structurally related drugs: Concurrent use can cause additive systemic effects and increase the risk of toxicity.
Drugs that can reduce hepatic blood flow or otherwise affect hepatic metabolic function: These drugs can increase the risk of bupivacaine toxicity.

Side effects

Common (more than 10%): Nausea, vomiting, and dizziness.
Less common (1-10%): Hypotension, bradycardia, dyspnea.
Rare but serious (less than 1%): Cardiac arrest, seizures, severe allergic reactions, and persistent neurological deficits.

Patient education

1. After receiving bupivacaine, avoid eating or drinking until sensation has returned to your mouth and throat.
2. Be aware that bupivacaine can cause dizziness or drowsiness. Do not drive or operate heavy machinery until these side effects have subsided.
3. If you experience any serious side effects such as seizures, severe dizziness or fainting, or slow heart rate, seek medical attention immediately.

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Cabergoline

ATC Code: G02CB03 Other Gynecologicals (Prolactine Inhibitors)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Cabergoline inhibits lactation.

Indications and Dosage

• Hyperprolactemia (idiopathic or due to primary pituitary adenomas): 0.25mg two times per week, titrate by 0.25mg/dose, serum prolactin level guides dose adjustment.

Off-label uses

Restless leg syndrome.

Contraindications

Hypersensitivity to cabergoline; Uncontrolled hypertension; Valvular heart disease.

Cautions

Raynaud's syndrome; Peptic ulcer; Gastrointestinal bleeding; Cardiovascular disease; History of serious mental disorders (especially psychotic disorders).
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Cabergoline 0.5 mg tablet
Prolin (Pharma international Jordan).

Pharmacokinetic parameters

Absorption First-pass effect is seen, however the absolute bioavailability is undetermined.
Distribution Vd= Undetermined, 40-42%protein bound.
Metabolism Extensively metabolized by the liver.
Elimination Renal elimination is 4% with half-life of 63-69 hours.

Drug interactions

Clarithromycin: clarithromycin increases levels of cabergoline by decreasing metabolism.
Isosorbide mononitrate: isosorbide mononitrate increases effects of cabergoline by decreasing metabolism, risk of increased SBP, angina pectoris.
Olanzapine: olanzapine decreases effects of cabergoline by pharmacodynamic antagonism.

Side effects

Common (more than 10%) Angina pectoris; Asthenia; Cardiac Valvulopathy; Confusion; Constipation; Dizziness; Drowsiness; Dyspepsia; Dyspnea; Gastritis; Hallucination; Headache; Hypotension; Movement disorders; Nausea; Edema; Pericardial effusion; Pericarditis; Sexual dysfunction; Sleep disorders; Vertigo; Vomiting.
Less common (1-10%) Delusions; Erythromelalgia; Hepatic function abnormal; Psychotic disorder; Rash; Respiratory disorders.
Rare but serious (less than 1%) Aggression; Fibrosis; Gastric ulcer; Pleural effusion; Psychosis; Valvulopathy.

Patient educations

Cabergoline may impair ability to drive or operate machinery; Monitor blood pressure, serum prolactin level (monthly until normalized), echocardiogram (at baseline and 6-12 monthly).

Calcium Carbonate

ATC Code: A12AA04 Mineral Supplements (Calcium)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

- Antacid: 500mg-2g as needed, (max 8g daily).
- Calcium supplement: 1g tid.

Off-label uses

Severe hyperkalemia; Malignant arrhythmias associated with hypermagnesemia.

Contraindications

Hypersensitivity to calcium carbonate; Calcium based renal calculi; Hypercalcemia; Ventricular fibrillation.

Cautions

Chronic renal impairment; Hypokalemia.

Dose adjustment in renal failure: CrCl less than 25ml per minute, dosage adjustment may be needed based on serum calcium levels.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Calcium carbonate 500 mg tab
Calcium-Kindi (Al-Kindi Iraq), **CALCIUM** (Wadi Al-Rafidain Iraq).

Pharmacokinetic parameters

Absorption Oral bioavailability depends on intestinal pH, the presence of food.
Distribution Vd=Undetermined, 40%protein bound.
Metabolism Converted to calcium chloride by gastric acid.
Elimination Renal elimination is 20%.

Drug interactions

Digoxin: Calcium carbonate will increase the level or effect of digoxin by increasing gastric pH.
Doxycycline: Calcium carbonate and doxycycline both decreases levels of the other by inhibition of GI absorption, separate by 2 hours.
Ketoconazole: Calcium carbonate will decrease the level or effect of ketoconazole by increasing gastric pH.
Nimodipine: Calcium carbonate will increase the level or effect of nimodipine by increasing gastric pH.
Tetracycline: Calcium carbonate and tetracycline both decreases levels of the other by inhibition of GI absorption, separate by 2 hours.

Side effects

Anorexia; Constipation; Flatulence; Hypercalcemia; Hypophosphatemia; Milk-alkali syndrome; Nausea; Vomiting.

Patient educations

Do not take within 1–2 hours of other oral medications, fiber-containing foods; Avoid excessive use of alcohol, tobacco, caffeine.

Calcium Chloride

ATC Code: B05XA07 Blood Substitutes And Perfusion Solutions (Electrolyte Solutions)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: There are no contraindications for breastfeeding

Indications and Dosage

Used in hypocalcemia, hyperkalemia, and hypermagnesemia. Dosage varies widely depending on the condition being treated and patient's calcium levels.

Off-label uses

the management of calcium channel blocker overdose.

Contraindications

Hypercalcemia; ventricular fibrillation; digitalis toxicity; hypersensitivity to calcium chloride.

Cautions

In patients with renal disease; respiratory impairment; cardiac disease or sarcoidosis.

Dose adjustment in renal failure: Adjustments may be needed; monitor calcium levels closely.

Dose adjustment in hepatic failure: No specific guidelines have been suggested.

Dosage forms and trade names available in Iraq

Calcium Chloride 10% (100mg/ml) 10ml injection

Calcium Chloride Injection (Pioneer Iraq).

Pharmacokinetic parameters

Calcium chloride provides ionized calcium, replacing the calcium found in serum. Its effects are largely local, and systemic pharmacokinetic parameters are not generally applicable.

Drug interaction

Digoxin: Hypercalcemia may predispose patients to digitalis toxicity.

Thiazide Diuretics: Can decrease renal excretion of calcium, leading to hypercalcemia.

Side effects

Common (more than 10%): Local burning or irritation with IV administration.

Less common (1-10%): Hypotension; bradycardia; nausea; vomiting.

Rare but serious (less than 1%): Hypercalcemia; cardiac arrest; arrhythmias; tissue necrosis (if extravasation occurs).

Patient education

Contact your healthcare provider immediately if you experience persistent nausea/vomiting, loss of appetite, unusual weight loss, mental/mood changes, signs of kidney problems (such as change in the amount of urine), or bone pain.

Candesartan

ATC Code: C09CA06 Agents Acting on The Renin-Angiotensin System (Angiotensin II Receptor Blockers (ARBs), plain)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: No data available.

Dosage forms and trade names available in Iraq

- Candesartan cilexetil 16mg tab
  Candasart (PIONEER IRAQ), **KANDESAT** (Al-Kindi Iraq).
- Candesartan cilexetil 8mg tab
  KANDESAT (Al-Kindi Iraq), **Candasart** (PIONEER IRAQ).

Indications and Dosage

• Hypertension: Initially, 8mg once daily, may titrate to 32mg once daily.

• Heart failure with reduce ejection fraction: 4mg once daily, may double dose at approximately 2-weeks intervals up to a target dose of 32mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to candesartan.

Cautions

Significant aortic stenosis and mitral stenosis; Unstented renal artery stenosis; Heart failure (may induce hypotension when treatment initiated).

Dose adjustment in renal failure: CrCl 15-60ml/min: 8mg daily.

Dose adjustment in hepatic failure: Use cautiously.

Pharmacokinetic parameters

Absorption F=15%, food has no effect on absorption.

Distribution Vd=0.13L, more than 99% protein bound.

Metabolism Minimal hepatic metabolism.

Elimination Renal elimination is 33% and fecal elimination is 67% with a half-life of 5-10 hr.

Drug interactions

ACE inhibitor: Coadministration of an ACE inhibitor in combination with a candesartan may increase the risk of hyperkalemia, hypotension, syncope, and renal dysfunction due to additive or synergistic effects on the renin angiotensin system.

Spironolactone: Concomitant use of candesartan and spironolactone may increase the risk of hyperkalemia.

Side effects

Abdominal pain; Albuminuria; Angioedema; Arthralgia; Back pain; Bronchitis; Coughing; Diarrhea; Dizziness; Dyspepsia; Fatigue; Gastroenteritis; Hypertriglyceridemia; Hyperuricemia; Nausea; Palpitation; Peripheral edema; Pharyngitis; Rash; Rhinitis; Tachycardia.

Patient educations

Hypertension requires lifelong control; Inform female patients regarding potential for fetal injury, mortality with second and third trimester exposure to candesartan; Report any sign of infection (sore throat, fever); Do not stop taking candesartan; Caution against exercising during hot weather (risk of dehydration; hypotension).

Capecitabine

ATC Code: L01BC06 Antineoplastic Agents (Pyrimidine Analogues)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C D X **N**

Lactation: Discontinue breast-feeding.

Indications and Dosage

• A nucleoside metabolic inhibitor indicated for: Colorectal Cancer, Breast Cancer, Gastric, Esophageal, or Gastroesophageal Junction Cancer, Pancreatic Cancer.
• Single agent; 1,250 mg/m2 twice daily orally for the first 14 days of each 21-day cycle for a maximum of 8 cycles.

Dosage forms and trade names available in Iraq

- Capecitabine 150mg tablet
- Capecitabine 500mg tablet

Xeloda (Roche Switzerland).

Off-label uses

Gastric cancer; Pancreatic cancer; Esophageal cancer; Ovarian cancer; Neuroendocrine tumors; Hepatobiliary cancer.

Contraindications

History of severe hypersensitivity reactions to fluorouracil or capecitabine.

Cautions

Bone marrow depression; Hepatic impairment; Elderly.
Dose adjustment in renal failure: CrCl 30-50ml per minute, 75% of normal dose; CrCl less than 30ml per minute, use of calcipotriol is contraindicated.
Dose adjustment in hepatic failure: Caution when patients with hepatic dysfunction.

Pharmacokinetic parameters

Absorption F=70%, food reduces rate and extent of absorption.
Distribution Vd=Undetermined, 60%protein bound.
Metabolism Enzymatically metabolized to fluorouracil.
Elimination Inactive metabolites are excreted primarily in urine, with half-life of 45 minutes.

Drug interactions

Enoxaparin: capecitabine increases effects of enoxaparin by unspecified interaction mechanism, an additive risk of bleeding with enoxaparin may be seen in thrombocytopenic patients receiving capecitabine.

Side effects

Common (more than 10%) Abdominal pain; Alopecia; Anemia; Anorexia; Bilirubin increased; Constipation; Dermatitis; Diarrhea; Dyspepsia; Dyspnea; Edema; Eye irritation; Fatigue; Fever; Hand and foot syndrome; Headache; Lymphopenia; Neutropenia; Pain; Paresthesia; Stomatitis; Thrombocytopenia; Vomiting.
Less common (1-10%) Angioedema; Back pain; Chest pain; Dehydration; Dermatitis; Dry mouth; Dyspepsia; Headache; Pruritus; Rash; Taste disturbance; Toxic leukoencephalopathy; Weakness.
Rare but serious (less than 1%) None.

Patient educations

Do not have immunizations without physician's approval (drug lowers body resistance); Promptly report fever.

Captopril

ATC Code: C09AA01 Agents Acting on The Renin-Angiotensin System (ACE Inhibitors, plain)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Hypertension: Initially, 12.5mg-25mg bid or tid, maintenance 50mg tid.

• Heart failure: Initially, 6.25mg-25mg tid, maintenance 50mg tid.

• Post-myocardial infarction: Initially 6.25mg, then 12.5mg tid, increase to 25mg-50mg tid.

• Type 1 diabetic Nephropathy: 25mg tid.

Off-label uses

Acute hypertensive crisis; Pediatric hypertension; Raynaud phenomenon.

Contraindications

Hypersensitivity to captopril; Anuria; Hereditary or idiopathic angioedema; Bilateral renal artery stenosis.

Dosage forms and trade names available in Iraq

- Captopril 25 mg tablet
  CAPTOSAM (SDI Iraq), **CAPTONEER** (PIONEER IRAQ), CAPTOPRIL (Al-KINDI Iraq).
- Captopril 50mg tablet
  CAPTOSAM (SDI Iraq), **CAPTONEER** (PIONEER IRAQ), **CAPTOPRIL** (Al-KINDI Iraq).

Cautions

Gout; Hypertrophic cardiomyopathy with outflow obstruction; Major surgery; Renal artery stenosis.

Dose adjustment in renal failure: CrCl 10-50ml/min: 75% of normal dosage; CrCl less than 10ml/min: 50% of normal dosage.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=70-75%, captopril taken on empty stomach.

Distribution Vd=0.7L/kg, 25-30% protein bound.

Metabolism Hepatic metabolism 50%.

Elimination Renal elimination is 95% with half-life of 2 hr.

Drug interactions

Aceclofenac: The risk or severity of renal failure, hyperkalemia, and hypertension can be increased when aceclofenac is combined with captopril.

Acetazolamide: The excretion of captopril can be decreased when combined with acetazolamide.

Acetylsalicylic acid: The therapeutic efficacy of captopril can be decreased when used in combination with acetylsalicylic acid.

Side effects

Common (more than 10%) Hyperkalemia.

Less common (1-10%) Chest pain; Cough; Hypotension; Palpitations; Proteinuria; Pruritus; Skin rash; Tachycardia.

Rare (less than 1%) None.

Patient educations

Tell patient to take drug 1 hour before meals on empty stomach; Advise patient to report fever, rash, sore throat, mouth sores, fast or irregular heartbeat, chest pain, or cough; Inform patient that dizziness, fainting, and light-headedness usually disappear once his body adjusts to drug; Tell patient his ability to taste may decrease during first 2 to 3 months of therapy.

Carbamazepine

ATC Code: N03AF01 Antiepileptics (Carboxamide Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Epilepsy, partial, generalized, and mixed types: 200mg bid, may titrate to 1200 mg daily.
• Trigeminal neuralgia: 100mg bid, may titrate to 1200mg daily prn or pain control.
• Bipolar disease, acute manic and mixed episodes: 200mg bid, may titrate to 1600mg daily.

Off-label uses

Neuropathic pain.

Contraindications

Hypersensitivity to carbamazepine; Atrioventricular block; Bone marrow depression.

Cautions

Cardiac disease; Increased intraocular pressure; Mixed seizure disorders; Glaucoma; Elderly males with prostatic hypertrophy; Psychiatric patients.
Dose adjustment in renal failure: Not required
Dose adjustment in hepatic failure: Avoid.

Dosage forms and trade names available in Iraq

Carbamazepine 200mg tab
KARBAZEPIN (AlKindy Iraq).

Pharmacokinetic parameters

Absorption F=89%, food has no effect on absorption.
Distribution Vd=0.59-2L/kg, 75-90% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 72% with an initial half-life of 25-65 hr, then 12-17 hours after 3-5 weeks due to autoinduction.

Drug interactions

Acetaminophen: Carbamazepine may increase the metabolism of acetaminophen, this may diminish the effect of acetaminophen and increase the risk of liver damage.

Side effects

Common (more than 10%) Ataxia; Dizziness; Drowsiness; Nausea; Vomiting.
Less common (1-10%) Dry mouth.
Rare (less than 1%) Hepatic failure; Myocardial infarction; Punctate cortical lens opacities; Stevens-Johnson syndrome; Syndrome of inappropriate antidiuretic hormone secretion (SIADH).

Patient educations

Tell patient to take drug with meals to minimize GI upset; Advise patient to avoid excessive sun exposure and to wear protective clothing and sunscreen.

Carbetocin

ATC Code: H01BB02 Pituitary and Hypothalamic Hormones and Analogues (Oxytocin and Analogues)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Dosage forms and trade names available in Iraq

Carbetocin 100mcg/ ml vial
Pabal RTS (Ferring Germany).

Indications and Dosage

• Prevention of postpartum hemorrhage due to uterine atony: By i.v. injection, 100mcg for 1 dose, to be given over 1 minute, administer as soon as possible after delivery.

Off-label uses

None.

Contraindications

Hypersensitivity to carbetocin; Pre-eclampsia; Eclampsia; Epilepsy.

Cautions

Asthma; Migraine; Hyponatremia.
Dose adjustment in renal failure: Avoid use in renal impairment.
Dose adjustment in hepatic failure: Avoid use in hepatic diseases.

Pharmacokinetic parameters

Absorption F=80%.
Distribution Undetermined.
Metabolism Undetermined.
Elimination Renal elimination is 1% with half-life of 40 minutes.

Drug interactions

Amlodipine: The risk or severity of adverse effects can be increased when carbetocin is combined with amlodipine.
Bosentan: Carbetocin may increase the hypotensive activities of bosentan.
Hydrochlorothiazide: The risk or severity of adverse effects can be increased when carbetocin is combined with hydrochlorothiazide.
Nebivolol: The risk or severity of adverse effects can be increased when carbetocin is combined with nebivolol.
Phenobarbital: Phenobarbital may increase the hypotensive activities of carbetocin.

Side effects

Abdominal pain; Anemia; Anxiety; Chest and back pain; Chills; Dizziness; Dyspnea; Feeling of warmth; Flushing; Headache; Hypotension; Metallic taste; Nausea; Pruritus; Sweating; Tachycardia; Tremor; Vomiting.

Patient educations

Teach patient to report increased blood loss, abdominal cramps, increased temperature; Advise patient that contractions will be similar to menstrual cramps, gradually increasing in intensity.

Carbimazole

ATC Code: H03BB01 Thyroid Therapy (Sulfur-Containing Imidazole Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Contraindicated during breastfeeding, as it may be excreted in human milk and affect the infant's thyroid function.

Dosage forms and trade names available in Iraq

Carbimazole 5mg tab
Neomercazole (Amdipharm France).

Indications and Dosage

Treatment of hyperthyroidism: 15-60 mg daily. After initial therapy and when thyroid function is normal, the dose is often reduced to 5-15 mg per day for maintenance therapy.

Off-label uses

None

Contraindications

Hypersensitivity to carbimazole; Pre-existing hematological conditions; History of acute pancreatitis.

Cautions

Carbimazole can cause serious blood disorders.
Dose Adjustment in Renal Failure: Should be closely monitored due to the potential for increased risk of adverse reactions.
Dose Adjustment in Hepatic Failure: Carbimazole is metabolized in the liver and can potentially cause liver injury. Therefore, it should be used with caution in patients with hepatic disease.

Pharmacokinetic parameters

Absorption Carbimazole is rapidly metabolised to thiamazole. After oral ingestion, peak plasma concentrations of thiamazole occur at 1 to 2 hours.
Distribution Vd=0.5 l/kg, thiamazole is moderately bound to plasma proteins.
Metabolism Carbimazole is extensively metabolized in the liver to its active metabolite, methimazole.
Elimination 90% of orally administered carbimazole is excreted in the urine as thiamazole with half-life of 5.3 to 5.4 hours.

Drug Interactions

Warfarin: Carbimazole may enhance the anticoagulant effect of warfarin, potentially increasing the risk of bleeding.
Beta-Blockers (like Propranolol): Carbimazole may increase the serum concentration of beta-blockers. This can increase the risk of side effects from the beta-blocker.

Side Effects

Common (more than 10%): Joint and muscle pain; Nausea and upset stomach; Skin rash.
Less Common (1-10%): Hair loss; Headache; Itching.
Rare but Serious (less than 1%): Agranulocytosis; Serious liver injury; Severe skin reactions.

Patient Education

Carbimazole take with food to minimize stomach upset. When you first start taking carbimazole, you will take it 2 or 3 times a day. Try to space the doses evenly throughout the day. If you take it 3 times a day, you could take it first thing in the morning, in the middle of the afternoon and at bedtime.

Carboplatin

ATC Code: L01XA02 Antineoplastic Agents (Platinum Compounds)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding.

C

Indications and Dosage

• Ovarian cancer: 360mg/m2 I.V on day 1, every 4 weeks; Do not repeat dose until neutrophil and platelet counts are within acceptable levels.

Off-label uses

Treatment of bony and soft tissue sarcoma; Germ cell tumor; Neuroblastoma pediatric brain tumor; Small cell lung cancer; Solid tumors of the bladder, cervix and testes; Squamous cell carcinoma of the esophagus.

Contraindications

Hypersensitivity to carboplatin; Severe bleeding; Severe myelosuppression.

Cautions

Moderate bone marrow depression; Renal impairment; Elderly.

Dose adjustment in renal failure: CrCl 41-59ml per minute decrease dose to 250mg/m2; CrCl 16-40ml per minute decrease dose to 200mg/m2.

Dose adjustment in hepatic failure: Not required

.

Dosage forms and trade names available in Iraq

Carboplatin 10mg/ml (15ml) vial
CARBOPLATIN (Pfizer Italy).
Carboplatin 10mg/ml (45ml) vial
CARBOPLATIN (pfizer Italy).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=16L, carboplatin is not bound to plasma protein.
Metabolism Carboplatin is predominantly eliminated as the unchanged parent compound.
Elimination Excreted mostly by the kidneys with half-life of 2.6–5.9 hours.

Drug interactions

Amphotericin B: Amphotericin B and carboplatin both increase nephrotoxicity and ototoxicity.

Side effects

Common (more than 10%) Alopecia; Anemia; Asthenia; Central neurotoxicity; Elevated alkaline phosphatase; Elevated AST; Leukopenia; Magnesium loss; Nausea; Neutropenia; Peripheral neuropathy; Thrombocytopenia; Vomiting.
Less common (1-10%) Elevated bilirubin; Immune hypersensitivity reaction.
Rare but serious (less than 1%) Dehydration; Stomatitis.

Patient educations

Nausea, vomiting generally abate within 24 hours; Do not have immunizations without physician's approval (drug lowers body's resistance); Avoid contact with those who have recently received live virus vaccine.

Carboxymethyl Cellulose

ATC Code: S01XA20 Ophthalmologicals (Other Ophthalmologicals)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No known risk; considered compatible with breastfeeding.

Indications and Dosage

Used as a lubricant for dry eyes. Instill 1 or 2 drops in the affected eye(s) as needed.

Off-label uses

None

Contraindications

Hypersensitivity to carboxymethylcellulose or any component of the formulation.

Cautions

Contact lens use (remove lenses prior to administration; may reinsert 15 minutes after administration).
Dose adjustment in renal failure: Not required
Dose adjustment in hepatic failure: Not required

Pharmacokinetic parameters

It acts primarily at the site of activity and systemic absorption is not significant.

Drug interaction

None known.

Side effects

Common (more than 10%): Eye irritation.
Less common (1-10%): Blurred vision, redness of the eye.
Rare but serious (less than 1%): Serious allergic reactions.

Patient education

- Do not use if the solution changes color or becomes cloudy.
- If you wear contact lenses, remove them before using eye drops and wait at least 15 minutes before reinserting.

Dosage forms and trade names available in Iraq

Carboxymethyl Cellulose 0.5% eye drop
Unifresh (Jamjoom KSA).

Cariprazine

ATC Code: N05AX15 Psycholeptics (Other Antipsychotics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Unknown if distributed in breast milk

Dosage forms and trade names available in Iraq

- Cariprazine Hcl 1.5 mg capsule
  Reagila (Gedeon richter Hungary).
- Cariprazine Hcl 3 mg capsule
  Reagila (Gedeon richter Hungary).
- Cariprazine Hcl 4.5mg capsule
  Reagila (Gedeon richter Hungary).
- Cariprazine Hcl 6 mg capsule
  Reagila (Gedeon richter Hungary).

Indications and Dosage

• Schizophrenia: Initial 1.5 mg daily, may be adjusted in increments of 1.5 mg or 3 mg per day, as tolerated, to the recommended dosage of 4.5 mg per day.
• Bipolar I disorder (manic or mixed episodes): Initially, 1.5 mg daily, may be adjusted in increments of 1.5 mg or 3 mg per day, as tolerated, to the recommended dosage of 3 to 6 mg per day.

Off-label uses

None

Contraindications

Hypersensitivity to cariprazine or any components of the formulation.

Cautions

It may increase the risk of suicidal thoughts or behavior in patients, adolescents, and young adults.
Dose adjustment in renal failure: No adjustment recommended.
Dose adjustment in hepatic failure: Caution advised, especially in severe impairment.

Pharmacokinetic parameters

Absorption Well absorbed; food does not affect the absorption.
Distribution Vd= 2,642 to 3,587 L; 91% to 97% protein bound.
Metabolism Hepatic via CYP3A4 to two active metabolites.
Elimination Primarily hepatic; Half-life of 2-5 days for cariprazine and metabolites.

Drug interaction

CYP3A4 inhibitors (e.g., ketoconazole): can increase cariprazine levels. Monitor for increased side effects.
CYP3A4 inducers (e.g., rifampin): can decrease cariprazine levels. Monitor for decreased efficacy.

Side effects

Common (more than 10%): Akathisia; extrapyramidal disorder; insomnia.
Less common (1-10%): Weight gain; fatigue; restlessness; tremors.
Rare but serious (less than 1%): Suicidal thoughts; Neuroleptic malignant syndrome; Tardive dyskinesia.

Patient educations

1. Do not stop taking this medication suddenly without talking to your doctor.
2. Report any unusual or bothersome side effects to your healthcare provider immediately.
3. Be cautious of doing tasks that require alertness until you know how the drug affects you as it may cause drowsiness.

Wadi Alrafidain
Pharmaceutical Products

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PHARMACEUTICAL PRODUCTS

WHO WE ARE

Wadi Al Rafidain for pharmaceutical manufacturing is one of the most important and well- established pharmaceutical companies in Iraq. It has an important role in manufacturing the pharmaceutical products among the national and local drug industries in Iraq, with its big role in providing the needs of Iraqi pharmaceutical drugs to the people in Iraq.

It was established in Baghdad since 1996, and it has recognized to be one of the leading pharmaceutical companies that working in the health and drug manufacturing in Iraq, Wadi Al Rafidain company is working hard to provide high quality of products with global industrial criteria to have a GMP certificate that matching the WHO requirements.

Finally, we are very proud to be a national pharmaceutical company that working with global standards to serve our people in Iraq.

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Carteolol

ATC Code: S01ED05 Ophthalmologicals (Beta Blocking Agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: No data available.

Indications and Dosage

• Open angle glaucoma, ocular hypertension: 1 drop to affected eye(s) bid.

Off-label uses

Combination with miotics decreases intraocular pressure in acute and chronic angle closure glaucoma; Treatment of secondary glaucoma; Malignant glaucoma; Angle closure glaucoma during or after iridectomy.

Dosage forms and trade names available in Iraq

Carteolol Hydrochloride 2% Eye drops
Carteol L.P. (Laboratoire chauvin France).

Contraindications

It is a beta blocker drug.
Hypersensitivity to carteolol; Bronchial asthma; COPD; Bronchospasm; Overt cardiac failure; Cardiogenic shock; Heart block greater than first degree; Persistently severe bradycardia.

Cautions

First degree AV block; Raynaud's disease; COPD; Diabetes; myasthenia gravis; Pheochromocytoma (caution in diabetes as may mask signs of hypoglycemia), nightmares, impotence, tiredness, etc.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Undetermined.
Distribution Vd=Undetermined, 20-30%protein bound.
Metabolism Undergoes hepatic metabolism by CYP2D6.
Elimination Excretion by urine with half-life of 6 hours.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) Burning sensation in eye; Conjunctival hyperemia; Excessive tear production; Eye irritation.
Less common (1-10%) Blurred and cloudy vision; Decreased night vision; Ocular signs (including blepharoconjunctivitis, abnormal corneal staining, and corneal sensitivity occurred occasionally); Photophobia; Ptosis.
Rare but serious (less than 1%) None.

Patient educations

Teach patient proper use of eye drops. Tell him to wash hands first, not to touch dropper tip to any surface, and not to use drops when contact lenses are in eyes; Inform patient that although eye drops commonly cause stinging and blurred vision, he should notify prescriber if these symptoms are severe. To reduce systemic side effects, the patient should be learned to close the eye for 5 minutes after applying this eye drop , or / press on the inner canthal area (lacrimal sac) for 3 minutes to reduce systemic absorption.

Carvedilol

ATC Code: C07AG02 Beta Blocking Agents (Alpha and Beta Blocking Agents)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Hypertension, heart failure, impaired left ventricular function, myocardial infarction: 6.25mg bid, (max 25mg bid).
• Angina: initially 12.5 once daily for 2 days increased to 25 mg twice daily
• 25 mg twice daily with sever heart failure in patient less than 85 KG weight

Off-label uses

Angina pectoris; Cardiac dysrhythmia.

Contraindications

Hypersensitivity to carvedilol; Bronchial asthma; Cardiogenic shock, 2nd or3rd degree AV block; Severe bradycardia; Sick sinus syndrome.

Cautions

Diabetes; Myasthenia gravis; Withdraw gradually to avoid acute tachycardia; Hypertension; Prinzmetal's angina; Pheochromocytoma.

Dose adjustment in renal failure: monitor renal function when patient have heart failure.
Dose adjustment in hepatic failure: Contraindicated in severe liver dysfunction
Pregnancy: when use closed to delivery , infants should be monitored for sign of alpha and beta blockade.

Dosage forms and trade names available in Iraq

- Carvedilol 3.125mg tab
  Unidil (The United Jordan).
- Carvedilol 6.25mg tab
  CARVEDISAM (SDI Iraq), **KARVEDOL** (AL-KINDI Iraq).
- Carvedilol 12.5mg tab
  Carvedilol Hexal (Hexal GERMANY).
- Carvedilol 25mg tab
  KARVEDOL (AL-KINDI Iraq), **Carvidol** (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=25-35%, food significantly increase AUC and Cmax.
Distribution Vd=115L, more than 95% protein bound.
Metabolism Hepatic metabolism 98%.
Elimination Renal elimination is 16% and 60% in feces with a half-life of 6-10 hr.

Drug interactions

Chlorpromazine: Carvedilol and chlorpromazine increases levels of the other by decreasing metabolism, use both drugs together is contraindicated.
Ergotamine: Increase the risk of peripheral vasoconstriction when given with ergotamine.

Side effects

Common (more than 10%) Diarrhea; Dizziness; Fatigue; Hyperglycemia; Hypotension; Weight gain.
Less common (1-10%) Angina; Atrioventricular block; Bradycardia; Cough; Dyspnea; Edema; Headache; Hypercholesterolemia; Hypertriglyceridemia; Nausea; Rhinitis; Syncope; Vomiting.
Rare (less than 1%) None.

Patient educations

Full therapeutic effect of blood pressure may take 1–2 weeks; Take with food; Abruptly stopping treatment or missing multiple doses may cause beta-blocker withdrawal symptoms (fast heart rate, high blood pressure, palpitations, sweating, tremors).

Caspofungin

ATC Code: J02AX04 Antimycotics for Systemic Use (Other Antimycotics for Systemic Use)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available.

Dosage forms and trade names available in Iraq

Caspofungin 50mg vial
CANCIDAS (Merck sharp and Dohme France).

Indications and Dosage

• Aspergillosis: Single 70mg loading dose on Day 1, followed by 50mg daily for 6-12 weeks.
• Candidemia: Initially, 70mg followed by 50mg daily for 14 days.
• Esophageal candidiasis: 50mg daily for 7-14 days.
• Empiric Therapy: Initially, 70mg then 50mg daily; may increase to 70mg daily if needed.

Off-label uses

None.

Contraindications

Hypersensitivity to caspofungin.

Cautions

None.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Decrease dose to 35mg/day.

Pharmacokinetic parameters

Absorption F=92%.
Distribution Vd=Undetermined, 97% protein bound.
Metabolism Slow and extensive.
Elimination Renal elimination 1.5%, half-life of 9-11 hours.

Drug interactions

Atorvastatin: Caspofungin increases toxicity (myopathy risk).
Rifampin: Decreases caspofungin levels by increasing metabolism.

Side effects

Common (more than 10%): Diarrhea, fever, hypotension, increased transaminases, increased serum alkaline phosphatase, phlebitis, rash, respiratory failure, septic shock, shivering.
Less common (1-10%): Abdominal pain, anemia, chills, dizziness, erythema, facial edema/flushing, hematuria, hyperbilirubinemia, hypokalemia, increased serum creatinine, induration, myalgia, nausea, neutropenia, pain, paresthesia, pleural effusion, pruritus, respiratory distress, sepsis, tachycardia, vomiting.
Rare but serious (less than 1%): Anaphylaxis, erythema multiforme, hepatic necrosis, liver failure, nephrotoxicity, pancreatitis, renal impairment, Stevens-Johnson syndrome.

Patient education

Report rash, facial swelling, itching, difficulty breathing, abdominal pain, yellowing of skin or eyes, dark-colored urine, nausea.

Cefaclor

ATC Code: J01DC04 Antibacterials for Systemic Use (Second-Generation Cephalosporins)

Pregnancy category:

FDA A **B** C D X N

TGA A **B1** B2 B3 C D X N

Lactation: Avoid; Cefaclor present in milk in low concentrations.

Dosage forms and trade names available in Iraq

- Cefaclor 250mg/5ml oral suspension
- Cefaclor 375mg/5ml oral suspension

Indications and Dosage

- Bronchitis: 500mg bid for 7 days.
- Lower respiratory tract infections: 250mg-500mg tid.
- Pharyngitis, skin infections, tonsillitis: 250mg-500mg tid.
- Urinary tract infections: 250mg-500mg tid.

Off-label uses

None.

Contraindications

Hypersensitivity to cefaclor or cephalosporins.

Cautions

History of penicillin allergy.

Dose adjustment in renal failure: Use with caution.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=50-75%, food may delay the rate but does not affect the extent of absorption.

Distribution Vd=Undetermined, 25%protein bound.

Metabolism No appreciable biotransformation in liver.

Elimination Renal elimination is 60-85% with half-life of 30-60 minutes.

Drug interactions

Estradiol: Cefaclor will decrease the level or effect of estradiol by altering intestinal flora, risk of contraceptive failure.

Furosemide: Cefaclor increases toxicity of furosemide by pharmacodynamic synergism, Increased risk of nephrotoxicity.

Piroxicam: Cefaclor will increase the level or effect of piroxicam by acidic drug competition for renal tubular clearance.

Side effects

Common (more than 10%) None.

Less common (1-10%) Diarrhea; Eosinophilia; Moniliasis; Increased transaminases; Rash; Vaginitis.

Rare but serious (less than 1%) Anemia; Jaundice; Nausea; Neutropenia; Pseudomembranous colitis; Stevens-Johnson syndrome; Vomiting.

Patient educations

Continue therapy for full length of treatment; Doses should be evenly spaced; May cause GI upset (may take with food, milk); Refrigerate oral suspension; Report persistent diarrhea.

Cefadroxil

ATC Code: J01DB05 Antibacterials for Systemic Use (First-Generation Cephalosporins)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding..

Indications and Dosage

• Urinary tract infection, skin infections, pharyngitis, tonsillitis: 500mg once daily or bid, (max 2g daily).

Off-label uses

Chronic suppression of prosthetic joint infection.

Contraindications

Hypersensitivity to cefadroxil or cephalosporins.

Cautions

History of penicillin allergy; History of gastrointestinal disease (colitis).

Dose adjustment in renal failure: CrCl 25-50ml per minute increase interval to every 12 hours; CrCl 10-25ml per minute increase interval to every 24 hours; CrCl less than 10ml per minute increase interval to every 36 hours.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Cefadroxil 500mg cap

Pharmacokinetic parameters

Absorption Almost completely absorbed from the gastrointestinal tract.

Distribution Vd= 0.31L/kg, 28%protein bound.

Metabolism Minimal hepatic metabolism.

Elimination Renal elimination is 90% with half-life of 60-120 minutes.

Drug interactions

Aspirin: Cefadroxil may increase the level or effect of aspirin by acidic (anionic) drug competition for renal tubular clearance.

Celecoxib: Cefadroxil may increase the level or effect of celecoxib by acidic (anionic) drug competition for renal tubular clearance.

Pyridoxine: Cefadroxil may decrease the level or effect of pyridoxine by altering intestinal flora.

Side effects

Common (more than 10%) Diarrhea.

Less common (1-10%) None.

Rare but serious (less than 1%) Abdominal pain; Anaphylaxis; Dyspepsia; Joint pain; Nausea; Neutropenia; Pseudomembranous colitis; Rash; Stevens-Johnson syndrome; Transaminases increased; Urticaria; Vaginal itching or discharge; Vomiting.

Patient educations

Continue therapy for full length of treatment; Doses should be evenly spaced; May cause gastrointestinal upset (may take with food, milk); Refrigerate oral suspension; Report persistent diarrhea.

Cefdinir

ATC Code: J01DD15 Antibacterials for Systemic Use (Third Generation Cephalosporins)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Community-acquired pneumonia: 300mg bid for 10 days (max 600mg daily).

• Acute maxillary sinusitis: 300mg bid or 600mg once daily for 10 days.

• Uncomplicated skin structure infections caused by Staphylococcus aureus, 300mg bid for 5-10 days.

Dosage forms and trade names available in Iraq

Cefdinir 125mg /5 ml Oral Susp.
CEFDINISAM (SDI Iraq). **Sefarin** (Pharma International Jordan).

cefdinir 300mg capsule
SFICARE (Pioneer Iraq), **Sefarin** (Pharma International Jordan).

Off-label uses

None.

Contraindications

Hypersensitivity to cefdinir; History of anaphylactic reaction to cephalosporins.

Cautions

Hypersensitivity to penicillins.

Dose adjustment in renal failure: CrCl less than 30ml/min: decrease interval to daily.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=25%, food decrease absorption by 30%.

Distribution Vd=0.06-0.64L/kg, 60-70% protein bound.

Metabolism Not metabolized.

Elimination Renal elimination is 18% with a half-life of 2 hr.

Drug interactions

Famotidine: Famotidine will decrease the level or effect of cefdinir by increasing gastric pH.

Heparin: Cefdinir increases effects of heparin by anticoagulation, cefdinir may decrease prothrombin activity.

Side effects

Common (more than 10%) Diarrhea.

Less common (1-10%) Decreased lymphocytes; Glycosuria; Headache; Increased alkaline phosphatase; Increased eosinophils; Increased platelets; Increased urine leukocytes; Increased urine protein; Nausea; Rash; Vaginal moniliasis.

Rare (less than 1%) None.

Patient educations

Take antacids 2 hours before or following medication; Continue medication for full length of treatment, do not skip doses; Doses should be evenly spaced; Report persistent severe diarrhea, rash, muscle aches, fever, enlarged lymph nodes, joint pain.

Cefepime

ATC Code: J01DE01 Antibacterials for Systemic Use (Fourth Generation Cephalosporins)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Avoid; Cefepime present in milk in low concentrations.

Dosage forms and trade names available in Iraq

Cefepime 1g vial
Cefepime-SDI (SDI IRAQ), **Cepime** (Pharma International Jordan), **Forpime** (PIONEER IRAQ).

Cefepime 500mg vial
Forpime (PIONEER IRAQ).

Indications and Dosage

• Pneumonia: IV injection, 1g-2g twice daily for 7-10 days.
• Intra-abdominal infections, skin infections: IV injection, 2g twice daily for 10 days.
• Urinary tract infections: IV or IM injection, 0.5g-2g twice daily for 7-10 days.
• Febrile neutropenia: IV injection, 2g three times daily.

Off-label uses

Brain abscess; Malignant otitis externa; Septic lateral, cavernous sinus thrombus.

Contraindications

Hypersensitivity to cefepime or cephalosporins.

Cautions

History of seizure disorder; Gastrointestinal disease (colitis); Elderly.
Dose adjustment in renal failure: CrCl 30-60ml/min, 500mg every 24h to 2g every 12h; CrCl 11-29ml/min, 500mg-2g every 24h; CrCl <10ml/min, 250mg-1g every 24h.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=82.3±15%.
Distribution Vd=18±2L, 20% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 85% with half-life of 2h.

Drug interactions

Aspirin: Cefepime may increase the level or effect of aspirin by acidic (anionic) drug competition for renal tubular clearance.

Side effects

Common (>10%) Positive Coombs test result without hemolysis.
Less common (1-10%) Diarrhea; Erythema at injection site; Fever; Headache; Pruritus; Rash.
Rare but serious (<1%) Agranulocytosis; Anaphylaxis; Coma; Encephalopathy; Hallucinations; Leukopenia; Myoclonus; Neuromuscular excitability; Neutropenia; Seizures; Thrombocytopenia.

Patient educations

Discomfort may occur with IM injection; Continue therapy for full length of treatment; Doses should be evenly spaced; Report persistent diarrhea.

Cefixim

ATC Code: J01DD08 Antibacterials for Systemic Use (Third-Generation Cephalosporins)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Excreted into human milk, use is not recommended

Indications and Dosage

• Acute exacerbations of chronic bronchitis, otitis media, pharyngitis, tonsillitis, uncomplicated urinary tract infections: 400 mg orally in single daily dose or 200mg every 12hours.

• Uncomplicated gonorrhea: 400 mg orally in single daily dose plus azithromycin 1 g orally once (preferred) or alternatively doxycycline 100 mg orally every 12hours for 7 days.

Dosage forms and trade names available in Iraq

Cefixim 200mg capsule
SAMAXIME (SDI Iraq), **CEFIX** (Pharma International Jordan).

Cefixime 400mg Capsules
SAMAXIME (SDI Iraq), **CEFIX** (Pharma International Jordan).

Cefixime 100mg/5ml Powder for oral suspension
SAMAXIME (SDI Iraq).

Off-label uses

Typhoid fever.

Contraindications

Hypersensitivity to cephalosporin antibiotics.

Cautions

History of gastrointestinal disease, history of penicillin allergy as cross-reactivity may occur, renal impairment.

Dose adjustment in renal failure: CrCl 21-60 ml per minute decrease dosage of cefixim to 260mg per day, CrCl less than 20ml per minute or continuous peritoneal dialysis decrease dosage of cefixim to 200mg per day.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=40-50%, food has no effect on absorption.

Distribution Vd=11-12L, 65% protein bound.

Metabolism Cefixim undergoes hepatic metabolism to form inactive metabolites.

Elimination Cefixim excreted in the urine with half-life of 3-4 hours.

Drug interactions

Oral contraceptives: Cefixime may reduce the effectiveness of oral contraceptives.

Warfarin: Cefixime increases effects of warfarin by unspecified interaction mechanism.

Side effects

Common (more than 10%): Abdominal pain; Diarrhea; Nausea.

Less common (1-10%): Dizziness; Headache; Skin rash.

Rare but serious (less than 1%): Anaphylaxis; Clostridium difficile-associated diarrhea; Severe skin reactions.

Patient education

Take cefixim as directed by healthcare provider, even if start to feel better; Do not skip doses or stop taking the medication early.

Cefotaxime

ATC Code: J01DD01 Antibacterials for Systemic Use (Third Generation Cephalosporins)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Use with caution since cefotaxime enters breast milk.

Dosage forms and trade names available in Iraq

Cefotaxime 0.5gm vial
Cefotaxime-SDI (SDI IRAQ).
Cefotaxime 1gm vial
Taxime (Pharma International Jordan), **Clafoneer** (PIONEER IRAQ).

Indications and Dosage

• Uncomplicated infections: By i.v. or i.m. injection, 1g every 12 hours.
• Mild to moderate infections: By i.v. or i.m. injection, 1g-2g every 8 hours.
• Severe infections: By i.v. or i.m. injection, 2g every 6-8 hours.
• Life threatening infections: By i.v. injection, 2g every 4 hours.
• Gonorrhea: By i.m. injection, 1 g as a single dose.
• Cesarean section: By i.v. injection, 1g as soon as umbilical cord is clamped, then 1g 6-12 hours after first dose.

Off-label uses

Surgical prophylaxis.

Contraindications

Hypersensitivity to cefotaxime or cephalosporins.

Cautions

History of penicillin allergy; Blood or bone marrow problems; Colitis; Heart arrhythmia.
Dose adjustment in renal failure: CrCl less than 10ml per minute increase interval to every 24 hours.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Rapidly absorbed following intramuscular injection.
Distribution Vd=Undetermined, 40%protein bound.
Metabolism Partially metabolized in liver to active metabolite desacetylcefotaxime.
Elimination Partly excreted in the urine with half-life of 1-1.5 hours.

Drug interactions

Aminoglycosides: Cefotaxime may enhance the nephrotoxic effect of aminoglycosides, cefotaxime may decrease the serum concentration of aminoglycosides.
BCG Vaccine (Immunization): Cefotaxime may diminish the therapeutic effect of BCG Vaccine, avoid combination.

Side effects

Colitis; Diarrhea; Elevated blood urea nitrogen (BUN) and creatinine; Elevated hepatic transaminases; Eosinophilia; Fever; Injection site pain; Nausea; Pruritus; Rash; Thrombocytopenia; Transient neutropenia; Vomiting.

Patient educations

Discomfort may occur with i.m. injection; Doses should be evenly spaced; Continue antibiotic therapy for full length of treatment; Cefotaxime should not be used to treat viral infections such as the common cold; Patients should contact their physician if diarrhea persists after discontinuing the drug.

Cefpodoxime

ATC Code: J01DD13 ANTIBACTERIALS FOR SYSTEMIC USE (Third-Generation Cephalosporins)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

- Chronic bronchitis, pneumonia: 200mg bid for 10-14 days.
- Gonorrhea: 200mg as a single dose.
- Skin infections: 400mg bid for 7-14 days.
- Pharyngitis, tonsillitis: 100mg bid for 5-10 days.
- Urinary tract infection: 100mg bid for 7 days.

Off-label uses

None.

Contraindications

Hypersensitivity to cefpodoxime or cephalosporins.

Cautions

History of penicillin allergy.

Dose adjustment in renal failure: CrCl less than 30ml per minute increase interval to every 24 hours.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

cefpodoxime 100 mg/5ml susp

Cefodox (Pharma International Jordan).

Cefpodoxime 100 mg tablet

Cefodox (Pharma International Jordan).

Cefpodoxime 200 mg tablet

Cefodox (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=50%, acid stable.

Distribution Vd=Undetermined, 18-23%protein bound.

Metabolism Metabolized in liver to active metabolite.

Elimination Renal elimination is 29-33% with half-life of 2-3 hours.

Drug interactions

Enoxaparin: Cefpodoxime will increase the level or effect of enoxaparin by anticoagulation, cephalosporins may decrease prothrombin activity.

Warfarin: Cefpodoxime will increase the level or effect of warfarin by anticoagulation, cephalosporins may decrease prothrombin activity

Side effects

Common (more than 10%) Diaper rash; Diarrhea in infants and toddlers.

Less common (1-10%) Abdominal pain; Diarrhea; Headache; Nausea; Rash; Vaginal infection; Vomiting.

Rare but serious (less than 1%) None.

Patient educations

Doses should be evenly spaced; Shake oral suspension well before using; Take tablets with food (enhances absorption); Continue antibiotic therapy for full length of treatment; Refrigerate oral suspension; Report persistent diarrhea.

Ceftazidime

ATC Code: J01DD02 Antibacterials for Systemic Use (Third Generation Cephalosporins)

Pregnancy category:

FDA A **B** C D X N

TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

Ceftazidime 1g vial

Ceftazidime-SDI (SDI IRAQ), **Fetazim** (Pharma International Jordan), **Zidima** (Pioneer IRAQ).

Indications and Dosage

• Urinary tract infection: By i.v. or i.m. injection, 250mg-500mg tid.

• Mild to moderate infections: By i.v. or i.m. injection, 1g tid.

• Uncomplicated pneumonia, skin infections: By i.v. or i.m. injection, 500mg-1g tid.

• Bone and joint infections: By i.v. injection, 2g bid.

• Meningitis, serious gynecologic and intra-abdominal infections: By i.v. injection, 2g tid.

Off-label uses

Bacterial endophthalmitis.

Contraindications

Hypersensitivity to ceftazidime or cephalosporins.

Cautions

History of penicillin allergy; Seizure disorder.

Dose adjustment in renal failure: CrCl 31-50ml per minute, 1g every 12 hours; CrCl 16-30ml per minute, 1g every 24 hours; CrCl 6-15ml per minute 500mg every 24 hours; CrCl less than 6ml per minute 500mg every 48 hours.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=15-20L, 5-22.8%protein bound.

Metabolism Ceftazidime is not appreciably metabolized.

Elimination Renal elimination is 85% with half-life of 2 hours.

Drug interactions

Acyclovir: Ceftazidime will increase the level or effect of acyclovir by acidic (anionic) drug competition for renal tubular clearance.

Furosemide: Ceftazidime increases toxicity of furosemide by pharmacodynamic synergism, increased risk of nephrotoxicity.

Side effects

Common (more than 10%) None.

Less common (1-10%) Diarrhea; Eosinophilia; Immune hypersensitivity reaction; Injection site pain; Phlebitis; Rash; Thrombocytosis; Transient increases in transaminases.

Rare but serious (less than 1%) Abdominal pain; Agranulocytosis; Fever; Hallucinations; Metallic taste; Photosensitivity; Pruritus; Seizures.

Patient educations

Discomfort may occur with i.m. injection; Doses should be evenly spaced; Continue antibiotic therapy for full length of treatment.

Ceftriaxone

ATC Code: J01DD04 Antibacterials for Systemic Use (Third-Generation Cephalosporins)

Pregnancy category:

FDA A **B** C D X N

TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Mild to moderate infections: By i.v. or i.m. injection, 1g-2 g once daily.

• Serious infections: By i.v. or i.m. injection, up to 4g daily in 2 divided doses.

• Perioperative prophylaxis: By i.v. or i.m. injection, 1g 0.5-2 hr before surgery.

Off-label uses

Complicated gonococcal infections; Sexually transmitted disease; Salmonellosis; Shigellosis; Atypical community acquired pneumonia; Urinary Tract Infection (UTI).

Contraindications

Hypersensitivity to ceftriaxone or cephalosporins; Hyperbilirubinemic neonates; Concomitant use with calcium containing solutions or products

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Dosage forms and trade names available in Iraq

Ceftriaxone 250mg vial

Ceftriaxone 500mg vial

Pioxone (PIONEER IRAQ).

Ceftriaxone 1g vial

Pioxone (PIONEER IRAQ).

Ceftriaxone 2000ng vial

Mesporin (Acino Germany).

Cautions

Ulcerative colitis; Antibiotic associated colitis; History of penicillin allergy.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%, Ceftriaxone is less than 1% bioavailable if given orally.

Distribution Vd=5.78-13.5L, 90%protein bound.

Metabolism Metabolism of ceftriaxone is negligible.

Elimination Renal elimination is 33-67% as unchanged drug, the reminder is eliminated in the bile and removed from the body via the feces with half-life of 6-9 hours

.

Drug interactions

Heparin: Ceftriaxone will increase the level or effect of heparin by anticoagulation, cephalosporins may decrease prothrombin activity.

Side effects

Common (more than 10%) Induration after i.m. injection.

Less common (1-10%) Diarrhea; Eosinophilia; Increased blood urea nitrogen; Leukopenia; Pain; Rash; Thrombocytosis.

Rare but serious (less than 1%) Agranulocytosis; Anemia; Bronchospasm; Candidiasis; Gallstones; Glycosuria; Headache; Hematuria; Hemolytic anemia; Increased creatinine; Jaundice; Leukocytosis; Phlebitis; Pruritus; Renal stones; Thrombocytopenia; Urinary casts; Vaginitis; Vomiting.

Patient educations

Discomfort may occur with i.m. injection; Doses should be evenly spaced; Continue antibiotic therapy for full length of treatment.

Cefuroxime

ATC Code: J01DC02 Antibacterials for Systemic Use (Second-Generation Cephalosporins)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Acute infective exacerbation of COPD, uncomplicated skin and subcutaneous tissue infection, acute bacterial maxillary sinusitis, uncomplicated urinary tract infection, acute otitis media, bronchitis, pharyngitis, tonsillitis: 250mg-500mg bid for 5-10 days.
• Gonorrhea uncomplicated: 1g as a single dose.

Dosage forms and trade names available in Iraq

- Cefuroxime 250mg tablet
  Zamur (Acino Germany).
- Cefuroxime 500mg tablet
  Cefutil (Pharma International Jordan).
- cefuroxime 750mg vial
  Zinax (PIONEER IRAQ).

Off-label uses

None.

Contraindications

Hypersensitivity to cefuroxime.

Cautions

History of penicillin allergy; Patients with history of colitis; GI malabsorption; Seizures.
Dose adjustment in renal failure: CrCl 10-30ml/min: 500mg every 24 hr; CrCl less than 10ml/min: 500mg every 48 hr.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=37%, food increase absorption to 52%.
Distribution Widely distributed to body tissues and fluids, including cerebrospinal fluid, 33-50% protein bound.
Metabolism Partially metabolized in liver.
Elimination Renal elimination is 50% with a half-life of 2 hr.

Drug interactions

Antacids: Antacids may decrease the serum concentration of Cefuroxime, administer cefuroxime at least 1 hour before or 2 hours after the administration of short-acting antacids.

Side effects

Common (more than 10%) Diarrhea (depends on duration).
Less common (1-10%) Decreased hemoglobin or hematocrit; Diaper rash; Eosinophilia; Nausea; Thrombophlebitis; Transient rise in hepatic transaminases; Vaginitis; Vomiting.
Rare (less than 1%) Anemia; Cholestasis; Colitis; Dyspnea; Epidermal necrolysis; Jaundice; Nephritis; Stevens Johnson syndrome; Stomach cramps; Transient neutropenia and leukopenia; Urticaria.

Patient educations

Advise patient to immediately report rash or bleeding tendency; Instruct patient to take drug with food every 12 hours as prescribed; Teach patient how to recognize signs and symptoms of superinfection.

Celecoxib

ATC Code: M01AH01 Antiinflammatory and Antirheumatic Products (Coxibs)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute pain primary dysmenorrhea: 200mg bid or prn.

Off-label uses

Gout.

Contraindications

Hypersensitivity to celecoxib and sulfonamides; Active GI bleeding; Asthma; Urticaria; Allergic reactions to aspirin or other NSAIDs; Treatment of perioperative pain in coronary artery bypass graft (CABG) surgery.

Cautions

History of GI bleeding or ulcers; Smoking; Alcohol; Elderly; Hypertension; Cerebrovascular disease; Ischemic heart disease; Heart failure.

Dose adjustment in renal failure: CrCl less than 30ml/min: avoid use.

Dose adjustment in hepatic failure: Moderate: reduce dose by 50%; Sever: avoid use.

Dosage forms and trade names available in Iraq

Celecoxib 200 mg cap
CELEBREX (Pfizer USA).

Pharmacokinetic parameters

Absorption F= undetermined, well absorbed, food increase absorption.
Distribution Vd=400L, 97% protein bound.
Metabolism Hepatic metabolism 97%.
Elimination Renal elimination is 27% with a half-life of 11 hr.

Drug interactions

Lisinopril: Celecoxib may decrease antihypertensive effect of ACE inhibitor lisinopril.

Side effects

Common (more than 10%) Headache; Hypertension.
Less common (1-10%) Abdominal pain; Arthralgia; Back pain; Cough; Diarrhea; Dizziness; Dyspepsia; Fever; Flatulence; Gastroesophageal reflux; Insomnia; Nausea; Peripheral edema; Pharyngitis; Rash; Sinusitis; Upper respiratory tract infection; Vomiting.
Rare (less than 1%) Anemia; Hepatitis; Jaundice; Stevens-Johnson syndrome; Toxic epidermal necrolysis.

Patient educations

Advise patient to immediately report bloody stools, vomiting of blood, or signs or symptoms of liver damage (nausea, fatigue, lethargy, pruritus, yellowing of eyes or skin, tenderness in upper right abdomen, or flulike symptoms); Instruct patient to take drug with food or milk; Tell patient to avoid aspirin and other NSAIDs during therapy.

Cephalexin

ATC Code: J01DB01 Antibacterials for Systemic Use (First-Generation Cephalosporins)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding..

Indications and Dosage

• Otitis media, respiratory tract infection, urinary tract infection, streptococcal pharyngitis, infection of skin and subcutaneous tissue: 250mg-1g qid, (max 4g daily).

Off-label uses

Bacterial endocarditis.

Contraindications

Hypersensitivity to cephalexin.

Cautions

Ulcerative colitis; Antibiotic associated colitis; History of penicillin allergy.

Dose adjustment in renal failure: CrCl less than 50ml/min: max. 500mg bid

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Cephalexin 125mg/5ml Susp
  Cephalaxine (SDI Iraq).
- Cephalexin 250mg/5ml oral Susp
  CEPHALEXIN (SDI Iraq), **PIOLEXINE** (Pioneer IRAQ).
- Cephalexin 250 mg cap
  CEPHALEXIN (SDI Iraq).
- Cephalexin 500 mg cap
  CEPHALEXIN (SDI Iraq), **PIOLEXINE** (Pioneer IRAQ).

Pharmacokinetic parameters

Absorption F=90%, food has little effect on absorption.

Distribution Distributed widely into most tissues and fluids; penetrates cerebrospinal fluid poorly, 6-15% protein bound.

Metabolism Minimally metabolized in liver.

Elimination Renal elimination is 80-100% with a half-life of 1 hr.

Drug interactions

Aminoglycosides: Cephalexin may enhance the nephrotoxic effect of aminoglycosides; cephalexin may decrease the serum concentration of aminoglycosides.

BCG Vaccine (Immunization): Cephalexin may diminish the therapeutic effect of BCG Vaccine (Immunization).

Metformin: Cephalexin may increase the serum concentration of metformin.

Side effects

Abdominal pain; Agitation; Anemia; Angioedema; Confusion; Diarrhea; Dizziness; Dyspepsia; Elevated transaminases; Eosinophilia hemolytic; Epidermal necrolysis; Erythema multiform; Fatigue; Hypersensitivity; Nephritis; Neutropenia; Pseudomembranous colitis; Transient hepatitis; Urticaria; Vaginal discharge; Vomiting.

Patient educations

Instruct patient to stop taking drug and contact prescriber immediately if he develops rash or difficulty breathing; Tell patient to take drug with full glass of water; Advise patient to report severe diarrhea.

Cetirizine

ATC Code: R06AE07 Antihistamines for Systemic Use (Piperazine Derivatives)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation: Avoid; Cetirizine concentrations in breastmilk were approximately %25 to %90 of drug concentrations in plasma.

Indications and Dosage

• Urticaria, perennial or seasonal allergic rhinitis: 5mg-10mg once daily.

Off-label uses

Atopic dermatitis.

Contraindications

Hypersensitivity to cetirizine; Acute asthma attacks; Angle closure glaucoma; Pyloroduodenal obstruction.

Cautions

Elderly; Safety and efficacy have not been established in children less than 2 years of age.

Dose adjustment in renal failure: CrCl less than 50ml/min: max. dose 5mg once daily.

Dose adjustment in hepatic failure: Max. dose 5mg once daily.

Dosage forms and trade names available in Iraq

- Cetirizine 1mg/1ml oral solution
- Cetirizine 10mg tab

Pharmacokinetic parameters

Absorption F=70%, limit effect of food on absorption.
Distribution Vd=0.5-0.8L/kg, 90% protein bound.
Metabolism Minimally hepatic metabolism.
Elimination Renal elimination is 70% with a half-life of 8.3 hr.

Drug interaction

Azithromycin: Azithromycin will increase the level or effect of cetirizine by P-glycoprotein efflux transporter.

Pregabalin: Pregabalin and cetirizine both increases effects of the other by pharmacodynamic synergism, coadministration of CNS depressants can result in serious, life-threatening, and fatal respiratory depression. Use lowest dose possible and monitor for respiratory depression and sedation.

Side effects

Common (more than 10%) Headache; Somnolence.
Less common (1-10%) Bronchospasm; Diarrhea; Dizziness; Dry mouth; Epistaxis; Fatigue; Malaise; Vomiting.
Rare (less than 1%) Angioedema; Drowsiness; Fussiness; Hallucinations; Hypotension; Tongue discoloration; Tremor.

Patient educations

• Tell patient to take with full glass of water; Inform patient that drug may impair alertness and that alcohol may exaggerate.

• This effect; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness.

Cetrimide

ATC Code: D08AJ04 Antiseptics and Disinfectants (Quaternary Ammonium Compounds)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Cleaning wounds and treating minor burns, abrasions and scalds, and for curing seborrheic dermatitis.

Off-label uses

None.

Contraindications

Hypersensitivity to cetrimide.

Cautions

it's for external use only Avoid contact with nose, ears, mouth and eyes, prolonged and repeated use.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Undetermined.

Distribution Undetermined.

Metabolism Undetermined.

Elimination Undetermined.

Dosage forms and trade names available in Iraq

Cetrimide 0.5% cream

Celyovex (Dubai Iraq).

Drug interactions

Not Available.

Side effects

Hypersensitivity, skin rash, red or itchy skin (allergic reaction) and Dryness.

Patient educations

Cetrimide is used only externally so do not swallow or ingest it. Avoid contact with nose, ears and mouth. If Cetrimide comes in contact with these areas accidentally, rinse with water or soap, iodine thoroughly.

Note

Cetrimide is a quaternary ammonium antiseptic with bactericidal action against gram positive and some gram negative (at higher concentrations) organisms, but ineffective against bacterial spore. It has variable antifungal activity and effective against some viruses.

Cetuximab

ATC Code: L01FE01 Antineoplastic Agents (Epidermal Growth Factor Receptor Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid; breastfeeding discontinue 2 months after the last dose.

Indications and Dosage

• Head and neck cancer, metastatic colorectal carcinoma: Initially i.v. injection, 400 mg/m^2 as a loading dose, then maintenance 250mg/m^2 infused over 60 min weekly, used in combination with radiation therapy or as a single agent

Off-label uses

Non–small cell lung cancer; Treatment of unresectable squamous cell skin cancer.

Contraindications

Hypersensitivity to cetuximab.

Cautions

Coronary artery disease; Heart failure; Arrhythmias; Pulmonary disease.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Cetuximab 5mg/ml injection
ERBITUX (Merck Germany).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=2-3L/m^2.
Metabolism Cetuximab undergo lysosomal degradation by the reticuloendothelial system and protein catabolism.
Elimination Elimination half-life is 112 hours.

Drug interactions

Fingolimod: Concomitant therapy is expected to increase the risk of immunosuppression.
Clonazepam: Antipsychotics clonazepam increase risk of agranulocytosis.

Side effects

Common (more than 10%) Anxiety; Confusion; Conjunctivitis; Constipation; Dehydration; Depression; Diarrhea; Dry skin; Dyspepsia; Dyspnea; Fatigue; Fever; Headache; Infections with neutropenia; Insomnia; Mouth dryness; Nail changes; Neutropenia; Paronychia; Pruritus; Sensory neuropathy; Skin fissure; Stomatitis; Vomiting.
Less common (1-10%) Arthralgia; Bone pain; Taste disturbance.
Rare but serious (less than 1%) Acne; Anorexia; Decreased weight; Infusion related reactions; Palmar plantar erythrodysesthesia syndrome; Pyrexia; Rash; Skin fissures; Stomatitis.

Patient educations

Do not have immunizations without physician's approval (drug lowers resistance); Avoid contact with anyone who recently received a live virus vaccine; Avoid crowds, those with infection; Wear sunscreen, limit sun exposure (sunlight can exacerbate skin reactions); Report cardiac or lung symptoms, severe rash.

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Chloramphenicol

ATC Code: J01BA01 Antibacterials for Systemic Use (Amphenicols)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Avoid; Because theoretical risk of bone marrow toxicity.

Indications and Dosage

• Bacterial conjunctivitis: Apply 2 drops to the affected eye every 3 hr, to be used during waking hours only; Small amount of the ointment to be applied to the affected eye at bed time, treatment should be continued for at least 48 hr after eye appears normal.

Off-label uses

None.

Contraindications

Hypersensitivity to chloramphenicol.

Cautions

Avoid prolonged use; Not indicated for the treatment of viral infections or for prophylaxis of bacterial infections.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Chloramphenicol 0.5% eye drops
Chloramphenicol 1% eye oint
SAMAPHENICOL (SDI Iraq).

Pharmacokinetic parameters

Absorption F=80%.
Distribution Vd= 0.6-1L/kg,50-60%protein bound.
Metabolism Hepatic metabolism, with 90% conjugated to inactive glucuronide.
Elimination Renal elimination is 5-15% with half-life of 1.5-3.5 hours.

Drug interactions

Bromocriptine: Chloramphenicol will increase the level or effect of bromocriptine by affecting hepatic and intestinal enzyme CYP3A4 metabolism.
Saxagliptin: Chloramphenicol will increase the level or effect of saxagliptin by affecting hepatic enzyme CYP3A4 metabolism.
Warfarin: Chloramphenicol increases effects of warfarin by decreasing metabolism.
Phenytoin: Chloramphenicol preventing the metabolism of phenytoin.
Tolbutamide: Chloramphenicol inhibits hepatic drug – metabolizing enzymes, thus increasing the elimination half- lives of tolbutamide.

Side effects

Common (more than 10%) Aplastic anemia; Bone marrow suppression; Diarrhea; Enterocolitis; Gray syndrome; Headache; Nausea; Nightmares; Optic neuritis; Peripheral neuropathy; Rash; Stomatitis; Vomiting.
Less common (1-10%) None.
Rare but serious (less than 1%) None.

Patient educations

Report sore throat, tiredness or unusual bleeding, numbness, tingling, pain in the extremities (even as late as several weeks after you finish the drug).

Chlordiazepoxide

ATC Code: N05BA02 Psycholeptics (Benzodiazepine Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Chlordiazepoxide 10 mg tablet
  Libroxide (SDI Iraq), **LIBROXIDE-KINDI** (Alkindi Iraq).
- Chlordiazepoxide 5 mg tablet
  Libroxide (SDI Iraq), **Libroksidin** (Alkindi Iraq).

Indications and Dosage

• Mild and moderate anxiety: 5mg-10mg tid or qid.
• Severe anxiety: 20mg-25mg tid or qid.
• Severe cases of acute alcohol withdrawal: Dose should not exceed 300 mg/day.

Off-label uses

None.

Contraindications

Hypersensitivity to chlordiazepoxide or any other benzodiazepine; Acute pulmonary insufficiency; Respiratory depression; Chronic psychosis; Porphyria; Myasthenia gravis; Severe sleep apnea; Severe depression with suicidal attempts.

Cautions

Physical and psychological dependence; Withdrawal syndrome; Impairs psychomotor performance; Aggression; Sedation; Blood dyscrasias (mainly agranulocytosis); Jaundice; Hepatic dysfunction.

Dose adjustment in renal failure: CrCl less than 10ml per minute use 50% of recommended dose.

Dose adjustment in hepatic failure: Data are not available.

Pharmacokinetic parameters

Absorption Almost complete.

Distribution Vd= 3.3L/kg, 90-98%protein bound.

Metabolism Hepatic metabolism, converted to desmethyldiazepam.

Elimination Renal elimination is 2-6% with half-life of 24-48 hours.

Drug interactions

There are about 400 drug interactions like morphine, ketamine, codeine, tramadol, pentazocine, L- methadyl acetate, digoxine, INH, OCCPs, MAO inhibitors, ketoconazole, cimetidine, rifampicine, metprolol, fluoxetine, fluvoxamine, barbiturates, enzalutamide& HIV drugs.

Side effects

Common (more than 10%) Ataxia; Decreased libido; Drowsiness; Increased appetite; Memory impairment; Menstrual irregularities; Micturition difficulties; Muscle weakness; Skin rash; Dryness of mouth; Weight gain.

Less common (1-10%) Confusion; Dermatitis; Disinhibition; Dizziness; Hypotension; Incontinence; Muscle cramps; Nasal congestion; Rigidity; Salivation increased; Sexual dysfunction; Tinnitus; Fine tremor.

Rare but serious (less than 1%) Arrhythmias; Syncope; Coma.

Patient educations

Advise the patient to avoid driving and operating machines when taking first few doses; Alcohol should be avoided and the patient has to be advised not to stop medication abruptly; Drug tapering should be scheduled by physician or pharmacist; Inform the patient that smoking reduces the drug effectiveness.

Chlorhexidine

ATC Code: A01AB03 Stomatological Preparations (Antiinfectives and Antiseptics for Local Oral Treatment)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Compatible with breastfeeding.

Indications and Dosage

• Chlorhexidine is an antiseptic used to sterilize for surgeries and in healthcare practice, to reduce pocket depth in periodontitis, and to treat gingivitis: 15ml oral rinse swish 30 seconds and spit bid (morning and evening) after tooth brushing.

Off-label uses

Oropharyngeal decontamination to reduce risk of ventilator associated pneumonia in critically ill patients.

Dosage forms and trade names available in Iraq

Chlorhexidine Gluconate 0.2% mouth wash **Chloro – Gluconate** (AL-Kindi Iraq).

Contraindications

Hypersensitivity to chlorhexidine.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Topically, chlorhexidine is unlikely to undergo any degree of systemic absorption. Orally administered chlorhexidine, such as that found in oral rinses for dental purposes, is very poorly absorbed from the gastrointestinal tract, no detectable plasma or urine chlorhexidine levels observed

Distribution Chlorhexidine is known to bind albumin in both serum and saliva, though the extent of this binding is unclear.

Metabolism Chlorhexidine is very poorly absorbed in the gastrointestinal tract; It is unlikely to undergo metabolic conversion to any significant extent.

Elimination Excretion of chlorhexidine gluconate occurs almost exclusively via the feces, with less than 1% of an ingested dose excreted in the urine.

Drug interactions

No interactions found.

Side effects

Allergic reactions (particularly in genital areas); Blisters; Dermatitis; Dry mouth; Dyspnea; Eczema; Erythema; Facial edema; Irritation; Nasal congestion; Pruritus; Rash; Sensitization; Skin irritation; Taste alteration; Urticaria.

Patient educations

Not intended for use in the eye, auditory canal; Chlorhexidine may stain teeth and tongue; Take separate from meals, may affect the taste of food and beverages; Avoid eating or drinking for 30 minutes following use.

Chlorpheniramine

ATC Code: R06AB02 Antihistamines for Systemic Use (Substituted Alkylamines)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Avoid; Chlorpheniramine may inhibit lactation and small amounts may be secreted in breast milk.

Dosage forms and trade names available in Iraq

- Chlorpheniramine maleate 10mg/ml AMP **Chlomal** (PIONEER IRAQ).
- Chlorpheniramine Maleate 2mg /5ml syrup **HISTADIN** (SDI Iraq), **HISTOFEN** (Al-Kindi Iraq), **Alerdain** (Wadi al rafidain Iraq), **Histamaxin** (Al-Mansour IRAQ).
- chlorpheniramine maleate 4 mg tab **HISTOFEN** (Al-Kindi Iraq), **Chlomal** (PIONEER IRAQ), **Alerdain** (Wadi al rafidain Iraq) , **HistaPollen** (Al-Mansour IRAQ).

Indications and Dosage

• Allergic rhinitis, common cold: 4mg every 4-6 hours, (max 24mg daily).

• Acute urticaria; Control of allergic reactions to insect bites and stings, food allergy; Anaphylaxis due to drugs or serum: By i.v. or i.m. injection, 10mg-20mg, (max 40mg within a 24-hr period).

Off-label uses

None.

Contraindications

Hypersensitivity to chlorpheniramine.

Cautions

Narrow angle glaucoma; Urinary retention; Prostatic hypertrophy; Bladder neck obstruction; Acute asthma; Severe hypertension; Bronchitis; Bronchiectasis; Thyrotoxicosis.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=25-50%.

Distribution Vd=6-12L/kg, 70%protein bound.

Metabolism Undergoes extensive first-pass metabolism in the liver by CYP450 enzymes to active and inactive metabolites.

Elimination Renal elimination is 22% with half-life of 14-24 hours.

Drug interactions

CNS depressants: Chlorpheniramine increased depressant effects of alcohol and other CNS depressants.

Side effects

Agranulocytosis; Anorexia; Arrhythmias; Blurred vision; Chills; CNS depression; Constipation; Diarrhea; Diplopia; Disturbed coordination; Drowsiness; Dryness of mouth, nose, and throat; Dysuria; Early menses; Epigastric distress; Euphoria; Facial dyskinesia; Faintness; Headache; Hemolytic anemia; Hepatitis; Hypertension; Impotence; Leukopenia; Muscular weakness; Nasal stuffiness; Nausea; Nervousness; Palpitation; Pancytopenia; Paresthesia; Restlessness; Sedation ranging from mild drowsiness to deep sleep; Seizures; Sweating; Tachycardia; Thickening of bronchial secretions; Thrombocytopenia; Tinnitus; Tremors; Urinary retention; Visual disturbances; Wheezing.

Patient educations

Chlorpheniramine may impair the ability to drive or operate machinery.

Ciclosporin

ATC Code: L04AD01 Immunosuppressants (Calcineurin Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

• Transplantation, prevention of organ rejection: 10mg-18mg/kg/dose given 4-12 hr before organ transplantation, maintenance 5mg-15mg/kg/day in divided doses, then tapered to 3mg-10mg/kg/day.
• Rheumatoid arthritis, psoriasis: Initially, 1.25mg/kg bid, (max 4mg/kg/day).
• Dry eye caused by Sjogren syndrome: Instill single dose eye drop in each affected eye bid.
• Atopic dermatitis; Psoriasis;Crohn's disease; nephrotic syndrome.

Off-label uses

Focal segmental glomerulosclerosis; Lupus nephritis; Severe ulcerative colitis.

Contraindications

Hypersensitivity to Ciclosporin; Uncontrolled hypertension; Renal malignancies.

Dosage forms and trade names available in Iraq

Ciclosporin 100mg/1ml oral solution
Sandimmun Neoral (Novartis Switzerland).

Cautions

History of seizures; Avoid live attemuated vaccines.
Dose adjustment in renal failure: Modify dose if serum creatinine levels 25% or above pretreatment levels.
Dose adjustment in hepatic failure: In severe impairment use with caution.

Pharmacokinetic parameters

Absorption F=30%.
Distribution Vd=4-8L/kg, 90-98%protein bound.
Metabolism Extensively metabolized by the liver by CYP3A4.
Elimination Excreted in bile, small amounts excreted unchanged in urine with half-life of 19 hours.

Drug interactions

Prednisone: Cyclosporine may enhance the neuroexcitatory and seizure potentiating effect of prednisone.

Side effects

Common (more than 10%) Abdominal discomfort; Diarrhea; Dyspepsia; Gum hyperplasia; Headache; Hirsutism; Hypertension; Hypertrichosis; Infection; Leg cramps; Nausea; Nephrotoxicity; Parathesia; Tremor.
Less common (1-10%) Acne; Convulsions; Flu-like syndrome; Hepatotoxicity; Hyperkalemia; Hypomagnesemia; Pancreatitis; Pruritus; increased risk of lymphoma.
Rare but serious (less than 1%) None.

Patient educations

Report severe headache, persistent nausea and vomiting, unusual swelling of extremities, chest pain; Do not take any newly prescribed or OTC medications unless approved by the prescriber who originally started treatment.

Cinacalcet

ATC Code: H05BX01 Calcium Homeostasis (Other Anti-Parathyroid Agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Cinacalcet 30mg tablet
- Cinacalcet 60mg tablet

Indications and Dosage

• Hypercalcemia in parathyroid carcinoma or for primary hyperparathyroidism or secondary hyperparathyroidism (HPT) in adult patients with end-stage renal disease (ESRD) on maintenance dialysis therapy: Initially, 30mg bid, titrate dosage sequentially (60mg bid, 90mg bid and 90mg tid or qid) every 2-4 weeks as needed to normalize serum calcium levels.

• To treat secondary hyperparathyroidism (HPT) in children aged 3 years and older with end-stage renal disease (ESRD) on maintenance dialysis therapy: The usual starting dose of Cinacalcet is no more than 0.20 mg/kg of body weight daily. The dose should be increased sequentially no more frequently than every 4 weeks. The dose can be increased up to a maximum dose of 2.5 mg/kg/day, not to exceed a total daily dose of 180 mg.

Off-label uses

None.

Contraindications

Hypersensitivity to cinacalcet; Hypocalcemia.

Cautions

Seizures, Liver problems, Heart failure.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Use with caution in moderate to severe impairment.

Pharmacokinetic parameters

Absorption F=20-25%, high fat food increase absorption.

Distribution Vd=1000L, 93-97%protein bound.

Metabolism Highly metabolized by CYP3A4, CYP2D6 and CYP1A2.

Elimination Renal elimination is 80% with half-life of 30-40 hours.

Drug interactions

Carbamazepine: it will decrease the level or effect of cinacalcet by affecting hepatic enzyme CYP3A4 metabolism.

Clarithromycin: it will increase the level or effect of cinacalcet by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Nausea; Vomiting.

Less common (1-10%) Diarrhea; Myalgia; Anorexia; Asthenia; Dizziness; Hypertension; Non cardiac chest pain; Seizures; reduced testosterone levels; (hyperkalaemia).

Rare but serious (less than 1%) (hypotension).

Patient educations

Take with food or shortly after a meal; Notify physician if vomiting, diarrhea, cramping, muscle pain, numbness occurs.

Cinnarizine

ATC Code: N07CA02 NERVOUS SYSTEM (Antivertigo Preparations)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Cinnarizine 25mg tablet

Indications and Dosage

• Vestibular symptoms (vertigo, tinnitus, nystagmus, nausea and vomiting): 25mg tid.

• Motion sickness: 25mg 2 hours before travel and 25mg every 8 hours during journey if necessary. children aged 6 to 12 years half of adult dose is recommended (half of 25 mg tablet)

Off-label uses

Memory and cognitive enhancer (nootropic drug); Adjunct therapy for peripheral arterial diseases.

Contraindications

Hypersensitivity to cinnarizine

Cautions

Patient with hypotension; Parkinson's disease; Porphyria.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Slowly absorbed.

Distribution Vd=Undetermined, 91%protein bound.

Metabolism Extensively metabolized mainly by CYP2D6.

Elimination 33% eliminated by urine and 66% by feces with half-life of 3-6 hours.

Drug interactions

Aceclofenac: The risk or severity of hyperkalemia can be increased when cinnarizine is combined with aceclofenac.

Acetaminophen: The metabolism of cinnarizine can be decreased when combined with acetaminophen.

Amlodipine: Amlodipine may increase the arrhythmogenic activities of cinnarizine.

Cholecalciferol: The metabolism of cinnarizine can be decreased when combined with cholecalciferol.

Side effects

Cholestatic jaundice; Drowsiness; Dyskinesia; Dyspepsia; Epigastric discomfort; Nausea; Extrapyramidal disorder; Fatigue; Gastrointestinal discomfort; Hyperhidrosis; Increased weight; Lethargy; Lichenoid keratosis; Muscle rigidity; Parkinsonism; Somnolence; Subacute cutaneous lupus erythematosus; Tremor; Upper abdominal pain; Vomiting.

Patient educations

Cinnarizine may cause drowsiness, if affected, do not drive or operate machinery. Cinnarizine may cause somnolence especially at the start of treatment. therefore, caution should be taken when alcohol, central nervous system (CNS) depressant or tricyclic antidepressants are used concomitantly

Ciprofloxacin

ATC Code: J01MA02 Antibacterials for Systemic Use (Fluoroquinolones)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid; If possible, do not use during lactation (risk of arthropathy to infant).

Dosage forms and trade names available in Iraq

- Ciprofloxacin 1000mg tab
- Ciprofloxacin 750mg tab
  CIPRONEER (Pioneer Iraq).
- Ciprofloxacin 500mg tab
  CIPROSAM (SDI IRAQ), **CIPRONEER** (Pioneer Iraq), **Ciprophar**m (Pharma International Jordan), **Ciprodain** (Wadi Al-Rafidain Iraq).
- Ciprofloxacin 250mg tab
  CIPRONEER (Pioneer Iraq).
- Ciprofloxacin 200mg/100ml I.V infusion
- Ciprofloxacin 3mg/1ml (0.3%) Eye Drops
  CIPRONEER (Pioneer Iraq).

Indications and Dosage

- Anthrax: 500mg bid at least 60 days.
- Bacterial prostatitis chronic: 500mg bid for 28 days.
- Bronchitis, lower respiratory tract infection, infection of bone, skin or soft tissue infection, sinusitis: 500mg-750mg bid for 7-14 days.
- Urinary tract infectious disease: 250mg-500mg bid for 3 days.

Off-label uses

Chancroid; Traveler's diarrhea.

Contraindications

Hypersensitivity to ciprofloxacin.

Cautions

History of QT prolongation; Hypokalemia; Use in children (due to adverse events to joints).

Dose adjustment in renal failure: CrCl 30-50ml/min: 250mg-500mg bid; CrCl 5-29ml/min: 250mg-500mg every 18 hr.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=50-85%, minor food effect.

Distribution Vd=2.1-2.7L/kg, 20-40% protein bound.

Metabolism Metabolized in liver.

Elimination Renal elimination is 30-50% with half-life of 3-6 hr.

Drug interactions

Clomipramine: Ciprofloxacin will increase the level or effect of clomipramine by affecting hepatic enzyme CYP1A2 metabolism.

Hydroxychloroquine: Hydroxychloroquine and ciprofloxacin both increase QT interval (avoid).

Side effects

Common (more than 10%) None.

Less common (1-10%) Abdominal pain; Diarrhea; Headache; Increased aminotransferase levels; Increased serum creatinine; Nausea; Rash; Restlessness; Vomiting.

Rare (less than 1%) Blurred vision; Bronchospasm.

Patient educations

Maintain adequate hydration to prevent crystalluria; Avoid caffeine; Report tendon pain or swelling; Avoid exposure to sunlight may cause photosensitivity reaction.

Cisplatin

ATC Code: L01XA01 Antineoplastic Agents (Platinum Compounds)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Cisplatin 10mg/20ml vial
Cisplatin „Ebewe“ (EBEWE Australia).
Cisplatin 50mg/50ml vial
Cisplatin (Pfizer Australia).

Indications and Dosage

• Advanced non-small-cell lung cancer : treated on a 28-day cycle with a very high-dose (IV) injection of cisplatin 100 mg/m2 on days 1 and 8.
Bladder cancer: 50mg–70mg/m2 every 3–4 weeks.
• Ovarian cancer: 75mg–100mg/m2 every 3–4 weeks.
• Testicular cancer: 20mg/m2 daily for 5 days repeated every 3 weeks.

Off-label uses

Breast, cervical, endometrial, GI cancers, head and neck, lung (small cell, non–small cell) carcinomas; lymphomas; Malignant melanoma; Neuroblastoma; Osteosarcoma; Wilms' tumor; Brain tumors.

Contraindications

Hypersensitivity to cisplatin; Hearing impairment; Myelosuppression.

Cautions

Elderly; Renal impairment.
Dose adjustment in renal failure: CrCl 10-50ml per minute use 75% of normal dose; CrCl less than 10ml per minute use 50% of normal dose.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=11-12L/m2, 90%protein bound.
Metabolism Undetermined.
Elimination Renal elimination is 90% with half-life of 20-30 minutes.

Drug interactions

Amikacin: Amikacin and cisplatin both increase nephrotoxicity and ototoxicity.
Aspirin: Aspirin and cisplatin shouldn't be used together.
Furosemide: Furosemide and cisplatin both increases toxicity of the other by pharmacodynamic synergism, Additive ototoxicity.

Side effects

Common (more than 10%) Nausea and vomiting; nephrotoxicity; Myelosuppression; Ototoxicity; Peripheral neuropathy; extravasation necrosis; sepsis;arrhythmias; Hypotension.
Less common (1-10%) Anorexia; Fatigue; alopecia; Diarrhea or constipation;Hemolytic anemia; GIT perforation.
Rare but serious (less than 1%) anaphylaxis; cardiotoxicity; Lung damage;thromboembolic events.

Patient educations

Report signs of ototoxicity (tinnitus, hearing loss); Do not have immunizations without physician's approval (lowers body resistance); Avoid contact with those who have recently taken oral polio vaccine; Report signs of peripheral neuropathy.

Citicoline

ATC CODE: N06BX06 Psychoanaleptics (Analgesics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Treatment of cognitive and neurological disorders associated with acute and sub-acute stroke or traumatic brain injuries: 500mg-2g daily depending on the severity of the symptoms to be treated.

Off-label uses

None.

Contraindications

Hypersensitivity to citicoline; Patients with hypertonia of the parasympathetic.

Cautions

Patients with persistent intracranial hemorrhage; Citicoline may exacerbate adrenocorticotropic hormone or cortisol hypersecretion related disorders including type 2 diabetes and major depressive disorder.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Citicoline 10g/100ml oral solution
  Somazina (Ferrer Internacional Spain).
- Citicoline 100mg/1ml (10g/100ml oral drop)
- Citicoline 500mg/ 4ml Ampule

Pharmacokinetic parameters

Absorption F=90%.

Distribution Distributed throughout the body, crosses blood brain barrier.

Metabolism Metabolized in the liver and gut wall via hydrolysis to choline and cytidine.

Elimination Mainly via respiratory and urine with half-life of 71 hours.

Drug interactions

Levodopa: Citicoline may enhance the effects of levodopa. The exact mechanism is unknown, but animal models suggest that citicoline may increase dopamine levels in the brain and improve dopaminergic cell survival. In patients with Parkinson's disease, a few studies have demonstrated levodopa-saving effects, whereby the addition of citicoline (500mg to 2g/day) allowed for lower dosages of levodopa to be used with stable or improved therapeutic efficacy and reduced side effects in some patients. However, data are limited.

Side effects

Bradycardia; Gastrointestinal disturbances; Hypotension; Restlessness; Tachycardia; Transient headaches.

Patient educations

Citicoline may be taken with or without food.

Cladribine

ATC CODE: L01BB04 Antineoplastic Agents (Purine Analogues)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid breast feeding that must be discontinued 6 months after last dose.

Indications and Dosage

Hairy cell leukemia: By i.v. infusion, 0.09–0.1mg/kg/day as continuous intravenous infusion for 7 days.

Off-label uses

Treatment of chronic lymphocytic leukemia; Non-Hodgkin's lymphoma; Acute myeloid leukemia.
Treatment of adult patients with highly active forms of relapsing-remitting multiple sclerosis: (10 mg) orally.

Dosage forms and trade names available in Iraq

Cladribine 10mg/10ml vial

Contraindications

Hypersensitivity to cladribine or any of its components

Cautions

Bone marrow suppression, neurological toxicity and nephrotoxicity particularly with high doses,Active infection; High tumour burden;hyperuricemia.
Dose adjustment in renal failure: In mild renal impairment (Creatinine Clearance CrCl 60-89 ml per minute) no dosage adjustment is recommended. In moderate to severe impairment (CrCl less than 60 ml per minute), cladribine is not recommended..
Dose adjustment in hepatic failure: In mild hepatic failure, no dosage adjustment is recommended. In moderate to severe hepatic failure (Child-Pugh > 6), cladribine is not recommended.

Pharmacokinetic parameters

Absorption complete bioavailability after parenteral administration,oral bioavailability is 34-48%
Distribution Vd=9L/kg, 20%protein bound.
Metabolism Metabolized in all cells with deoxycytidine kinase.
Elimination Renal elimination is 28.5% with half-life of 5.4 hours.

Drug interactions

Caution when Cladribine injection is given with other immunosuppressive or myelosuppressive agents.
Natalizumab: should not be given in combination with cladribine to avoid adverse effects specially the risk of concurrent infection.

Side effects

Common (more than 10%) Decreased appetite; Fatigue; Fever; Headache; Lymphopenia; Upper respiratory tract infection; Vomiting.
Less common (1-10%) Abdominal pain; Alopecia; Arthralgia and arthritis; Asthenia; Bronchitis; Chills; Constipation; Depression; Diarrhea; Dizziness; Edema; Erythema; Hypertension; Insomnia; Petechia; Pruritus; Purpura.
Rare but serious (less than 1%) Aplastic anemia; Cellulitis; Eosinophilia; Fungal infection; Hemolytic anemia; Pancytopenia; Pneumonia; Seizures.

Patient educations

Avoid crowds and contact with individuals with known infections; report signs of infection at once (fever, flu-like symptoms);Avoid contact with those who have recently received live attenuated virus vaccine; Avoid pregnancy.

Clarithromycin

ATC CODE: J01FA09 Antibacterials for systemic use (Macrolides, lincosamides, and streptogramins)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 **B3** C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Community acquired pneumonia, skin infection, sinusitis, pharyngitis: 250mg bid for 7-14 days.

• H. pylori GI tract infection: 500mg bid for 10-14 days in combination with various other antibiotics and PPIs.

Off-label uses

Bacterial endocarditis prophylaxis for high risk patients.

Contraindications

Hypersensitivity to clarithromycin; History of QT prolongation or ventricular arrhythmias.

Cautions

Myasthenia gravis; Coronary artery disease; Patients at risk of prolonged cardiac repolarization; Hypokalemia; Hypomagnesemia; Bradycardia.

Dose adjustment in renal failure: CrCl less than 30ml/min: reduce dose by 50%.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Clarithromycin 125mg/5ml susp
  KLACID (Abbott Italy).
- Clarithromycin 250mg/5ml susp
  KLACID (Abbott Italy).
- Clarithromycin 250mg tab
- Clarithromycin 500mg tab
  Claritrom (PIONEER IRAQ), **CLARITHROSAM** (SDI Iraq), **Cipropharm** (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=50%, clarithromycin can be taken without regard to food.

Distribution Distributed widely into most body tissues except central nervous system, 42-50% protein bound.

Metabolism Partially metabolized by liver.

Elimination Renal elimination is 20-40% with a half-life of 5-7 hr.

Drug interactions

Alfuzosin: Clarithromycin may increase the serum concentration of alfuzosin.

Side effects

Common (more than 10%) Abdominal pain.

Less common (1-10%) Abnormal taste; Diarrhea; Dyspepsia; Headache; Heartburn; Nausea; Rash; Vomiting.

Rare (less than 1%) Anorexia; Anxiety; Clostridium difficile colitis; Dizziness; Dyspnea; Hypoglycemia; Jaundice; Leukopenia; Manic behavior; Neuromuscular blockade; Neutropenia; Pancreatitis; Psychosis; QT prolongation; Seizures; Stevens-Johnson syndrome; Thrombocytopenia.

Patient educations

Advise patient to take drug with full glass of water, either with food or on an empty stomach; Tell patient using oral suspension not to refrigerate it, and to discard it 14 days after mixing.

Clindamycin

ATC Code: J01FF01 Antibacterials for Systemic Use (Lincosamides)

Pregnancy category:
FDA A **B** C D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Bacterial infectious disease, susceptible infections due to anaerobic organisms, staphylococci, streptococci, pneumococci, infection of skin and subcutaneous tissue, infectious disease of abdomen, lower respiratory tract infection, pelvic inflammatory disease, septicemia: 150mg-450mg qid.
• Bacterial vaginosis: 1 full applicator inserted intravaginally at night for 3 days in nonpregnant patients and for 7 days in pregnant patients.
• Acne vulgaris: Apply a thin film to affected area bid.

Off-label uses

Bacterial vaginosis; Streptococcal pharyngitis in penicillin allergic patients.

Contraindications

Hypersensitivity to clindamycin.

Dosage forms and trade names available in Iraq

Clindamycin 1% topical solution
Clindamycin 150mg caps
lanacin (Pharma International Jordan).
Clindamycin 2% vaginal cream
Climycen (Help Greece).
Clindamycin 300mg/2ml inj
Clindamycin 600mg/4ml vial
Clindamycin (Siegfried Hameln Germany).

Cautions

Colitis, Renal failure, Hepatic failure, Prematurity.
Dose adjustment in renal failure: CrCl less than 30ml/min: reduce dose by 50%.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.
Distribution Vd=2L/kg.
Metabolism Minor hepatic metabolism.
Elimination Renal elimination route is 5-28% with a half-life of 1.5-5 hr, some of it eliminated by feces and as hepatic inactive metabolites.

Drug interactions

Digoxin: Clindamycin will increase the level or effect of digoxin by altering intestinal flora.
Pyridoxine: Clindamycin will decrease the level or effect of pyridoxine by altering intestinal flora.

Side effects

Abdominal pain; Diarrhea; Nausea; Vomiting; Agranulocytosis; Eosinophilia (transient); Granulocytopenia; Neutropenia; Thrombocytopenia; Thrombophlebitis; Hypotension; Polyarthritis; Fungal overgrowth (Candidiasis); Intestinal dysbiosis ; Pseudomembranous colitis; Rashes; Burning ; oily skin; Renal dysfunction; Stevens-Johnson syndrome; Urticaria.

Patient educations

Tell patient to take drug with food if it causes stomach upset; Tell patient that i.v. use may cause bitter taste.

Clobetasol

ATC CODE: D07AD01 Corticosteroids, Dermatological Preparations (Corticosteroids, Very Potent (Group IV))

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Avoid.

Indications and Dosage

• Plaque psoriasis, skin disorders corticosteroid responsive: Apply thin layer topically to affected area bid for a max 2 weeks.

Off-label uses

Oral lichen planus.

Contraindications

Hypersensitivity to clobetasol; Viral and fungal skin lesions.

Cautions

Percutaneous absorption of clobetasol may cause manifestations of cushing syndrome.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Clobetasol (0.5mg/1g) 0.05% Ointment

DERMODIN (SDI Iraq), **Dermosam** (Dubai Co. Pharmaceutical Industries IRAQ), **Dermatozol** (AL-Kindi Iraq), **Dermodad** (Wadi Al-Rafidain Iraq).

Clobetasol (0.5mg/1g) 0.05% Cream

DERMODIN (SDI Iraq), **Dermosam** (Dubai Co. Pharmaceutical Industries IRAQ) , **Dermodad** (Wadi Al-Rafidain Iraq), **Delor** (Pharma International Jordan), **Dermatozol** (AL- Kindi Iraq).

Pharmacokinetic parameters

Absorption Minimal percutaneous absorption unless covering large surface area or covering areas lacking skin integrity.

Distribution Undetermined.

Metabolism Hepatic metabolism.

Elimination Renal elimination and fecal elimination.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) None.

Less common (1-10%) Burning sensation; Stinging; Pruritus at site of administration; Discomfort skin; Dry skin; Skin atrophy; Telangiectasia.

Rare (less than 1%) Hypothalamic axis suppression has been reported when used with occlusive dressings.

Patient educations

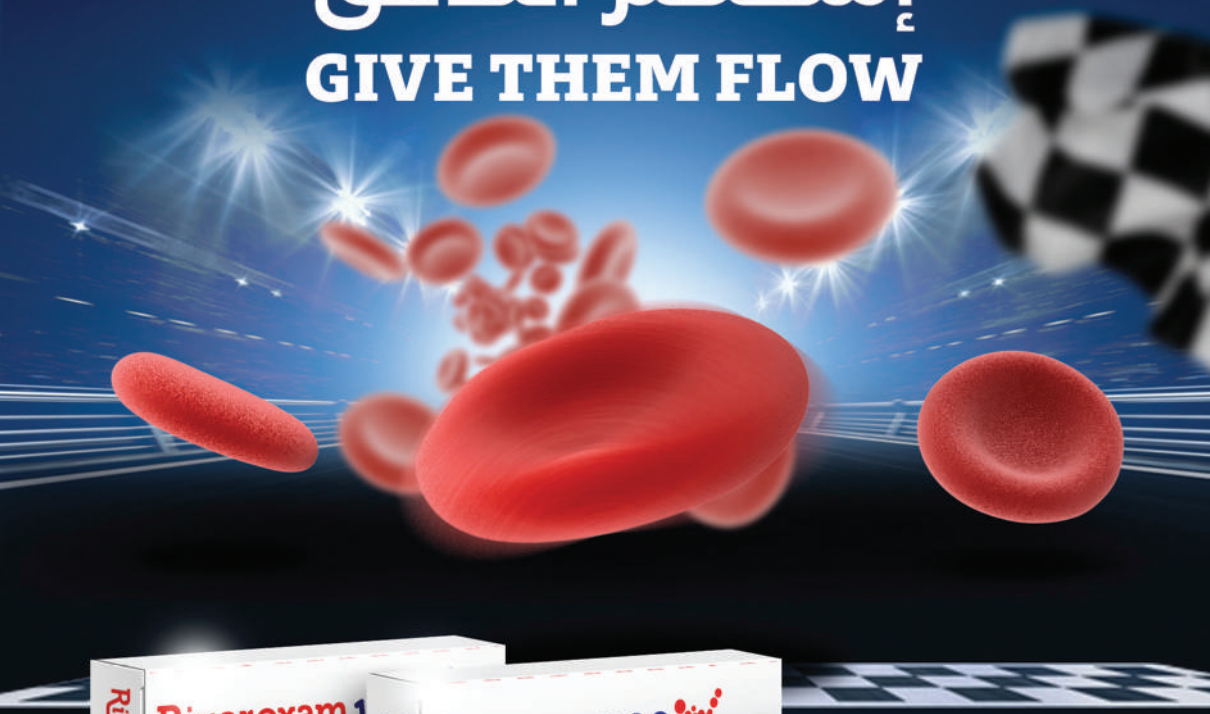
Avoid use with occlusive dressing; Avoid contact with face (i.e. eyes, nose, mouth), axillae, or groin; Instruct patient on correct technique of medication administration; Emphasize importance of avoiding the eyes; Caution patient to use only as directed; Avoid using cosmetics, bandages, dressings, or other skin products over the treated area unless directed by health care professional; Advise parents of pediatric patients not to apply tight-fitting diapers or plastic pants on a child treated in the diaper area, these garments work as an occlusive dressing and may cause more of the drug to be absorbed; Caution women that medication should not be used extensively, in large amounts, or for protracted periods if they are pregnant or planning to become pregnant; Instruct patient to inform health care professional if symptoms of underlying disease return or worsen or if symptoms of infection develop.

Rivaroxam

RIVAROXBAN 15, 20 MG

إمنحهم التدفق

GIVE THEM FLOW



Indications :Prophylaxis of venous thromboembolism following knee or hip replacement surgery, Treatment of deep-vein thrombosis, Treatment of pulmonary embolism, Prophylaxiso frecurrent deep- vein thrombosis ,Prophylaxis of recurrent pulmonary embolism, Prophylaxis of stroke and systemic embolism in patients withnon-valvular atrial fibrillation and with at least one ofthe followingrisk factors: congestive heart failure, hypertension, previous stroke or transient ischaemic attack, age ≥ 75 years, or diabetes mellitus, Prophylaxis of atherothrombotic events following an acute coronary syndrome.

Composition : Each tablet contains: - Rivaroxban 15, 20 mg.

ALSAIDALY

SCIENTIFIC BUREAU

SDI

Clomiphene

ATC Code: G03GB02 Sex Hormones and Modulators of The Genital System (Ovulation Stimulants, Synthetic)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid; Clomiphene may inhibit lactation.

Dosage forms and trade names available in Iraq

- Clomiphene citrate 50mg tab

Indications and Dosage

• Infertility in females due to anovulation or irregular ovulation: 50mg daily for 5 days (first course); start the regimen on the fifth day of cycle. Increase dose only if unresponsive to cyclic 50mg, (max 50mg bid for 5 days). Do not exceed 6 courses of treatment.

Off-label uses

Infertility in men.

Contraindications

Hypersensitivity to clomiphene; Liver dysfunction; Abnormal uterine bleeding; Enlargement or development of ovarian cyst; Uncontrolled thyroid or adrenal dysfunction in the presence of an organic intracranial lesion such as pituitary tumor.

Cautions

Ovarian cancer; Polycystic ovarian syndrome; Uterine fibroids.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Contraindicated.

Pharmacokinetic parameters

Absorption F=90%.

Distribution Vd=4000L.

Metabolism metabolized in the liver, undergoes enterohepatic recirculation.

Elimination Renal elimination is 8% with half-life of 5 days.

Drug interactions

Captopril: Clomiphene and captopril both increases effects of the other by pharmacodynamic synergism, increases risk of hypotension.

Side effects

Common (more than 10%) Diarrhea; Ovarian enlargement; Vasomotor flushing.

Less common (1-10%) Abdominal discomfort: Blurred vision; Breast discomfort; Nausea; Vomiting.

Rare but serious (less than 1%) None.

Patient educations

Teach patient about appropriate measures to avoid dehydration caused by vomiting and diarrhea; Tell patient to seek medical advice if signs and symptoms of dehydration occur (such as dizziness, light-headedness, fainting spells, or decreased urine output).

Clonazepam

ATC Code: N03AE01 Antiepileptics (Benzodiazepine derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 **B3** C D X N

Lactation: Present in milk, and should be avoided.

Indications and Dosage

• Panic disorder: 0.25mg bid, may titrate by 0.25mg every 3 days, (max 4mg daily in 2-3 divided doses).
• Seizure: 0.5mg tid, may titrate by 0.25mg every 3 days, (max 4mg daily in 2-3 divided doses).

Off-label uses

Restless legs syndrome; Rapid eye movement sleep behavior disorder.

Contraindications

Hypersensitivity to clonazepam; Active narrow angle glaucoma; Coma; Current alcohol abuse; Current drug abuse; Respiratory depression; Patients with significant liver disease.

Cautions

Acute porphyrias , airways obstruction . brain damage. cerebellar ataxia. depression. spinal ataxia. suicidal ideation: The effectiveness of clonazepam may decrease significantly after weeks or months of continuous therapy.
Dose adjustment in renal failure: Start with small doses.
Dose adjustment in hepatic failure: Reduce dose by 50%.

Dosage forms and trade names available in Iraq

Clonazepam 2mg tab
Clonotril (Remedica Cyprus).

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.
Distribution Vd=1.5-3L, 85% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 1% with a half-life of 30-40 hours.

Drug interactions

Opioids: The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression because of actions at different receptor sites in the CNS that control respiration.
Phenytoin: Clonazepam has the potential to influence concentrations of phenytoin.

Side effects

Common (more than 10%) Somnolence.
Less common (1-10%) Abnormal coordination; Ataxia; Confusion; Coughing; Decreased libido; Depression; Fatigue; Impotence; Memory impairment; Rhinitis; Upper respiratory infection; Urinary frequency.
Rare (less than 1%) None.

Patient educations

Advise patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness; Caution patient not to stop taking drug abruptly; Advise him to consult prescriber for dosage-tapering schedule if he wishes to discontinue drug; Advise patient not to drink alcohol.

Clopidogrel

ATC Code: B01AC04 Antithrombotic Agents (Platelet Aggregation Inhibitors Excl. Heparin)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Clopidogrel 75mg tab
PLAVIKIN (AL- Kindi IRAQ), **Platil** (Pharma International Jordan), **PLAVINEER** (Pioneer Iraq), **PLAVEDAIN** (Wadi Al-Rafidain IRAQ).

Indications and Dosage

• Acute ST and non–ST segment elevation myocardial infarction: 300mg-600mg loading dose, followed by 75mg once daily (in combination with aspirin).
• Thrombosis prevention in arteriosclerotic vascular disease, following stroke, in peripheral arterial occlusive disease: 75 mg once daily.

Off-label uses

Thrombosis prevention in atrial fibrillation or following percutaneous coronary intervention.

Contraindications

Hypersensitivity to Clopidogrel; Acute pathologic bleeding (e.g. peptic ulcer, intracranial hemorrhage).

Cautions

Conditions with increase bleeding risk such as major surgery or Trauma.

Dose adjustment in renal failure: Not required. but monitor for thrombotic or bleeding events

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=50%, food has no effect on absorption.
Distribution Protein bound 98%.
Metabolism Metabolized in liver.
Elimination Renal elimination is 50% with a half-life of 6 hr.

Drug interactions

Fluoxetine: Fluoxetine decreases effects of clopidogrel by affecting hepatic enzyme CYP2C19 metabolism. Clopidogrel efficacy may be reduced by drugs that inhibit CYP2C19. Inhibition of platelet aggregation by clopidogrel is entirely due to an active metabolite. Clopidogrel is metabolized to this active metabolite in part by CYP2C19.
Fluoxetine, Esomeprazole and Omeprazole: Omeprazole decreases effects of clopidogrel by affecting hepatic enzyme CYP2C19 metabolism.

Side effects

Common (more than 10%) None.
Less common (1-10%) Arthralgia; Chest pain; Depression; Diarrhea; Dizziness; Flulike syndrome; Headache; Pain; Rash; Rhinitis; Upper respiratory tract infection; Urinary tract infection.
Rare (less than 1%) Acute liver failure; Aplastic anemia; Eczema; Hypotension; Myalgia; Severe neutropenia; Stevens-Johnson syndrome; thrombocytopenic purpura (TTP),Hemorrhage

Patient educations

It may take longer to stop bleeding during drug therapy; Report any unusual bleeding; Inform physicians, dentists if clopidogrel is being taken especially before surgery is scheduled.

Clotrimazole

ATC Code: G01AF02 Gynecological Antiinfectives and Antiseptics (Imidazole Derivatives)

Pregnancy category:

FDA A **B** C D X N

TGA **A** B1 B2 B3 C D X N

Lactation: No data available; Systemic absorption is minimal after topical and vaginal administration.

C

Indications and Dosage

• Vulvovaginal candidiasis: 1 applicatorful or 1 vaginal tablet at bedtime for 7-14 days.

• Cutaneous candidiasis or tinea corporis, tinea cruris, tinea pedis: Apply cream or solution to affected area bid for 8 weeks.

Off-label uses

Treatment of paronychia; Tinea barbae; Tinea capitis.

Contraindications

Hypersensitivity to clotrimazole.

Cautions

Patients who have had more than 2 infections of candidal vaginitis for the past 6 months; History of sexual transmitted disease or exposure to partner with sexual transmitted disease; Irregular or abnormal bleeding; Vaginal ulcers; Diarrhea; Dysuria; Lower abdominal pain; Fever or chills.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=3-10%.

Distribution Vd=Undetermined, 98% protein bound.

Metabolism Hepatic metabolized to inactive metabolites.

Elimination Elimination half-life is 2 hours.

Dosage forms and trade names available in Iraq

- Clotrimazole 1% Cream

  Fugeden (AL-Kindi Iraq), **Clotridain** (Wadi Al-Rafidain Iraq), **Fugizol** (Dubai Iraq).
- Clotrimazole 1% solution
- Clotrimazole 10mg/1gm vag cream
- Clotrimazole 10mg/1ml ear drop
- Clotrimazole 100mg vag tab

  CANESTEN (Bayer switzerland).

Drug interactions

Bosutinib: Clotrimazole increases levels of bosutinib by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Everolimus: Clotrimazole will decrease the level or effect of everolimus by P-glycoprotein efflux transporter, contraindicated.

Warfarin: Clotrimazole increases levels of warfarin by decreasing metabolism.

Side effects

Blistering; Burning; Edema; Elevated serum AST (SGOT) concentrations; Erythema; General irritation of the skin; Peeling; Pruritus; Skin fissures; Stinging; Urticaria.

Patient educations

Take the full course of drug therapy, even if symptoms improve. Continue during menstrual period if vaginal route is being used; Vaginal creams should be inserted high into the vagina; Use hygiene measures to prevent reinfection or spread of infection; With vaginal use, refrain from sexual intercourse or advise partner to use a condom to avoid reinfection; Use a sanitary napkin to prevent staining of clothing.

Colchicine

ATC Code: M04AC01 Antigout Preparations (Preparations with No Effect on Uric Acid Metabolism)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C **D** X N

Lactation: Colchicine is excreted into breast milk. Caution is advised.

C

Indications and Dosage

Used to treat gout and Familial Mediterranean Fever (FMF). The usual dosage for acute gout is 1.2 mg at the first sign of a flare followed by 0.6 mg one hour later. For FMF, the dosage is typically 1.2 to 2.4 mg daily.

Off-label uses

Treatment of pericarditis; Behcet's disease; pseudogout.

Contraindications

Patients with renal or hepatic impairment who are also taking P-glycoprotein or strong CYP3A4 inhibitors should avoid using colchicine.

Cautions

Bone marrow depression, neuromuscular toxicity, and gastrointestinal symptoms can occur, especially with prolonged use.

Dose adjustment in renal failure: used with caution. Dose adjustments are necessary.

Dose adjustment in hepatic failure: used with caution. Dose adjustments are necessary.

Dosage forms and trade names available in Iraq

- Colchicine 0.5gm tablet
  Colchicum (Recordati Ilac Turkey)

Pharmacokinetic parameters

Absorption Nearly completely absorbed after oral administration.

Distribution Not well known.

Metabolism Hepatic; via CYP3A4 and P-gp.

Elimination Primarily excreted in the feces.

Drug interaction

Strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole): These can increase blood levels of colchicine, leading to potentially serious side effects.

P-glycoprotein inhibitors (e.g., cyclosporine): These can increase blood levels of colchicine, leading to potentially serious side effects.

Side effects

Common (more than 10%): Diarrhea, nausea, vomiting, abdominal pain.

Less common (1-10%): Lactose intolerance, muscular pain, skin rash.

Rare but serious (less than 1%): Bone marrow depression, neuromuscular toxicity, and severe skin reactions.

Patient educations

- Avoid grapefruit products, as they can interact with colchicine and lead to unwanted side effects.
- Report any unexplained muscle weakness or pain, numbness, or tingling to your doctor right away.

Co-Trimoxazole

ATC Code: J01EE01 Antibacterials for Systemic Use (Combinations of Sulfonamides and Trimethoprim)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C D X **N**

Lactation: caution is recommended especially with premature infants.

Dosage forms and trade names available in Iraq

- Cotrimoxazol 240mg/5ml susp.
  METHEPRIM (SDI Iraq), **DADPRIM** (Wadi Al-Rafidain IRAQ), **KINDIPRIM** (Al-Kindi IRAQ).
- Cotrimoxazol 480mg tab
  KINDIPRIM (Al-Kindi IRAQ), **Piotrim** (Pioneer IRAQ), **Dumethiprim** (Dubai co. Iraq), **CO-TRIMOXAZOLE** (Wadi Al-Rafidain IRAQ), **METHEPRIM** (SDI Iraq).
- Cotrimoxazol 960mg tab

Indications and Dosage

• Acute infective exacerbation of COPD: trimethoprim 160mg and sulfamethoxazole 800mg bid for 21 days.
• HIV infection, pneumocystis pneumonia: trimethoprim 320mg and sulfamethoxazole 1600mg bid for 21 days.
• Traveler's diarrhea: trimethoprim 160mg and sulfamethoxazole 800mg bid for 5 days.
•Urinary tract infection: trimethoprim 160mg and sulfamethoxazole 800mg bid for 10-14 days.

Off-label uses

Sinusitis.

Contraindications

Hypersensitivity to any sulfa drug; Infants younger than 4 weeks; Megaloblastic anemia.

Cautions

G6PD deficiency; Porphyria; Asthma; Elderly; Alcoholism; Thyroid dysfunction.
Dose adjustment in renal failure: CrCl 15-30ml/min: reduce dose by 50%; CrCl less than 15ml/min: avoid.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.
Distribution Protein bound trimethoprim 44%, sulfamethoxazole 70%.
Metabolism Hepatic metabolism more than 90%.
Elimination Sulfamethoxazole renal elimination is 10-30% with a half-life of 8-11 hr; trimethoprim renal elimination is 50-75% with a half-life of 6-17 hr.

Drug interactions

Acyclovir: Acyclovir may decrease the excretion rate of sulfamethoxazole which could result in a higher serum level.

Side effects

Common (more than 10%) Nausea, Vomiting, Diarrhea, Loss of appetite
Less common (1-10%) Rash,Itching, Changes in skin color, Joint pain, DizzinessTiredness
Rare but serious (less than 1%) Allergic reactions, like severe rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

Crizotinib

ATC Code: L01ED01 Antineoplastic Agents (Anaplastic Lymphoma Kinase (ALK) Inhibitors)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Not recommended during treatment and for 45 days after the final dose.

Dosage forms and trade names available in Iraq

- Crizotinib 200mg capsules
  Xalkori (Pfizer canada).
- Crizotinib 250mg capsule
  Xalkori (Pfizer canada).

Indications and Dosage

For treatment of patients with anaplastic lymphoma kinase (ALK) - positive metastatic NSCLC, the recommended oral dosage is 250 mg taken twice daily until disease progression or unacceptable toxicity.

Off-label uses

Might be used in other ALK or ROS1-positive cancers.

Contraindications

No known absolute contraindications.

Cautions

Hepatotoxicity, interstitial lung disease/pneumonitis, QTc prolongation, bradycardia, severe visual loss.

Dose adjustment in renal failure: No dose adjustment is recommended for patients with mild to moderate renal impairment. Insufficient data in patients with severe renal impairment.

Dose adjustment in hepatic failure: Dosage adjustment is recommended for patients with mild and moderate hepatic impairment.

Pharmacokinetic parameters

Absorption Bioavailability is 43%.

Distribution Vd= 1772 L, 91% protein bound.

Metabolism Primarily hepatic, via CYP3A4/5.

Elimination Primarily fecal excretion, with a half-life of 42 hours.

Drug interaction

CYP3A inhibitors (e.g., ketoconazole): can increase crizotinib plasma concentrations.

CYP3A inducers (e.g., rifampin): can decrease crizotinib plasma concentrations.

Side effects

Common (more than 10%): Vision disorders; nausea; diarrhea; vomiting; edema; constipation; elevated transaminases.

Less common (1-10%): Neutropenia; lymphopenia; fatigue; decreased appetite.

Rare but serious (less than 1%): Interstitial lung disease; QT prolongation; hepatotoxicity.

Patient education

1. Inform your healthcare provider of any side effects immediately, particularly vision changes or cardiac symptoms.
2. Do not consume grapefruit or grapefruit juice during treatment, as it can affect how the drug works.
3. If you miss a dose, take it as soon as you remember unless it's within 6 hours of your next dose. Never take two doses at once to make up for a missed one.

Cromoglicate

ATC Code: R01AC03 Nasal Preparation (Antiallergic Agents, Excl. Corticosteroids)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not yet known. caution is advised

Indications and Dosage

For the prevention and relief of ocular itching due to allergic conjunctivitis. Apply 1-2 drops in each eye 4-6 times daily.

Off-label uses

None.

Contraindications

Hypersensitivity to Cromoglicate.

Cautions

Not to be used while wearing contact lenses.
Dose adjustment in renal failure: None.
Dose adjustment in hepatic failure: None.

Pharmacokinetic parameters

Absorption Minimal (eye drops)
Distribution Not applicable
Metabolism Not metabolized
Elimination Primarily via kidneys, with a half-life of approximately 80 minutes.

Drug interactions

No major interactions have been reported.

Side effects

Common (more than 10%) Temporary stinging or burning in the eye.
Less common (1-10%) Eye irritation, dryness or redness.
Rare but serious (less than 1%) Severe allergic reactions.

Patient educations

• Do not touch the dropper tip or let it touch your eye or any other surface to avoid contamination.
• Wait at least 10 minutes before replacing your contact lenses after using.
• If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Use your next dose at the regular time.

Dosage forms and trade names available in Iraq

Sodium Cromoglicate 20mg/1ml eye drop
Allergotin (Cooper Greece).

Crotamiton

ATC Code: D04AX Antipruritics, Incl. Antihistamines, Anesthetics, Etc (Other Antipruritics)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 **B2** B3 C D X N

Lactation: Avoid application to nipple area.

Dosage forms and trade names available in Iraq

Crotamiton 10% (100mg/1g) cream

EURAXDAIN (WADI AL RAFIDAIN Iraq).

Crotamiton 10% lotion

EURAX (Novartis Switzerland).

Indications and Dosage

• Scabies: Apply thin layer of medicine onto skin of entire body from neck to toes after bathing and drying preferably in the evening, and rub in well; repeat in 24 hours without washing off the first coat of this medication; bath 24 hours after final application to cleanse body, may repeat treatment after 7-10 days if live mites present.

• Pruritus: Apply and massage into affected areas until medication completely absorbed, repeat prn.

Off-label uses

Pediculosis capitis.

Contraindications

Hypersensitivity to crotamiton, Acute exudative dermatoses.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=10%.

Distribution Undetermined

Metabolism Undetermined

Elimination Renal elimination is 4.8-8.8%.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) None.

Less common (1-10%) Allergic contact dermatitis or primary irritation; pruritus; Local hypersensitivity reaction; Rash; Localized warm sensation.

Rare but serious (less than 1%) None.

Patient educations

For external use only; avoid eyes and mucous membranes; Take a bath or shower prior to application; Apply from neck down to toes; Trim fingernails and apply under nails (can use toothbrush, which should be disposed of after use); Take a cleansing bath 24 hours after the final application; Contaminated clothing and bed linens should be washed on hot cycle or dry-cleaned and all clothing and bedding should be changed the day after application; Avoid application to the face, eyes, mouth, or on acutely inflamed, denuded, or weeping skin.

Cyanocobalamin B12

ATC Code: B03BA01 Antianemic Preparations (Vitamin B12 (Cyanocobalamin and Analogues))

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: It is safe for use during breastfeeding.

Indications and Dosage

Cyanocobalamin is indicated for vitamin B12 deficiency. Dosage varies depending on the severity of the deficiency, usually from 100 mcg to 2000 mcg daily, weekly or monthly.

Off-label uses

There is some evidence that vitamin B12 can be used off-label for treating sleep disorders and boosting mood or energy.

Contraindications

Allergy to cobalt and/or vitamin B12.

Cautions

Be cautious in early Leber's disease, as it can lead to optic nerve damage.

Dose adjustment in renal failure: No dose adjustment needed.

Dose adjustment in hepatic failure: No dose adjustment needed.

Dosage forms and trade names available in Iraq

Cyanocobalamin B12 1000mcg/1ml amp **Jectin-12** (Hikma Jordan).

Pharmacokinetic parameters

Absorption When administered orally, cyanocobalamin absorption depends on the presence of intrinsic factor.

Distribution Vd= Not Available, protein binding is low.

Metabolism Liver.

Elimination Primarily renal excretion with half-life of about 6 days (after intravenous injection).

Drug interaction

- Chloramphenicol can interfere with the response to vitamin B12 therapy.
- Prolonged use of proton pump inhibitors and H2 blockers can decrease the absorption of Vitamin B12.

Side effects

Common (more than 10%): Injection site reactions.

Less common (1-10%): Headache, dizziness, nausea.

Rare but serious (less than 1%): Allergic reactions, including anaphylaxis.

Patient education

Report any side effects, including allergic reactions, to your healthcare provider immediately.

Cyclopentolate

ATC Code: S01FA04 Ophthalmologicals (Anticholinergics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Mydriasis, cycloplegia diagnosis: 1-2 drops in eye, may repeat in 5 minutes, mydriasis and cycloplegia may last for 24 hr.

Off-label uses

None.

Contraindications

Hypersensitivity to cyclopentolate; Narrow angle glaucoma.

Cautions

Patient with Down syndrome; Debilitated patients; Children with spastic paralysis or brain damage.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption May be systemically absorbed by trans corneal absorption.
Distribution Undetermined.
Metabolism Undetermined.
Elimination Undetermined.

Dosage forms and trade names available in Iraq

Cyclopentolate 1% eye drop
Pentolate (API Jordan).

Drug interactions

Amitriptyline: The risk or severity of adverse effects can be increased when amitriptyline is combined with cyclopentolate.
Cyproheptadine: The risk or severity of adverse effects can be increased when cyproheptadine is combined with cyclopentolate.
Escitalopram: The risk or severity of adverse effects can be increased when cyclopentolate is combined with escitalopram.
Trospium: The risk or severity of adverse effects can be increased when trospium is combined with cyclopentolate.

Side effects

Blurred vision; Burning sensation in eye; Conjunctivitis; Drowsiness; Light intolerance; Raised intraocular pressure; Tachycardia.

Patient educations

Cyclopentolate may cause transient blurring of vision and increased sensitivity to light, if affected, do not drive or operate machinery; Remove contact lenses prior to administration and reinsert after 15 minutes.

Cyclophosphamide

ATC Code: L01AA01 Antineoplastic Agents (Nitrogen Mustard Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Cyclophosphamide 500mg vial
ENDOXAN (Baxter Oncology Germany).

Indications and Dosage

• Acute lymphocytic, acute nonlymphocytic, chronic myelocytic, chronic lymphocytic leukemias, ovarian cancer, breast carcinomas, neuroblastoma, retinoblastoma, Hodgkins, non-Hodgkins lymphomas, multiple myeloma: By i.v. injection, 40mg–50mg/kg in divided doses over 2–5 days or 10mg–15mg/kg every 7-10 days or 3mg–5mg/kg twice weekly, or orally 1mg–5 mg/kg daily.
• Nephrotic syndrome: 2mg/kg/day for 60–90 days.

Off-label uses

Treatment of adrenocortical, bladder, cervical, endometrial, prostatic, testicular carcinomas; Ewing's sarcoma; Multiple sclerosis; non–small cell, small cell lung cancer; Organ transplant rejection; Osteosarcoma; Ovarian germ cell; Primary brain, trophoblastic tumors; Rheumatoid arthritis; Soft-tissue sarcomas; Systemic dermatomyositis; Systemic lupus erythematosus; Wilms tumor.

Contraindications

Hypersensitivity to cyclophosphamide; Severely depressed bone marrow function; Urinary outflow obstruction.

Cautions

Severe leukopenia; Thrombocytopenia; Tumor infiltration of bone marrow; Cardiac impairment; Active urinary tract infection.
Dose adjustment in renal failure: Use with caution.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=75%.
Distribution Vd=30-50L, 20%protein bound.
Metabolism Converted to active drug by the liver.
Elimination Renal elimination is 30% with half-life of 4-6.5 hours.

Drug interactions

Etanercept: The incidence of non-cutaneous solid malignancies may be increased in patients receiving TNF blocking agents with cyclophosphamide, coadministration is not recommended.

Side effects

Abdominal discomfort or pain; Alopecia; Anorexia; Diarrhea; Fever; Hemorrhagic colitis; Jaundice; Nausea; Neutropenia; Oral mucosal ulceration; Pigmentation of skin and changes in nails; Skin rash; Vomiting.

Patient educations

Encourage copious fluid intake, frequent voiding (assists in preventing cystitis) at least 24 hours before, during, after therapy; Avoid pregnancy for up to 1 year after completion of treatment.

Piovit-D3

Colecalceferol (Vitamin D)

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Cyproheptadine

ATC Code: R06AX02 Antihistamines for Systemic Use (Other Antihistamines for Systemic Use)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Allergic condition: 4mg tid.

• Migraine (prophylaxis): 0.2mg-0.4mg/kg/day bid, not exceed 0.5mg/kg/day.

Off-label uses

Stimulation of appetite; Treatment of serotonin syndrome.

Contraindications

Hypersensitivity to cyproheptadine; Acute asthmatic attack.

Cautions

Hypertension; Ischemic heart disease; Hyperthyroidism; History of bronchial asthma; Chronic breathing disorders; Increased intraocular pressure; Acute porphyria.

Dose adjustment in renal failure: Elimination is reduced in renal insufficiency; administer lower doses, and monitor closely.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Cyproheptadine Hcl 2mg/5ml syrup
CYPRODAD (WADI AL RAFIDAIN Iraq).

cyproheptadine HCl 4 mg tablet
Cibtaden (Alkindi Iraq), **CYPRODAD** (WADI AL RAFIDAIN Iraq).

Pharmacokinetic parameters

Absorption Peak plasma time 6-9 hours.

Distribution Undetermined.

Metabolism Almost completely metabolized in the liver via glucuronidation primarily to quaternary ammonium glucuronide conjugate.

Elimination Renal elimination is 40%, feces (2-20%) with half-life of 16 hours.

Drug interactions

Selegiline: Selegiline (MAO inhibitors) may prolong and intensify the anticholinergic effects of cyproheptadine, cyproheptadine may diminish the serotonergic effect of MAO inhibitors.

Side effects

Anorexia; Blurred vision; Chills; Cholestasis; CNS depression; Constipation; Delirium; Diarrhea; Diplopia; Dizziness; Dizziness; Drowsiness; Dryness of mouth; Dysuria; Early menses; Eczema; Epigastric distress; Euphoria; Facial dyskinesia; Faintness; Headache; Heart block; Hepatitis; Hypertension; Hypotension; Impotence; Insomnia; Irritability; Jaundice; Nasal stuffiness; Nausea; Nervousness; Palpitation; Popular rash; Paresthesia; Pruritus; Restlessness; Sedation; Seizures; Sweating; Tachycardia; Thickening of bronchial secretions; Tightness of chest; Tinnitus; Toxic; Psychosis; Tremors; Urinary retention; Vertigo; Visual disturbances; Vomiting; Weakness; Wheezing; Widened QRS.

Patient educations

Advise patient to take drug with food to minimize GI upset; Caution patient not to use other CNS depressants, sleep aids, or alcohol during therapy.

Cytarabine

ATC Code: L01BC01 Antineoplastic Agents (Pyrimidine Analogues)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

• Acute nonlymphocytic leukemia: By i.v. injection, 100mg-200mg/m2/day for 5-10 days, begin second course in 2-4 weeks after initial therapy if necessary.
• Meningeal leukemia: Intrathecal injection, 30mg/m2 every 4 days.

Off-label uses

Carcinomatous meningitis; Hodgkin's and non-Hodgkin's lymphomas; Myelodysplastic syndrome.

Contraindications

Hypersensitivity to cytarabine; Active meningeal infection.

Cautions

Prior drug induced bone marrow suppression.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Cytarabine 100 mg/5ml vial
CYTARABINE (Pfizer Australia).
Cytarabine 100mg/10ml vial
CYTARABINE (Pfizer Australia).
Cytarabine 50mg/1ml (20ml vial)
Alexan Ebewe (EBEWE Austria).

Pharmacokinetic parameters

Absorption F=20%.
Distribution Vd=3±11.9L/kg, 13%protein bound.
Metabolism Metabolized mostly by the liver.
Elimination Renal elimination is 10% with half-life of 1-3 hours.

Drug interactions

Deferiprone: myelosuppressive agents may enhance the neutropenic effect of deferiprone, avoid the concomitant use of deferiprone and myelosuppressive agents whenever possible, if this combination cannot be avoided monitor the absolute neutrophil count more closely.

Side effects

Common (more than 10%) None.
Less common (1-10%) Anemia; Anorexia; Bleeding; Bone pain; Cellulitis; Chest pain; Conjunctivitis; Diarrhea; Fever; Headache; Hepatic dysfunction; Infectious disease; Jaundice; Kidney disease; Leukopenia; Malaise; Myalgia; Myelosuppression; Nausea; Neuritis; Neuropathy; Oral and anal inflammation; Pericarditis; Pneumonia; Rash; Sepsis; Skin ulcers; Thrombocytopenia; Thrombophlebitis; Urinary retention; Vomiting.
Rare but serious (less than 1%) None.

Patient educations

Increase fluid intake (may protect against hyperuricemia); Do not have immunizations without physician's approval (drug lowers resistance); Avoid contact with those who have recently received live virus vaccine; Promptly report fever, sore throat, signs of local infection, unusual bleeding from any site.

Dabigatran

ATC Code: B01AE07 Antithrombotic Agents (Direct Thrombin Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

• Treatment and prevention of initial or recurrent deep venous thrombosis and pulmonary embolism: 150mg bid (after 5-10 days treatment with parenteral anticoagulant).
• Prevention of stroke and systemic embolism in patient with nonvalvular atrial fibrillation: 75 or 150 mg b.i.d
• Prophylaxis following hip surgery: 110mg on day one (1–4 hours postoperative) then 110mg bid for up to 35 days.

Off-label uses

Prevention of thromboembolism after orthopedic surgery.

Contraindications

Hypersensitivity to dabigatran; Active major bleeding; Patients with mechanical prosthetic heart valves.

Dosage forms and trade names available in Iraq

- Dabigatran Etexilate 75 mg capsule
  Pradaxa (Boehringer Ingelheim Germany).
- Dabigatran Etexilate 110 mg capsule
  Pradaxa (Boehringer Ingelheim Germany).
- Dabigatran Etexilate 150 mg cap
  Pradaxa (Boehringer ingelheim Germany).

Cautions

Invasive procedures; Spinal anesthesia; Major surgery; Patients with congenital or acquired bleeding disorders; Elderly; Valvular heart disease.
Dose adjustment in renal failure: CrCl 15-30ml/min: 75mg bid; CrCl less than 15ml/min: avoid.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=3-7%, food has no effect on absorption.
Distribution Vd=50-70L, 35% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 80% with a half-life of 12-17 hr.

Drug interactions

Heparin: Dabigatran and heparin both increase anticoagulation, both drugs have the potential to cause bleeding; concomitant use may increase risk of bleeding.

Side effects

Common (more than 10%) Dyspepsia; Gastritis.
Less common (1-10%) Life-threatening bleed; Major bleed.
Rare (less than 1%) Intracranial hemorrhage; Pruritus; Rash; Urticaria.

Patient educations

Do not chew, crush, open, or divide capsules; Use electric razor, soft toothbrush to prevent bleeding; Report any sign of red or dark urine, black or red stool, coffee-ground vomitus, red speckled mucus from cough; Treatment may increase risk of bleeding into the brain; Report difficulty speaking, headache, numbness, paralysis, vision changes, seizures.

Dacarbazine

ATC Code: L01AX04 Antineoplastic Agents (Alkylating Agents).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Unknown if excreted in breast milk, use caution.

Dosage forms and trade names available in Iraq

Decarbazine 200mg vial
Decarbazine (Medac Germany).

Indications and Dosage

• Metastatic Malignant Melanoma: 2 to 4.5 mg/kg IV once a day for 10 days; repeat every 4 weeks OR 250 mg/m2 IV once a day for 5 days; repeat every 3 weeks.
• Hodgkin's disease as a second-line therapy: 150 mg/m2 IV once a day for 5 days in combination therapy; repeat every 4 weeks OR 375 mg/m2 IV on Day 1 in combination therapy; repeat every 15 days.

Off-label uses

None.

Contraindications

Hypersensitivity to dacarbazine or any component of the formulation, severe myelosuppression, severe hepatic or renal impairment.

Cautions

Caution is advised in patients with pre-existing bone marrow suppression, compromised liver or kidney function, and in those with a history of thrombocytopenia or bleeding disorders, Avoid pregnancy.

Dose adjustment in renal failure:
• CrCl 46-60 mL/min: 80% of regular dose.
• CrCl 31-45 mL/min: 75% of regular dose.
• CrCl <30 mL/min: 70% of regular dose.

Dose adjustment in hepatic failure: Data not available.

Pharmacokinetic parameters

Absorption Dacarbazine is administered intravenously and is 100% bioavailable.
Distribution Volume of distribution information is not readily available; approximately 30-35% protein bound.
Metabolism Dacarbazine undergoes hepatic metabolism via various pathways.
Elimination Mostly excreted in urine; elimination half-life is approximately 5-10 hours.

Drug interactions

• Concurrent use with strong CYP1A2 inhibitors (e.g., fluvoxamine) may increase the plasma concentrations of dacarbazine, potentially leading to toxicity.
• Concurrent use with live vaccines may result in reduced vaccine efficacy or increased risk of vaccine-related adverse reactions.

Side effects

Common (more than 10%): Nausea, vomiting, myelosuppression (e.g., leukopenia, thrombocytopenia), anorexia.
Less common (1-10%): Flushing, fever, fatigue, alopecia, Photosensitivity, Flu-like syndrome.
Rare but serious (less than 1%): Anaphylaxis, severe neutropenia, pulmonary toxicity, Hepatic necrosis.

Patient educations

Report any new or worsening symptoms, particularly signs of infection (e.g., fever, sore throat) or bleeding, to your healthcare provider promptly.

Dacomitinib

ATC Code: L01EB07 Antineoplastic Agents (Protein Kinase Inhibitors).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Advise women not to breastfeed during treatment and for at least 17 days after last dose.

Dosage forms and trade names available in Iraq

- DACOMITINIB 15mg tablet
  Vizimpro (Pfizer Germany).
- DACOMITINIB 30mg tablet
  Vizimpro (Pfizer Germany).
- DACOMITINIB 45mg tablet
  Vizimpro (Pfizer Germany).

Indications and Dosage

Dacomitinib is typically indicated for the treatment of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 substitution mutations, 45 mg PO qDay, continue until disease progression or unacceptable toxicity occurs.

Off-label uses

None.

Contraindications

Hypersensitivity to dacomitinib or any component of the formulation.

Cautions

Caution is advised in patients with pre-existing interstitial lung disease, hepatic impairment, or renal impairment, pregnant or breastfeeding.

Dose adjustment in renal failure:

• Mild or moderate (CrCl 30-89 mL/min estimated by Cockcroft-Gault equation): No dosage adjustment necessary.

• Severe (CrCl <30 mL/min): Recommended dose not established.

Dose adjustment in hepatic failure: No dosage modification recommended in patients with mild, moderate or severe hepatic impairment (Child-Pugh A, B or C).

Pharmacokinetic parameters

Absorption Peak plasma concentration: 108 ng/mL, Peak plasma time (single 45-mg dose): 6 hr , AUC: 2213 ng·hr/mL ,Time to steady-state: 14 days, Bioavailability: 80%.

Distribution Vd (steady-state): 1889 L, Protein binding: 98%

Metabolism Primarily metabolized in the liver via CYP3A4.

Elimination Half-life (single 45-mg dose): 70 hr, Clearance (single 45-mg dose): 24.9 L/hr, Excretion: Feces 79% (20% unchanged); urine 3% (<1% unchanged).

Drug interactions

• **Concurrent use with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin)** may increase dacomitinib plasma concentrations, increasing the risk of adverse effects.

• **Concurrent use with strong CYP3A4 inducers (e.g., rifampicin, carbamazepine)** may decrease dacomitinib plasma concentrations, reducing its efficacy.

• **Drugs that reduce stomach acidity:** The use of these drugs reduces the levels of dacomitinib by reducing its absorption in the digestive system.

Side effects

• **Common (more than 10%):** Diarrhea, rash, stomatitis, paronychia (nail disorder), decreased appetite, Anemia.

• **Less common (1-10%):** Fatigue, dry skin, pruritus, nausea, vomiting, Dysgeusia.

• **Rare but serious (less than 1%):** Interstitial lung disease, hepatotoxicity, cardiotoxicity.

Danazol

ATC Code: G03XA01 Sex Hormones and Modulators of The Genital System (Antigonadotropins and Similar Agents)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

D

Indications and Dosage

• Endometriosis: Initially, 100mg - 200mg bid, maintenance 400mg bid for 3-9 months (Danazol should be uninterrupted course).

• Fibrocystic breast disease: 100mg-200mg bid for 4-6 months (Danazol should be uninterrupted course).

Dosage forms and trade names available in Iraq

Danazol 100mg caps

Danol (Sanofi Aventis U.K.).

Danazol 200mg caps

Danol (Sanofi Aventis U.K.).

Off-label uses

Treatment of gynecomastia; Menorrhagia; Precocious puberty; Premenstrual syndrome.

Contraindications

Hypersensitivity to danazol; Cardiac impairment; Undiagnosed genital bleeding; Porphyria.

Cautions

Epilepsy; History of thromboembolic disease; Migraine; Diabetes; Polycythemia; Hypertension; Porphyria; Lipoprotein disorder.

Dose adjustment in renal failure: In severe renal failure use of danazol is contraindicated.

Dose adjustment in hepatic failure: In severe hepatic failure use of danazol is contraindicated.

Pharmacokinetic parameters

Absorption High fat food increase absorption.

Distribution Vd=3.4L.

Metabolism Extensively metabolized in the liver to 2-hydroxymethyl danazol and ethisterone.

Elimination Half-life is 3-10 hours after a single dose and 24-26 hours with repeated administration.

Drug interactions

Warfarin: Danazole increases levels of warfarin by decreasing metabolism.

Simvastatin: Danazole Increases the Simvastatin toxicity by decreasing the metabolism.

Side effects

Common (more than 10%) Weight gain; Acne; Changes in menstrual flow; Hot flashes; Sweating; Mood changes; Oily skin or hair

Less common (1-10%) Voice changes/deepening of the voice; Hair loss; Unwanted facial/body hair; Decreased breast size; Vaginal dryness/itching

Rare but serious (less than 1%) Persistent or severe headache; jaundice; Dark urine; Unusual fatigue; Stomach/abdominal pain; Mental/mood changes (such as new or worsening depression)

Patient educations

1- A sensitive test (beta subunit test) should be used to determine early pregnancy is recommended immediately prior to the use of this therapy

2- A non-hormonal method of contraception should be used during therapy. And If the patient becomes pregnant while receiving therapy, administration of the drug should be discontinued and the patient should be apprised of the potential risk to the fetus.

Dapagliflozin

ATC Code: A10BK01 Drugs Used in Diabetes (Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

• To treat Diabetes mellitus (type 2), reduce risk of sustained eGFR decline , end stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease who are at risk of disease progression: Initially, 5mg once daily in the morning, may increase to 10mg once daily

Dosage forms and trade names available in Iraq

- Dapagliflozin 5mg tablet
  PIOXIGA (PIONEER IRAQ).
- Dapagliflozin 10mg tablet
  Dapaxosin (SDI IRAQ), **PIOXIGA** (PIONEER IRAQ).

Off-label uses

None.

Contraindications

Hypersensitivity to dapagliflozin; patient on Dialysis.

Cautions

Hypotension; Elderly; Hypovolemia; Dehydration; History of genital mycotic infection; Active bladder cancer; Diabetic ketoacidosis; Type 1 diabetes mellitus.

Dose adjustment in renal failure: CrCl less than 60ml per minute, avoid use.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=78%, food has no effect on absorption.

Distribution Vd=118L, 91%protein bound.

Metabolism Dapagliflozin is primarily glucuronidated to become the inactive 3-O-glucuronide metabolite.

Elimination Renal elimination is 75% and 21% in the feces with half-life of 12.9 hours.

Drug interactions

Glimepiride: Glimepiride and dapagliflozin both increases effects of the other by pharmacodynamic synergism,

Side effects

Common (more than 10%): Back pain; Dizziness; Dyslipidemia; Increase hematocrit.

Less common (1-10%): Constipation; Discomfort with urination; Dyslipidemia; Extremity pain; Female genital mycotic infections; Increased urination; Influenza; Male genital mycotic infections; Nasopharyngitis; Nausea; Urinary tract infection.

Rare but serious (less than 1%): Acute kidney injury and renal impairment; Hypoglycemia; Ketoacidosis; Rash; Urosepsis and pyelonephritis.

Patient educations

Diabetes mellitus requires lifelong control, diet and exercise are principal parts of treatment, do not skip or delay meals; Test blood sugar regularly; Monitor daily calorie intake; Genital itching or discharge may indicate yeast infection; Drink plenty of fluids; Dapagliflozin may increase risk of bladder cancer.

Dapoxetine

ATC Code: G04BX14 Urologicals (Other Urologicals)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Dapoxetine is not indicated for use by women.

D

Indications and Dosage

• Treatment of premature ejaculation: 30mg taken as needed approximately 1 to 3 hrs. prior to sexual activity, (max 60mg). indicated in age 18-64 years. not indicated for continuous regular daily use.

Off-label uses

None.

Contraindications

Hypersensitivity to dapoxetine; Bipolar disorder; History of syncope or mania; Severe depression; Significant cardiac disease and mild to moderate hepatic impairments.

Cautions

Angle closure glaucoma or raised intraocular pressure; Bleeding disorders; Epilepsy.

Dose adjustment in renal failure: CrCl less than 30ml/min: avoid use dapoxetine.

Dose adjustment in hepatic failure: In moderate to severe hepatic failure use of dapoxetine is contraindicated.

Dosage forms and trade names available in Iraq

- Dapoxetine 30mg tablet
  Priligy (Menarini Germany).
- Dapoxetine 60mg tablet
  Long-joy (SDI IRAQ).

Pharmacokinetic parameters

Absorption F=42%, food has no effect on absorption.

Distribution Vd=162L, 99%protein bound.

Metabolism Extensively metabolized to multiple metabolites primarily through N-oxidation, N-demethylation, naphthyl hydroxylation, glucuronidation and sulfation.

Elimination Renal elimination as conjugates with half-life of 19 hours.

Drug interactions

Clarithromycin: Dapoxetine concomitant treatment with clarithromycin may significantly increase exposure of dapoxetine; The maximum dose of dapoxetine should be 30 mg if dapoxetine is combined with clarithromycin. Also with Ketoconazole, Lithium, Alcohol, Warfarin.

Side effects

Common (more than 10%) Headache, Nausea, but drinking a full glass of water at the same time can reduce these effects

Less common (1-10%) Abdominal discomfort, Asthenia, Depression, Hypotension, Hot flush, Mydriasis, Pruritis, Sinus bradycardia, Vertigo.

Rare but serious (less than 1%) Defecation urgency, Dizziness, Sudden onset of sleep.

Patient educations

Due to postural hypotension and syncope patients should be advised to maintain hydration and to sit or lie down until symptoms such as nausea, dizziness, and sweating subside.

Daptomycin

ATC Code: J01XX09 Antibacterials for Systemic Use (Other Antibacterials)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: : It is not yet known. caution is advised.

Dosage forms and trade names available in Iraq

Daptomycin 500mg vial
Xeracine (MS Pharma Jordan).

Indications and Dosage

Daptomycin is indicated for the treatment of complicated skin and skin structure infections, right-sided endocarditis due to Staphylococcus aureus and bacteremia due to S. aureus. The usual dose is 4-6 mg/kg IV once daily.

Off-label uses

Treatment of prosthetic joint infection, osteomyelitis, and urinary tract infection.

Contraindications

Hypersensitivity to daptomycin.

Cautions

In patients with pre-existing muscle disorders and in those receiving medications known to cause neuromuscular toxicity.

Dose adjustment in renal failure: Dose adjustment is required in patients with a creatinine clearance of <30 mL/min.

Dose adjustment in hepatic failure: Not required

Pharmacokinetic parameters

Absorption Not applicable for IV medications.
Distribution Vd= 0.1 L/kg, ~92% protein bound.
Metabolism Not metabolized significantly.
Elimination Primarily renal excretion with half-life of 8-9 hours.

Drug interaction

Concurrent use of statins: Increased risk of myopathy and rhabdomyolysis.
Concurrent use of warfarin: Anticoagulant effect may be enhanced.

Side effects

Common (more than 10%): Headache, dizziness, rash.
Less common (1-10%): Gastrointestinal symptoms, such as nausea and vomiting.
Rare but serious (less than 1%): Eosinophilic pneumonia, rhabdomyolysis, anaphylaxis, and Clostridium difficile-associated diarrhea.

Patient education

• This medication is used to treat serious bacterial infections; ensure you finish the entire course of treatment.
• Report any signs of muscle pain or weakness, unusual fatigue, or dark urine to your healthcare provider immediately.
• Monitor for signs of an allergic reaction, such as rash, itching, swelling, severe dizziness, or trouble breathing.

Daratumumab

ATC Code: L01FC01 Antineoplastic and Immunomodulating Agents (CD38 (Clusters of Differentiation 38) Inhibitors)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 **C** D X N

Lactation: Unknown whether it's excreted into human milk.

D

Indications and Dosage

Used for the treatment of multiple myeloma. Dosage is 16mg/kg administered as an intravenous infusion. The frequency varies depending on the treatment cycle and combination therapy.

Off-label uses

None.

Contraindications

Hypersensitivity to daratumumab or any of its excipients.

Cautions

Risk of infusion reactions; monitor patient closely during infusions. Increased risk of infections.

Dose adjustment in renal failure: Not required

Dose adjustment in hepatic failure: Not required

Dosage forms and trade names available in Iraq

Daratumumab 400mg/20ml Vial

Darzalex (Janssen-Cilag Belgium).

Daratumumab 100mg/5ml Vial

Darzalex (Janssen-Cilag Belgium).

Pharmacokinetic parameters

Being a monoclonal antibody, daratumumab has complex pharmacokinetics. It's not readily measured by traditional parameters.

Drug interaction

• **Interference with serological testing:** Daratumumab binds to CD38 on red blood cells and may cause a positive Indirect Antiglobulin Test (Coombs test).

• Not known to interact with CYP450 **substrates.**

Side effects

Common (more than 10%): Infusion reactions, fatigue, nausea, back pain, fever, cough, and upper respiratory tract infection.

Less common (1-10%): Pneumonia, neutropenia, thrombocytopenia.

Rare but serious (less than 1%): Severe infusion reactions, severe infections.

Patient education

1. Inform your doctor immediately if you have signs of an allergic reaction during or after the infusion.
2. Report signs of infection such as fever, chills, persistent cough.
3. Expect regular blood tests to monitor your blood cells and kidney function during treatment.

Who is SAJA ?

SAJA is a joint venture between the premier Saudi healthcare company Tamer Industries and two of the leading Japanese Pharmaceutical companies which are Daiichi Sankyo Company Ltd and Astellas Pharma Inc. SAJA was established in 1996 and introduced the first product to Saudi market in 2000. Since then, SAJA is expanding geographically and diversifying its unique portfolio

Olmetec Plus

Olmestran Medoxomil Hydrochlorothiazide ,
OLMETEC PLUS is indicated for the treatment of hypertension. It is also indicated for use in patients whose blood pressure is not adequately controlled by Olmesartan Medoxomil or hydrochlorothiazide alone.

Sevikar HCT

Olmesartan Medoxomil / Amlodipine / Hydrochlorothiazide ,
SEVIKAR HCT is used to treat high blood pressure in subjects who are already taking either (a) a fixed-dose combination of Olmesartan medoxomil and Amlodipine (b) a fixed-dose combination of Olmesartan medoxomil and Hydrochlorothiazide plus the Amlodipine as a single tablet or (c) a fixed-dose combination of Olmesartan medoxomil and Amlodipine plus Hydrochlorothiazide as a single tablet.

Group Al-Thuraya
Reach. Excellence. Integrity

Darbepoetin Alfa

ATC Code: B03XA02 Antianemic Preparations (Other Antianemic Preparations)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: No data available.

D

Indications and Dosage

•Anemia due to chemotherapy: 2.25mcg/kg weekly, dose adjusted based on changes in hemoglobin levels.
• Anemia of chronic kidney disease: Patients not on dialysis, 0.45mcg/kg once every 4 weeks, patients on dialysis 0.75mcg/kg once every 2 weeks, dose adjusted based on changes in hemoglobin levels.
•Anemia due to Myelodysplastic syndrome: Initial, 240 mcg weekly for 16 weeks. The dose was adjusted to maintain the major or minor erythroid response (based on changes in Hb levels).

Off-label uses

Treatment of symptomatic anemia in myelodysplastic syndrome.

Contraindications

Hypersensitivity to darbepoetin alfa; Pure red cell aplasia that begins after treatment with darbepoetin alfa or other erythropoietin protein drugs; Uncontrolled hypertension.

Dosage forms and trade names available in Iraq

- Darbepoetin alfa 20 mcg pfs
  Aranesp (Amgen USA).
- Darbepoetin alfa 40 mcg pfs
  Aranesp (Amgen USA).
- Darbepoetin alfa300µg pfs
  Aranesp (Amgen USA).

Cautions

Thalassemia; Porphyria; Seizures; Hemolytic anemia; Sickle cell anemia; Lack or loss of response to drug.
Dose adjustment in renal failure: Reduce or interrupt dose when Hb exceeds 11g/dl (on dialysis) or 10g/dl (not on dialysis) in adult.
Dose adjustment in hepatic failure: no data available.

Pharmacokinetic parameters

Absorption F=37%, food has no effect on absorption.
Distribution Vd=52ml/kg.
Metabolism Hepatic metabolism.
Elimination Minimal renal elimination with a half-life of 46 hr dialysis); 70 hr (not on dialysis). Adult (cancer): 74 hr (range, 24 to 144 hr).

Drug interactions

Nandrolone: Nandrolone may enhance the stimulatory effect of erythropoiesis-stimulating agents.

Side effects

Common (more than 10%) Abdominal pain; Arthralgia; Diarrhea; Diarrhea; Fatigue; Fever; Headache; Headache; Hyper/Hypotension; Infectious disease; Nausea; Peripheral edema; Spasm; Upper respiratory infection.
Less common (1-10%) Cardiac arrest; Cardiac dysrhythmia; Cerebrovascular accident; Congestive heart failure; Cough; Deep vein thrombosis; Dizziness; Dyspnea; Edema; Limb pain; Myalgia; Myocardial infarction; Pneumonia; Pulmonary embolism; Red cell aplasia; Vomiting.
Rare (less than 1%) Hypertensive encephalopathy; Hypertensive encephalopathy; Seizure; Transient ischemic attack.

Decitabine

ATC Code: L01BC08 Antineoplastic Agents (Pyrimidine Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Myelodysplastic syndrome: By i.v. injection, 15mg/m2 over 3 hr, repeat tid for 3 days, repeat cycle every 6 weeks for a minimum of 4 cycles. Alternatively, 20mg/m2 over 1 hr once daily for 5 days, repeat cycle every 4 weeks.

Dosage forms and trade names available in Iraq

Decitabine 50mg vial
DACOGEN (Janssen-Cilag Belgium).

Off-label uses

None.

Contraindications

Hypersensitivity to decitabine.

Cautions

Myelosuppression; History of severe CHF or clinically unstable cardiac disease.
Dose adjustment in renal failure: Use with caution.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=4.59±1.42L/kg, (< 1%) plasma protein binding.
Metabolism Mostly metabolized by the liver.
Elimination Renal elimination is 1% with half-life of 0.5 hours.

Drug interactions

Chloramphenicol (ophthalmic): Chloramphenicol may enhance the adverse effect of myelosuppressive agents.
Acetylsalicylic acid: The risk or severity of bleeding can be increased when Acetylsalicylic acid is combined with Decitabine.
Abatacept: The risk or severity of adverse effects can be increased when Decitabine is combined with Abatacept.

Side effects

Common (more than 10%) Abdominal pain; Anemia; Anorexia; Anxiety; Constipation; Cough; Crackles in lung; Diarrhea; Dizziness; Dyspepsia; Ecchymosis; Edema; Erythema; Febrile neutropenia; Headache; Hyperbilirubinemia; Hyperglycemia; Hyperkalemia; Hypoalbuminemia; Hypoesthesia; Hypokalemia; Hypomagnesemia; Hyponatremia; Insomnia; Lethargy; Leukopenia; Limb pain; Lymphadenopathy; Nausea; Neutropenia; Pallor; Peripheral edema; Petechia; Pharyngitis; Pneumonia; Pruritus; Pyrexia; Rash; Rigors; Skin lesion; Stomatitis; Tenderness; Thrombocytopenia; Vomiting.
Less common (1-10%) Abdominal distension; Abrasion; Alopecia; Ascites; Aspartate aminotransferase increase; Bacteremia; Blurred vision; Chest discomfort; Dehydration; Dysphagia; Dysuria; Hematoma; Hemorrhoids; Hypotension; Hypoxia; Lip ulcerationPostnasal drip; Protein total decrease; Pulmonary edema; Rales; Sinusitis; Staphylococcal infection; Tongue ulceration; Transfusion reaction; Upper abdominal pain; Urinary frequency; Urinary tract infection; Urticaria.
Rare but serious (less than 1%) Interstitial lung disease; Sweet's syndrome (acute febrile neutrophilic dermatosis).

Patient educations

Perform complete blood and platelet count regularly and prior to each treatment cycle.

Deferasirox

ATC Code: V03AC03 All Other Therapeutic Products (Iron Chelating Agents)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 **C** D X N

Lactation: No data available.

Indications and Dosage

• **Iron overload due to transfusions:** Initially, 20mg/kg once daily, maintenance 5mg-10mg/kg/day every 3–6 months based on serum ferritin levels, (max 40mg/kg once daily).

• **Thalassemia syndromes:** Initially, 10mg/kg once daily, may increase to 20mg/kg once daily after 4 weeks.

Off-label uses

None.

Contraindications

Hypersensitivity to deferasirox; Platelet counts less than 50000 cells/mm3; Poor performance status; High risk myelodysplastic syndromes; advanced malignancies; CrCl <40ml/min or serum creatinine >2times the age-appropriate upper limit of normal

Dosage forms and trade names available in Iraq

Deferasirox 125 mg Dispersible tablet
PIOSIROX (Pioneer Iraq).

Deferasirox 500 mg Dispersible tablet
PIOSIROX (Pioneer Iraq).

Cautions

Elderly.

Dose adjustment in renal failure: CrCl 40-60ml per minute, reduce starting dose by 50%; For increase in serum creatinine greater than 33% on 2 consecutive measures, reduce daily dose by 10mg/kg.

Dose adjustment in hepatic failure: For severe or persistent elevations in hepatic function tests, consider dose reduction or discontinuation; Moderate hepatic failure, reduce initial dose by 50%.

Pharmacokinetic parameters

Absorption F=70%.

Distribution Vd=14.37±2.69L, 99%protein bound.

Metabolism Undergoes hepatic metabolism via glucuronidation by uridine diphosphate glucuronosyltransferase (UGT) 1A1 and to a lesser extent by UGT1A3.

Elimination Renal elimination is 8% with half-life of 8-16 hours.

Drug interactions

Bisphosphonate derivatives: Bisphosphonate may enhance the adverse effect of deferasirox, the risk for gastrointestinal ulceration and irritation or gastrointestinal bleeding may be increased.

Side effects

Common (more than 10%): Abdominal pain; Cough; Diarrhea; Headache; Nausea; Proteinuria; Pyrexia; Rash; Vomiting.

Less common (1-10%): Acute tonsillitis; Arthralgia; Back pain; Bronchitis; Ear infection; Respiratory tract infection; Rhinitis; Urticaria.

Rare but serious (less than 1%): Agranulocytosis; Angioedema; Cytopenias; Leukocytoclastic vasculitis; Thrombocytopenia.

Patient educations

Take on empty stomach 30 minutes before food; Do not take aluminum-containing antacids concurrently; Report severe skin rash, changes in vision or hearing, or yellowing of skin or eyes.

Deferiprone

ATC Code: V03AC02 All Other Therapeutic Products (Iron Chelating Agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

• Transfusional iron overload caused by thalassemia syndromes: 75mg/kg/day divide the total daily dosage bid or tid based on the tablet round dose to the nearest 500mg, (max 99mg/kg/day).

Off-label uses

None.

Contraindications

Hypersensitivity to deferiprone; Neutropenia; History of agranulocytosis.

Cautions

Immunocompromised patients.
Dose adjustment in renal failure: CrCl less than 15ml per minute use deferiprone with caution.
Dose adjustment in hepatic failure: In sever hepatic failure use with caution.

Dosage forms and trade names available in Iraq

Deferiprone 500mg tab
Ferriprox (Apotex Canada).

Pharmacokinetic parameters

Absorption F=44%.
Distribution Vd= 1-1.6L/kg, 10%protein bound.
Metabolism Metabolized by uridine diphosphate glucuronosyl transferases (UGT)1A6 to the inactive metabolite, 3-O-glucuronide.
Elimination Renal elimination is 75-90% with half-life of 1.9 hours.

Drug interactions

Capecitabine: Deferiprone and capecitabine both either increases toxicity of the other by pharmacodynamic synergism.
Hydroxyurea: deferiprone and hydroxyurea both increases toxicity of the other by pharmacodynamic synergism, avoid use of deferiprone with other drugs known to be associated with neutropenia or agranulocytosis, if an alternative is not possible, monitor absolute neutrophil count more frequently.

Side effects

Common (more than 10%) Nausea.
Less common (1-10%) Abdominal pain; Agranulocytosis; Arthralgia; Arthropathy; Back pain; Decrease appetite; Diarrhea; Dyspepsia; Headache; Neutropenia; Pain in extremity; Vomiting.
Rare but serious (less than 1%) None.

Patient educations

This drug may cause reddish brown discoloration of urine.

Deferoxamine

ATC Code: V03AC01 All Other Therapeutic Products (Iron Chelating Agents).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not yet known, caution is advised.

D

Indications and Dosage

Used for acute iron intoxication and chronic iron overload due to transfusion-dependent anemias, dosage is highly individualized.

Off-label uses

Aluminum overload in chronic renal failure.

Contraindications

Anuria; severe renal disease or dysfunction.

Cautions

Potential for ocular and auditory toxicity with prolonged use; neurologic disturbances.
Dose adjustment in renal failure: Use with caution, monitor renal function.
Dose adjustment in hepatic failure: No data available.

Dosage forms and trade names available in Iraq

Deferoxamine Mesylate 500mg vial
Desfonak (Ronak Pharmaceutical Iran).

Pharmacokinetic parameters

Absorption Variable absorption following IM administration.
Distribution Vd= not defined, not significantly protein bound.
Metabolism Minimal metabolism.
Elimination Primarily kidney excretion, half-life of about 20 minutes (IV) to 6 hours (IM).

Drug interaction

Vitamin C: Excessive vitamin C can enhance deferoxamine toxicity, especially in patients with renal impairment.
Prochlorperazine: Concurrent use can cause temporary impairment of consciousness.

Side effects

Common (more than 10%): Injection site reactions; allergic reactions.
Less common (1-10%): GI upset; skin rashes.
Rare but serious (less than 1%): Ocular toxicity; auditory toxicity; neurologic disturbances.

Patient education

1. This medication is used to remove excess iron from your body. Follow your healthcare provider‘s instructions carefully.
2. Report any changes in vision or hearing to your healthcare provider immediately.
3. Do not take vitamin C supplements while on this medication without your healthcare provider‘s advice.

Deflazacort

ATC Code: H02AB13 Corticosteroids for Systemic Use (Glucocorticoids)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding in doses up to 50mg/day.

Indications and Dosage

• Duchenne muscular dystrophy (DMD): 0.9mg/kg/day in patients 5 years of age and older.
• Allergic and inflammatory disorders: Initially, up to 120 mg daily, maintenance 3mg-18mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to deflazacort; Systemic infection; Concurrent administration of live virus vaccines.

Cautions

Patient with infection; History of TB; Cardiac disease or CHF; Hypertension; Thromboembolic disorders; Gastritis; Diverticulitis; Ulcerative colitis; Peptic ulcer; Pyogenic infections; Diabetes mellitus; Osteoporosis; Epilepsy; Emotional instability; History of corticosteroid induced myopathy; Hypothyroidism; Ocular herpes simplex.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Deflazacort 30mg tablet
  Defal (Faes Farma Spain).
- Deflazacort 6mg tablet
  Defal (Faes Farma Spain).

Pharmacokinetic parameters

Absorption Well absorbed from the GI tract.
Distribution Vd=204±84L, 40%protein bound.
Metabolism Converted to the active metabolite by plasma esterase.
Elimination Renal elimination is 70% with half-life of 1.1-1.9 hours.

Drug interactions

Phenobarbital: Phenobarbital will decrease the level or effect of deflazacort by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Cough; Cushingoid appearance; Increased appetite; Pollakiuria; Upper respiratory tract infection; Weight increased.
Less common (1-10%) Abdominal discomfort; Acne; Affect lability; Aggression; Alopecia; Back injury; Back pain; Central obesity; Dyspepsia; Dysuria; Emotional disorder; Erythema; Fibula fracture; Greenstick fracture; Heart rate irregular; Heat exhaustion; Hirsutism; Hot flush; hypertonic bladder; Hypoventilation; Impetigo; Influenza; Irritability; Muscle spasms; Myalgia; Nasopharyngitis; Neck mass; Neck pain; Otitis externa; Pain in extremity; Pharyngitis; Psychomotor hyperactivity; Rhinorrhea; Sleep disorder; Testicular pain; Thirst; Tooth abscess; Urinary tract infection; Vascular disorders; Viral infection.
Rare but serious (less than 1%) None.

Patient educations

A Patient education is not currently available for this monograph.

Denosumab

ATC Code: M05BX04 Drugs for Treatment of Bone Diseases (Other Drugs Affecting Bone Structure And Mineralization).

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C **D** X N

Lactation: There is no information.

Indications and Dosage

Osteoporosis: 60mg subcutaneously every 6 months.

Off-label uses

None.

Contraindications

Hypocalcemia; known clinical hypersensitivity to denosumab or to any of the product components.

Cautions

Risk of hypocalcemia; risk of severe infection including skin infections; risk of dermatologic adverse events; risk of osteonecrosis of the jaw; potential risk of atypical femoral fracture.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not studied.

Dosage forms and trade names available in Iraq

Denosumab 60mg/1ml prefilled syringe

Prolia (Amgen USA).

Pharmacokinetic parameters

Absorption Bioavailability is 62% following subcutaneous administration.

Distribution Vd= not well defined; the medication is expected to bind to bone matrix.

Metabolism Metabolized through reticuloendothelial system.

Elimination Mostly eliminated in the urine, half-life is about 26 days.

Drug interaction

No known significant drug interactions.

Side effects

Common (more than 10%): Back pain; pain in extremity; musculoskeletal pain; hypercholesterolemia; cystitis.

Less common (1-10%): Hypocalcemia; skin infections; eczema; increased sweating.

Rare but serious (less than 1%): Osteonecrosis of the jaw; atypical femoral fracture; severe infection.

Patient education

• Inform your healthcare provider about any signs of infection, such as fever; chills; skin sores.

• This medication can cause low calcium levels. Take calcium and vitamin D as directed by your healthcare provider.

• Report any new or unusual thigh, hip, or groin pain to your healthcare provider.

Dequalinium

ATC Code: D08AH01 Antiseptics and Disinfectants (Quaternary Ammonium Compounds).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: It is not yet known.

Indications and Dosage

Vaginal infections - 1 tablet to be inserted into the vagina at bedtime for 10 consecutive days.

Off-label uses

None.

Contraindications

Hypersensitivity to dequalinium chloride or any component of the formulation.

Cautions

In patients with vaginal abrasions or lesions (increased systemic absorption may occur).

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not studied, but due to the minimal systemic absorption, no dose adjustment would likely be required.

Dosage forms and trade names available in Iraq

Dequalinium Chloride 10 mg Vaginal tablet

Fluomizin (Medinova Switzerland).

Pharmacokinetic parameters

Absorption Minimal systemic absorption when used vaginally.

Distribution, Metabolism, Elimination Due to its local action, these pharmacokinetic parameters are not significant.

Drug interaction

No known significant interactions due to its local action and minimal systemic absorption.

Side effects

Common (more than 10%): Local irritation.

Less common (1-10%): Skin rash.

Rare but serious (less than 1%): Severe allergic reactions.

Patient education

- Report any signs of severe local irritation or allergic reaction.
- Do not ingest orally; this product is for vaginal use only.

Desflurane

ATC Code: D03AX03 Topical preparation for wounds and ulcers

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Desflurane is not recommended during breastfeeding

Dosage forms and trade names available in Iraq

Desflurane Solution for inhalation
Suprane (Baxter USA).

Indications and Dosage

It is used for induction and maintenance of general anesthesia, Dosage and rate of administration should be individualized and titrated to the desired effect, according to patient age, clinical status, and concomitant use of other drugs.

Off-label uses

None.

Contraindications

In individuals with known sensitivity to desflurane or to other halogenated agents; in patients with known or suspected genetic susceptibility to malignant hyperthermia.

Cautions

Hepatic and renal dysfunction; malignant hyperthermia; cardiovascular instability.

Dose adjustment in renal failure: No specific guidelines available.

Dose adjustment in hepatic failure: No specific guidelines available.

Pharmacokinetic parameters

Absorption It's a volatile substance used by inhalation so it's absorbed quickly via the lungs.
Distribution Vd= not applicable, it stays mainly in the bloodstream until it's exhaled, % protein bound - minimal.
Metabolism Minimal (< 0.02%), primarily in the lungs.
Elimination Nearly all desflurane is eliminated unchanged in the breath.

Drug interaction

Benzodiazepines and opioids: May enhance the CNS depressant effect of desflurane.
Beta-Blockers: Anesthetics (Inhalation) may enhance the hypotensive effect of Beta-Blockers.

Side effects

Common (more than 10%): Nausea; vomiting; increase in heart rate and blood pressure.
Less common (1-10%): Cough; breath holding; apnea.
Rare but serious (less than 1%): Malignant hyperthermia; arrhythmia.

Patient educations

1. It's normal to feel drowsy or tired after anesthesia; do not drive or operate heavy machinery until fully recovered.
2. Hydrate well before and after the procedure as desflurane can cause dehydration.
3. Report any serious side effects like difficulty breathing or irregular heartbeat to your doctor immediately.

Desloratadine

ATC Code: R06AX27 Antihistamines for Systemic Use (Other Antihistamines for Systemic Use)

Pregnancy category:

FDA A B **C** D X N

TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Allergic rhinitis, urticaria: 5mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to desloratadine.

Cautions

None.

Dose adjustment in renal failure: Dosage is decreased to 5mg every other day.

Dose adjustment in hepatic failure: Dosage is decreased to 5mg every other day.

Pharmacokinetic parameters

Absorption F=50%, food has no effect on absorption.

Distribution Vd=49L/kg, 82-87%protein bound.

Metabolism Desloratadine is metabolized to the active metabolite 3-hydroxydesloratadine

Elimination Renal elimination is 87% with half-life of 27 hours.

Dosage forms and trade names available in Iraq

Desloratadine 0.5mg/ml Syrup

DESLORASAM (SDI Iraq), **Delora** (Al-Mansour Iraq), **DESLORADAIN** (Wadi al-Rafedain Iraq), **Larius** (Pioneer Iraq).

Desloratadine 5mg tablet

DESLORASAM (SDI Iraq), **Desloratadine KP** (Alkindi Iraq).

Drug interactions

Metoclopramide: Desloratadine and metoclopramide both increases effects of the other, avoid use of metoclopramide or use depending on importance of drug to patient.

Side effects

Common (more than 10%) Cough; Diarrhea; Fever; Headache; Irritability; Upper respiratory infection.

Less common (1-10%) Bronchitis; Dizziness; Dysmenorrhea; Epistaxis; Erythema; Fatigue; Somnolence; Urinary tract infection.

Rare but serious (less than 1%) None.

Patient educations

Drink plenty of water (may cause dry mouth); Avoid tasks that require alertness, motor skills until response to drug is established (may cause drowsiness); Avoid alcohol.

Desmopressin

ATC Code: H01BA02 Pituitary and Hypothalamic Hormones and Analogues (Vasopressin and Analogues)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

D

Indications and Dosage

• Primary nocturnal enuresis: 0.2mg–0.6mg once before bedtime.

• Central cranial diabetes insipidus: 0.05mg bid. By i.v. or subcutaneous injection: 1mcg–2mcg bid. Intranasal, 10mcg–40mcg in 1–3 doses/day.

• Hemophilia A, Von Willebrands disease (Type 1): By slow i.v. infusion over 15-30 minutes, 0.3mcg/kg.

Dosage forms and trade names available in Iraq

- Desmopressin acetate 0.1 mg/ml (50 dose of 10µg) nasal spray
  Minirin (Ferring Germany).
- Desmopressin as acetate sublingual tab 120mcg
  MINIRIN MELT (Ferring GERMANY)

Off-label uses

Uremic bleeding occurring with acute or chronic renal failure; Prevent surgical bleeding in patients with uremia.

Contraindications

Hypersensitivity to desmopressin; Hyponatremia.

Cautions

Predisposition to thrombus formation; Conditions with fluid and electrolyte imbalance; Coronary artery disease; Cardiovascular disease; Elderly patients; Cystic fibrosis; Heart failure; Renal impairment; Polydipsia; Hemophilia.

Dose adjustment in renal failure: CrCl less than 50ml per minute, use of desmopressin not recommended.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=1-20%.

Distribution Vd=0.2-0.32L/kg,17.3±1.5% protein bound.

Metabolism Not metabolized.

Elimination Renal elimination is 65% with half-life of 3.3-3.5 hours.

Drug interactions

Mometasone inhaled: Mometasone inhaled increases toxicity of desmopressin, Corticosteroids may enhance the hyponatremic effect of intranasal desmopressin.

Side effects

Common (more than 10%) Dry mouth.

Less common (1-10%) Abdominal pain; Asthenia; Chills; Conjunctivitis; Dizziness; Epistaxis; Eye edema; Gastrointestinal disorder; Headache; Hyponatremia; Lachrymation disorder; Nausea; Nostril pain; Rhinitis.

Rare but serious (less than 1%) Abnormal blood pressure; Atrial fibrillation; Dizziness; Flushing; Hyponatremia; Hyposmolality; Increased blood pressure; Increased heart rate; Nasal congestion; Nasal discomfort; Seizure; Thromboembolic disorder; Water intoxication syndrome.

Patient educations

Avoid overhydration; Follow guidelines for proper intranasal administration.

Desogestrel

ATC Code: G03AC09 Sex Hormones And Modulators Of The Genital System (Progestogens)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Contraception: 75mcg once daily from day 1 of the woman‘s natural cycle.

Off-label uses

None.

Contraindications

Hypersensitivity to desogestrel; Known or suspected sex steroid sensitive malignancies; Undiagnosed vaginal bleeding; Active venous thromboembolic disorder; Acute porphyria.

Dosage forms and trade names available in Iraq

Desogestrel 0.075 mg tablet

Cerazette (Organon NETHERLAND).

Cautions

Women with breast cancer; Liver cancer; Functional ovarian cyst; Hypertension; History of thromboembolic disorders; Previous ectopic pregnancy; Diabetes mellitus; Severe gastrointestinal disturbances; SLE with positive antiphospholipid antibodies; Depression; Migraine; History of chloasma gravidarum; Women undergoing prolonged immobilization due to surgery or illness.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In severe hepatic failure, use of desogestrel is contraindicated.

Pharmacokinetic parameters

Absorption F=60-80%.

Distribution Vd=1.5 L/kg, 96-98% protein bound.

Metabolism Desogestrel is rapidly metabolized to 3-keto-desogestgrel.

Elimination Renal elimination is 85% with half-life of 30 hours.

Drug interactions

Liraglutide: Desogestrel decreases effects of liraglutide by pharmacodynamic antagonism, oral contraceptives may decrease hypoglycemic effects of antidiabetics by impairing glucose tolerance, monitor for glycemic control in diabetic patients.

Metformin: Desogestrel decreases effects of metformin by pharmacodynamic antagonism.

Side effects

Abdominal pains; Appetite changes; Breast discharge; Breast enlargement; Cerebral hemorrhage; Chloasma; Contact lens intolerance; Depressed mood; Diarrhea; Edema; Emotional lability; Gallbladder disease; Headache; Hepatic adenomas; Hypertension; Menstrual cramps; Migraine; Mood altered; Nausea; Optic neuritis; Rash; Vaginal candidiasis; Vaginal discharge; Weight increased.

Patient educations

Teach patient to use sunscreen or to avoid sunlight; photosensitivity can occur; Teach patient to take at same time each day to ensure equal product level; to take another tablet as soon as possible if one is missed; Teach patient that after desogestrel is discontinued, pregnancy may not occur for several months; Instruct patient to report gastrointestinal symptoms that occur after 4 months.

Dexamethasone

ATC Code: H02AB02 Corticosteroids for Systemic Use (Glucocorticoids)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding for occasional use and in low doses.

Indications and Dosage

- Anti-inflammatory: 0.5mg-10mg daily for adults.
- Cerebral Oedema associated with malignancy: 8mg-16mg daily orally or i.v. to temporarily reduce oedema.
- Ocular inflammatory conditions: Apply every 30-60 minutes until control then reduce to 4-6 times per day.

Off-label uses

COVID-19; Antiemetic; Treatment of croup; Treatment of acute mountain sickness; High altitude cerebral edema.

Contraindications

Hypersensitivity to dexamethasone; Systemic fungal infections; Cerebral malaria.

Cautions

Thyroid disease; Cardiovascular disease; Diabetes; Glaucoma; Cataracts; Myasthenia gravis, patients at risk for seizures; Osteoporosis; Peptic ulcer; Post-myocardial infarction; Elderly.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Dexamethasone 0.5 mg/5ml Syrup
Dexon (SDI Iraq), **Dexaphar** (Dubai Iraq), **DEXACURE** (Pioneer Iraq), **AWZARON** (AlKindy Iraq), **Dexamethasone** (Wadi Al-Rafidain Iraq), **Dexacure** (PIONEER IRAQ).

Dexamethasone 0.5mg tab
DEXON (SDI Iraq), **Dexaphar** (Dubai Iraq), **KINDIXONE** (AL-Kindi Iraq), **Dexamethasone** (Wadi Al-Rafidain Iraq).

Dexamethasone 1mg/ml (0.1%) eye drop
Dexacure (PIONEER IRAQ).

Dexamethasone phosphate 8mg/2ml amp
Dexacure (PIONEER IRAQ).

Pharmacokinetic parameters

Absorption F=85%.
Distribution Vd=2L/kg, greater than 90% bound to plasma protiens.
Metabolism Hepatic metabolism.
Elimination Primarily renal elimination with a half-life of 2-2.5 hr.

Drug interactions

Antacids: Antacids may decrease the absorption of dexamethasone consider separating doses by 2 or more hours.

Side effects

Common (more than 10%) Gastrointestinal upset.
Less common (1-10%) Hypertension; Impaired skin healing; Osteoporosis; Depression; Euphoria; Hyperglycemia.
Rare but serious (less than 1%) Primary adrenocortical insufficiency; Cushing syndrome; Decreased body growth; Increased risk of infection.

Patient educations

Tell the patient to take oral drug with or after meals; Inform patient that drug makes him more susceptible to infection, advise him to avoid crowds and exposure to illness; Caution patient not to stop taking drug abruptly to avoid adrenal insufficiency.

Note

Accelerate fetal lung maturation when dexamethasone administered to mother i.m. within 48 hours proceeding premature delivery. Dexamethasone suppression test is used for diagnosis of Cushing's syndrome.

Dexmedetomidine

ATC Code: N05CM18 Psycholeptics (Other Hypnotics and Sedatives)

Pregnancy category:
FDA A B **C** D X N
TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

Dexmedetomidine Hydrochloride 200µg/2ml vial **Dexmedetomidine EVER Pharma** (Ever Pharma Germany).

Indications and Dosage

• Sedation: Loading dose of 1mcg/kg over 10 min followed by maintenance infusion of 0.2mcg–0.7mcg/kg/hr.
• Agitation associated with schizophrenia or bipolar I or II disorder : subligual/buccal (120-180mcg according to severity) if agitation persists up to 2 additional doses each half the initial starting dose and they may be administered at least 2 hours a part.

Off-label uses

Treatment of shivering; Awake craniotomy.

Contraindications

Hypersensitivity to dexmedetomidine.

Cautions

Heart block; Bradycardia; Hypovolemia; Diabetes; Hypotension; Chronic hypertension; Severe ventricular dysfunction; Elderly; Use of vasodilators or drugs decreasing heart rate.

Dose adjustment in renal failure: no specific guidelines but should be used with caution in the patients due to the risk of hemodynamic instability.

Dose adjustment in hepatic failure: they may have reduced metabolism and clearance of the drug, The manufacturer recommends a dose reduction in patients with hepatic impairment, but does not specify an exact adjusted dose. Use with caution.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=118 L, 94%protein bound.
Metabolism Mostly metabolized by the liver.
Elimination Renal elimination is 95% with half-life of 2 hours.

Drug interactions

Metoclopramide: Dexmedetomidine and metoclopramide both increases effects of the other, avoid use of metoclopramide or interacting drug, depending on importance of drug to patient.

Side effects

Common (more than 10%) Hypertension; Hypotension; Nausea.
Less common (1-10%) Acidosis; Agitation; Anemia; Atelectasis; Atrial fibrillation; Bradycardia; Chills; Dry mouth; Hyperglycemia; Hyperthermia; Hypocalcemia; Hypovolemia; Hypoxia; Oliguria; Pleural effusion; Pulmonary edema; Pyrexia; Sinus tachycardia; Tachycardia; Thirst; Urine output decreased; Vomiting.
Rare but serious (less than 1%) Peripheral edema; Ventricular tachycardia; Wheezing.

Patient educations

Patient educations is not currently available for this monograph.

Dexpanthenol

ATC Code: A11HA30 Vitamins (Other Plain Vitamin Preparations)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Dermatoses, eczema: Apply topically to affected area once daily or bid.

Off-label uses

None.

Contraindications

Hypersensitivity to dexpanthenol.

Cautions

External use only; Avoid eyes.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Undetermined.
Distribution Undetermined.
Metabolism Dexpanthenol is readily converted to pantothenic acid which is widely distributed into body tissues, mainly as coenzyme A.
Elimination Renal elimination is 70%.

Drug interactions

There are no known significant interactions.

Side effects

Allergic reactions; Irritation; Itching; Tingling; Urticaria.

Patient educations

A Patient education is not currently available for this monograph.

Dosage forms and trade names available in Iraq

Dexpanthenol 0.05 g/1g cream
Dexpanthen (Wadi al-Rafedain IRAQ).
Dexpanthenol 50mg/gm ointment
Dexpanthen (Wadi al-Rafedain IRAQ).

Dextromethorphan

ATC Code: R05DA09 Cough and Cold Preparations (Opium Alkaloids and Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Cough: 10mg-20mg every 4 hours or 30mg tid or qid, (max 120mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to dextromethorphan; Asthma; Bronchitis; Emphysema.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Dextromethorphan 15mg/5ml syr
SEDILAR (SDI Iraq), **SEDILARIN** (Wadi al Rafidain Iraq), **SEDACOUGH** (AL- Kindi Iraq),**CoughAway** (AL-Mansour Iraq), **SEDIPHAR** (Dubai Co. Iraq).

Dextromethorphan 15mg tablet
SEDILAR (SDI Iraq).

Pharmacokinetic parameters

Absorption F=11%.

Distribution Vd=5-6.7L/kg, 60-70%protein bound.

Metabolism Metabolized to dextrorphan an active metabolite.

Elimination Dextromethorphan and dextrorphan are renally excreted with half-life of 3-30 hours.

Drug interactions

Memantine: Dextromethorphan may enhance the adverse effect of memantine.

Side effects

Common (more than 10%) Confusion; Constipation; Dizziness; Drowsiness; Nausea; Nervousness; Sedation; Vomiting.

Less common (1-10%) None.

Rare but serious (less than 1%) None.

Patient educations

Advise patient to avoid irritants, such as smoking, dust, and fumes; Suggest use of humidifier to filter air pollutants; Inform patient that treatment aims to decrease coughing frequency and intensity without completely eliminating protective cough reflex; Instruct patient to contact health care provider if cough lasts more than 7 days.

Note

Abuse potential much lower than codeine, about 15mg-30mg dextromethorphan equal to 8mg-15mg codeine as an antitussive.

Dextrose

ATC Code: V06DC01 General Nutrients (Carbohydrates).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Considered safe; not known to pass into breast milk.

Dosage forms and trade names available in Iraq

Dextrose 5.0 g/100ml 5% I.V inj. 500 ml **DEXTROSE** (SDI IRAQ), **Dextrose** (Pioneer Iraq).

Indications and Dosage

It is primarily used for hydration and calorie provision hypoglycemia, hyperkalemia, nutrition and after operation.The dosage depends on the age, weight, clinical condition of the patient, and laboratory determinations.

Off-label uses

It can be used to dilute other intravenous medications.

Contraindications

Hypersensitivity to dextrose; hyperglycemia; intracranial hemorrhage and in patients with known allergy to corn or corn products.

Cautions

Caution should be used in patients with diabetes; renal or cardiac disease.

Dose adjustment in renal failure: Depends on the clinical scenario, hydration status and serum electrolyte levels.

Dose adjustment in hepatic failure: No specific adjustment guidelines, but should be used with caution.

Pharmacokinetic parameters

Absorption N/A, it's given intravenously.

Distribution Rapidly distributed throughout total body water, no protein binding.

Metabolism Rapidly metabolized to carbon dioxide and water.

Elimination N/A, metabolized to carbon dioxide and water.

Drug interaction

There are no major known drug interactions with dextrose 5% water solution.

Side effects

Common (more than 10%): Overhydration; electrolyte imbalance.

Less common (1-10%): Injection site reactions.

Rare but serious (less than 1%): Pulmonary edema; hypersensitivity reactions.

Patient educations

1. The solution is used for hydration and does not have any nutritional content.
2. If you notice any swelling; discomfort; or redness around the IV site, let your nurse or doctor know immediately.
3. The healthcare team will regularly monitor your blood sugar and electrolyte levels while you are receiving this treatment.

Diazepam

ATC Code: N05BA01 Psycholeptics (Benzodiazepine Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding for occasional use and in low doses.

Indications and Dosage

• Anxiety, seizure: 2mg-10mg every 6-12 hr.
• Alcohol withdrawal syndrome: 10mg qid in first 24 hours, then 5mg tid or prn.
• Muscle spasm (skeletal muscle relaxant) adjunct: 5mg-10mg every 4 hours (larger dose needed in tetanus).

Off-label uses

Panic attacks; Adjunct to general anesthesia; Tremors; Insomnia.

Contraindications

Hypersensitivity to diazepam; Acute narrow angle glaucoma; Severe respiratory depression; Severe hepatic insufficiency; Sleep apnea syndrome; Myasthenia gravis; Children younger than 6 months (oral); Do not use in patients with soy protein hypersensitivity, CNS depression and hyperkinesis.

Dosage forms and trade names available in Iraq

Diazepam 10mg amp
Pioval (Pioneer IRAQ).
Diazepam 2 mg tab
Diazedain (Wadi Al-Rafidain Iraq).
Diazepam 5 mg tab
VALIAPAM (SDI Iraq), **VALIUPAM** (Al-Kindi IRAQ), **Diazedain** (Wadi Al-Rafidain Iraq), **Duzepam** (Dubai Iraq).
Diazepam 10 mg tab
VALIAPAM (SDI Iraq).
Diazepam 2mg/5ml syrup
VALIAPAM (SDI Iraq), **Valiupam** (Alkindi Iraq).

Cautions

Depression; History of drug and alcohol abuse; Respiratory disease; Impaired gag reflex; Elderly; Petit mal seizures.
Dose adjustment in renal failure: Reduce by 50%. Only for prolong use (more or equal than 4 months)
Dose adjustment in hepatic failure: Decrease dose by 50%.

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.
Distribution Vd=1-2L/kg, 96% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 75% with a half-life of 20-95 hours.

Drug interactions

Gabapentin, cimetidine rifampin: Gabapentin may increase CNS depression.
Carbamazepine, grapefruit, isoniazid: Carbamazepine may increase levels or effects of diazepam.

Side effects

Common (more than 10%) Blurred vision; Changes in salivation; Depression; Dysarthria; Fatigue; Headache; Hypotension; Incontinence; Muscle weakness; Respiratory depression; Skin rash; Urinary retention, palpitation and vomiting
Less common (1-10%) Diarrhea; hypersalivation; Rash; Somnolence.and slurred speech
Rare but serious (less than 1%) Carpal tunnel syndrome; Jaundice; Neutropenia; Phlebitis; Thrombophlebitis; Tissue necrosis; Neutropenia; Nystagmus, bradycardia ,cardiac arrest and memory loss.

Patient educations

Avoid alcohol and limit caffeine; Diazepam may cause drowsiness; Diazepam may be habit forming; Avoid abrupt discontinuation of diazepam after prolonged use; Avoid driving.

Diclofenac

ATC Code: M01AB05 Antiinflammatory and Antirheumatic Products (Acetic Acid Derivatives and Related Substances)

Pregnancy category:

FDA A B **C** **D** X N

TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

• Pain: 25mg-50mg tid.
• Dysmenorrhea: 50mg tid.
• Osteoarthritis; Rheumatoid arthritis: 100mg daily or bid.
• Acute Pain due to minor strains or sprains: 1 patch bid applied on most painful area.
• Arthritis pain: Apply gel to affected area qid.
• Cataract surgery: 1 drop in affected eye qid for 2 weeks, beginning 24 hours post-surgery.

Off-label uses

Dental pain; Treatment of juvenile idiopathic arthritis.

Contraindications

Hypersensitivity to diclofenac; Asthma; Urticaria; Perioperative pain in setting of CABG surgery.

Cautions

Heart failure; Hypertension; Bleeding ulcers; Elderly.
Dose adjustment in renal failure: CrCl less than 30ml/min: avoid.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Diclofenac sodium 100mg supp.
- Diclofenac sodium 25mg supp.
- Diclofenac sodium 12.5mg supp.
- Diclofenac potassium 50 mg granules sachet
- Diclofenac potassium 50mg tab
- Diclofenac sodium 1% gel
- Diclofenac sodium 100mg cap
- Diclofenac sodium 25mg tab
- Diclofenac sodium 1mg/1ml 0.1% eye drops
- Diclofenac sodium 75mg/2ml Ampule

Pharmacokinetic parameters

Absorption F=50%, minimal food effect on absorption.
Distribution Vd=1.3L/kg.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 65% with a half-life of 2 hr.

Drug interactions

Methotrexate: Diclofenac increases levels of methotrexate by decreasing renal clearance; Concomitant administration of NSAIDs with high dose methotrexate has been resulting in deaths from severe hematologic and GI toxicity.

Side effects

Abdominal pain; Acute hepatitis; Asthma; Cholestasis; Decreased hemoglobin; Dyspepsia; Edema; Epistaxis; Fluid retention; Hemolytic anemia; Hypertension; Leukopenia; Nausea; Nephrotoxicity; Peptic ulcer or GI bleeding; Pruritus; Rash; Tinnitus.

Patient educations

Avoid aspirin, alcohol during therapy (increases risk of gastrointestinal bleeding), if gastrointestinal upset occurs, take with food, milk.

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Dienogest

ATC Code: G03DB08 Sex Hormones and Modulators of The Genital System (Pregnadien Derivatives)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Endometriosis: 2mg once daily.

Off-label uses

None.

Contraindications

Heart attack, stroke or heart disease; Hypersensitivity to Dienogest; Active venous thromboembolic disorder; Active or history of arterial and cerebral vascular disease; Diabetes with vascular involvement; Presence or history of liver tumor; Sex hormone dependent malignancies; Undiagnosed vaginal bleeding; Ocular lesion due to vascular ophthalmic disease; Migraine with focal aura; Cirrhosis.

Dosage forms and trade names available in Iraq

Dienogest 2 mg tab

VISANNE (Bayer Germany).

Cautions

Osteoporosis; Hormonal contraceptives; Known or suspected breast cancer; Old age patient; Hypertension; Gestational diabetes; Hypercholesterolemia; Morbid obesity; Smokers; Depression.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In severe hepatic failure, use of dienogest is contraindicated.

Pharmacokinetic parameters

Absorption F=91%.

Distribution Vd=40L, 90%protein bound.

Metabolism Metabolized in the liver by CYP3A4 enzyme to inactive metabolites.

Elimination Elimination half-life is 11 hours.

Drug interactions

Tranexamic acid: Tranexamic acid and dienogest both increases toxicity of the other by pharmacodynamic synergism, coadministration of tranexamic acid and dienogest increases thrombotic risk.

Side effects

Common (more than 10%) Headache.

Less common (1-10%) Acne; Breast pain; Discomfort; Irregular menstruation; Metrorrhagia; Nausea; Tenderness; Vomiting; Weight gain.

Rare but serious (less than 1%) Depression; Gallbladder disease or cholestasis; Jaundice; Venous thromboembolism.

Patient educations

Avoid smoking.

Digoxin

ATC Code: C01AA05 Cardiac Therapy (Digitalis glycosides)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Caution is recommended.

D

Indications and dosage

• Atrial fibrillation: Loading dose 250mcg every 2 hr to a total dose of 1500mcg, then 125mcg-250mcg once daily.
• Heart failure: Loading dose 500mcg-750mcg once followed by 125mcg-250mcg qid to achieve response followed by 125mcg-500mcg daily.
• Supraventricular tachyarrhythmia: Loading dose 750mcg-1500mcg then 125mcg-500mcg once daily.

Off-label uses

Fetal tachycardia with or without hydrops; Decrease ventricular rate in supraventricular tachyarrhythmias.

Contraindications

Hypersensitivity to digoxin; Ventricular fibrillation.

Cautions

Sinus nodal disease; Acute myocardial infarction within 6 months; Second or third degree heart block; Hyperthyroidism; Hypothyroidism; Hypokalemia; Hypocalcemia.

Dose adjustment in renal failure: CrCl 10-50ml/min: 62.5mcg every 24 hours; CrCl less than 10ml/min 62.5mcg every 48 hours.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Digoxin BP 0.05mg /ml Pediatric Elixir
  LANOXIN (Aspen Germany).
- Digoxin 125 mcg tab
  LANOXIN (Aspen Germany).
- Digoxin 250 mcg tab
  LANOXIN (Aspen Germany).
- Digoxin 250 mcg/ml, (2 ml amp.)
  LANOXIN (Glaxo Smith Kline U.K.).

Pharmacokinetic parameters

Absorption F=60-80%, food reduce absorption rate.
Distribution Vd=4-7L/kg, 25% protein bound.
Metabolism Metabolized by liver.
Elimination Renal elimination is 57-80% with a half-life of 1.3-2.2 days.

Drug interactions

Spironolactone: Spironolactone may diminish the therapeutic effect of cardiac glycosides. in particular, the inotropic effects of digoxin appear to be diminished. potassium-sparing diuretics may increase the serum concentration of cardiac glycosides.

Side effects

Common (more than 10%) None.
Less common (1-10%) Diarrhea; Dizziness; Headache; Maculopapular rash; Mental disturbances; Nausea; Vomiting.
Rare (less than 1%) Anorexia; Cardiac dysrhythmia.

Patient educations

Tell patient to take digoxin at same time every day; Instruct patient not to stop digoxin abruptly; Teach patient how to recognize and report signs and symptoms of digoxin toxicity.

Diloxanide

ATC Code: P01AC01 Antiprotozoals (Dichloroacetamide Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: No data available.

Dosage forms and trade names available in Iraq

Diloxanide furoate 500mg tab
DILOXAN (Al-Furat Iraq).

Indications and Dosage

• Intestinal amoebiasis: 500mg tid for 10 days.

Off-label uses

None.

Contraindications

Hypersensitivity to diloxanide.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%.

Distribution Undetermined.

Metabolism Hydrolyzed to furoic acid and diloxanide.

Elimination Renal elimination is 90% with half-life of 3 hours.

Drug interactions

There are no known significant interactions.

Side effects

Anorexia; Flatulence; Nausea; Pruritus; Urticaria; Vomiting.

Patient educations

A Patient educations is not currently available for this monograph.

Diltiazem

ATC Code: C08DB01 Calcium Channel Blockers (Benzothiazepine Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Hypertension: 60mg-120mg bid, may titrate to 360mg daily.
• Stable chronic angina: 60mg bid, may titrate to 360mg daily.

Off-label uses

Unstable angina; Coronary artery bypass graft surgery; Tardive dyskinesia; Migraine; Hyperthyroidism; Raynaud's phenomenon.

Contraindications

Hypersensitivity to diltiazem; Atrial flutter or fibrillation associated with shortened refractory period; Recent myocardial infarction or pulmonary congestion; Cardiogenic shock; ventricular tachycardia; Sick sinus syndrome; second or third degree atrioventricular block; Hypotension.

Dosage forms and trade names available in Iraq

- Diltiazem HCl 60mg tab
  ALTIAZEM (MENARINI Italy).
- Diltiazem HCl 90mg tab
  BI-TiLDIEM SR (Sanofi France).
- Diltiazem HCl 120mg tab
  BI-TILDIEM (Sanofi Aventis France).

Cautions

Heart failure; Hypertrophic obstructive cardiomyopathy.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use cautiously.

Pharmacokinetic parameters

Absorption F=35-40%, food decrease absorption.
Distribution Vd=305-391L, 77-93% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 35% with a half-life of 3-6.6 hr.

Drug interactions

Atorvastatin: Atorvastatin may increase the serum concentration of diltiazem and diltiazem may increase the serum concentration of atorvastatin, using lower atorvastatin doses when used together with diltiazem.

Side effects

Common (more than 10%): Edema; Headache.
Less common (1-10%): AV block; Bradyarrhythmia; Bronchitis; Congestion; Constipation; Diarrhea; Dizziness; Drug-induced gingival hyperplasia; Dyspnea; Extrasystoles; Flushing; Headache; Hypotension; Myalgia; Nausea; Peripheral edema; Sinus congestion; Vasodilation; Vomiting.
Rare (less than 1%): Congestive Heart Failure; Extrapyramidal symptoms; Hemolytic anemia; Increased Alkaline phosphatase as well as ALT and AST; Photosensitivity; Syncope; Thrombocytopenia; Toxic epidermal necrolysis.

Patient educations

Advise patient to change position slowly to minimize light-headedness and dizziness; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness.

Dimetindene

ATC Code: D04AA13 Antipruritics, Incl. Antihistamines, Anesthetics, Etc. (Antihistamines for topical use))
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: There is limited information available. best to be avoided

Indications and Dosage

It treats signs and symptoms of allergic reactions like urticaria, eczema and pruritus in eruptive skin diseases. It is also used to treat allergies of the upper respiratory tract like hay fever and perennial rhinitis, food and drug allergies. Dosage to be determined by the healthcare provider.

Dosage forms and trade names available in Iraq

Dimetindene maleate 1mg/1ml Oral drop
FENISTIL-KIDS (SDI Iraq), **Fenisdain** (Wadi Al-Rafidain Iraq).

Off-label uses

None.

Contraindications

Hypersensitivity to Dimetindene or any of its components; Urinary retention; Paralytic ileus.

Cautions

Epilepsy; Gastrointestinal tract obstruction. driving as it causes drowsiness
Dose adjustment in renal failure: may be necessary; Specific guideline not available
Dose adjustment in hepatic failure: may be necessary; Specific guideline not available.

Pharmacokinetic parameters

Absorption Undetermined.
Distribution Undetermined.
Metabolism Undetermined.
Elimination Undetermined.

Drug interactions

Atropine: The therapeutic efficacy of dimetindene can be decreased when used in combination with atropine.
Domperidone: The therapeutic efficacy of Domperidone can be decreased when used in combination with Dimetindene.

Side effects

Common (more than 10%): Drowsiness; Dry mouth; Sedation; Excitability.
Less common (1-10%): Headache; Dizziness; Tachycardia; Urinary Retention; Fluid retention.
Rare but serious (less than 1%): Allergic reactions; Cardiac arrhythmias; Vision changes.

Patient education

- Take dimetindene as prescribed by your healthcare provider and follow the recommended dosage.
- Be cautious when performing tasks that require alertness, as dimetindene may cause drowsiness.
- If you experience any severe side effects or allergic reactions, seek immediate medical attention.

Dinoprostone

ATC Code: G02AD02 Other Gynecologicals (Prostaglandins)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Dinoprostone is not indicated in breastfeeding women.

Indications and Dosage

• Induction of labour: 3mg to be inserted high into the posterior fornix. A second 3mg may be inserted after 6-8 hours if labour is not established, (max dose 6mg).

Off-label uses

None.

Contraindications

Hypersensitivity to dinoprostone; Active cardiac disease; Active pulmonary disease; Acute pelvic inflammatory disease;
Cephalopelvic disproportion; Evidence of placeta previa and unexplained vaginal bleeding during pregnancy; Fetal distress; Fetal malpresentation;
Major uterian surgery; Prolonged uterian contraction in cases of previous caesarean section.

Dosage forms and trade names available in Iraq

Dinoprostone 3 mg vaginal tablet
Prostin E2 (Pfizer Belgium).

Cautions

Asthma; Glaucoma; Cardiovascular or pulmonary disease; Epilepsy; Multiple pregnancy.
Dose adjustment in renal failure: Contraindicated.
Dose adjustment in hepatic failure: Contraindicated.

Pharmacokinetic parameters

Absorption Undetermined.
Distribution Undetermined.
Metabolism Extensively metabolized in the lungs, forming metabolites which are further metabolized in the liver and kidney.
Elimination Mainly via urine with half-life of 2.5-5 minutes.

Drug interactions

Carbetocin: Dinoprostone may enhance the adverse effect of carbetocin, carbetocin oxytocic effects may be enhanced, avoid combination.
Oxytocin: Dinoprostone may enhance the adverse effect of oxytocin. specifically, oxytocic effects may be enhanced, concomitant use of dinoprostone and oxytocin is not recommended. if used sequentially, administer oxytocin 30 minutes after removing dinoprostone vaginal insert and 6 to 12 hours after the application of dinoprostone gel.

Side effects

Arrhythmia; Blurred vision; Chest pain; Chest tightness; Dehydration; Diaphoresis; Endometritis; Eye pain; Hearing impairment; Hot flashes; Paresthesia; Skin discoloration; Syncope; Vaginitis; Vulvitis.

Patient educations

Report promptly fever, chills, foul smelling increased vaginal discharge, uterine cramps, pain.

Diosmin

ATC Code: C05CA03 Vasoprotectives (Capillary Stabilizing Agents, Bioflavonoids)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Indications and Dosage

• Venous insufficiency: 600mg once daily on an empty stomach.
• Varicose veins: 600mg bid or tid.

Off-label uses

None.

Contraindications

Hypersensitivity to diosmin.

Cautions

None.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Diosmin is rapidly absorbed in the gastrointestinal tract.
Distribution Vd=62.1±7.9L, Diosmin binds to serum albumin.
Metabolism Degradation products of diosmin such as alkyl-phenolic acids confirm a metabolic pattern similar to that of other flavonoids.
Elimination Absence of urinary elimination for diosmin and its aglycone diosmetin, minor metabolites are found to be eliminated in the urine as glucuronic acid conjugates with half-life of 26-43 hours.

Drug interactions

There are no known significant interactions.

Side effects

Abdominal pain; Diarrhea; Headache.

Patient educations

A Patient educations is not currently available for this monograph.

Dosage forms and trade names available in Iraq

Diosmin 600mg tab
Phlebodia (Laboratoires Innothera France).

Diphenhydramine

ATC Code: R06AA02 Antihistamines for Systemic Use (Aminoalkyl Ethers)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Discontinue breast-feeding.

D

Indications and Dosage

• Allergic reaction: Orally, 25mg–50mg tid. By i.v. or i.m. injection, 10mg/dose, (max 300mg daily).
• Motion sickness: 25mg-50mg 30 min before motion.
• Antitussive: 25mg every 4 hr, (max 150mg daily).
• Nighttime sleep aid: 25mg–50mg at bedtime.

Off-label uses

None.

Contraindications

Hypersensitivity to diphenhydramine; Acute exacerbation of asthma; newborn or premature infants; Narrow angle glaucoma; Prostatic hypertrophy; Bladder neck obstruction; Stenosing peptic ulcer.

Cautions

Narrow angle glaucoma; Stenotic peptic ulcer; Prostatic hypertrophy; Asthma; COPD; Increased IOP; Cardiovascular disease; Hyperthyroidism; Elderly.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Diphenhydramine Hcl 10mg/1ml Amp
ALLERMIN (SDI Iraq), **Difen** (PIONEER IRAQ).

Diphenhydramine HCl 10 mg/5ml Syrup
ALLERMINE (SDI Iraq), **DuAllerm** (Dubai co. Iraq), **KINDIRAMIN** (Kindi Iraq).

Diphenhydramine HCl 25 mg tab
Alledramine (Dubai co. Iraq), **ALLERMIN** (SDI Iraq), **KINDIRAMIN** (Kindi Iraq).

Pharmacokinetic parameters

Absorption F=40-60%.
Distribution Vd=3.3-6.8L/kg, 78-85%protein bound.
Metabolism 95% metabolized by the liver.
Elimination Renal elimination is 1% with half-life of 2.4-7 hours.

Drug interactions

Metoclopramide: Diphenhydramine and metoclopramide both increases effects of the other, avoid use of metoclopramide or interacting drug, depending on importance of drug to patient.

Side effects

Agranulocytosis; Anorexia; Anticholinergic effects; Blurred vision; Confusion; Constipation; Convulsions; Diplopia; Dry nasal mucosa; Euphoria; Hemolytic anemia; Hypotension; Menstrual irregularities; Nervousness; Neuritis; Palpitations; Pharyngeal dryness; Restlessness; Sedation; Tachycardia; Thick bronchial sputum; Thrombocytopenia; Tinnitus; Urinary retention; Vertigo; Xerostomia.

Patient educations

Advise patient to avoid alcohol and other depressants such as sedatives while taking diphenhydramine; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness.

Dipyridamole

ATC Code: B01AC07 Antithrombotic Agents (Platelet Aggregation Inhibitors Excl. Heparin)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Thromboprophylaxis after heart valve replacement: 75mg qid as an adjunct to warfarin therapy.

Off-label uses

Prevention of myocardial reinfarction (given with aspirin); Thrombotic thrombocytopenia purpura.

Contraindications

Hypersensitivity to dipyridamole.

Cautions

Hypotension; Hepatic insufficiency; Severe coronary artery disease; Not indicated for children less than 12 years.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Dipyridamole 75mg tab.
PERSANTIN (Boehringer Inglheim Germany).

Pharmacokinetic parameters

Absorption F=27-66%.

Distribution Vd=2.43-3.38L/kg, 99% protein bound.

Metabolism Extensive hepatic metabolism.

Elimination Dipyridamole elimination in bile with a half-life of 10 hours.

Drug interactions

Adenosine: Dipyridamole may enhance the adverse effect of adenosine, specifically cardiovascular effects of adenosine may be enhanced, adenosine dose reduction may be needed.

Atenolol: Dipyridamole may enhance the bradycardic effect of atenolol.

Rivaroxaban: Dipyridamole with antiplatelet properties may enhance the anticoagulant effect of rivaroxaban, carefully consider risks and benefits of this combination and monitor closely.

Side effects

Common (more than 10%) Abnormal ECG: Angina exacerbation; Chest pain; Dizziness; Headache.

Less common (1-10%) Abdominal discomfort; Extra systole; Flushing; Generalized pain; Headache; Hypotension; Nausea; ST changes.

Rare (less than 1%) None.

Patient educations

Advise patient to take drug 1 hour before or 2 hours after meals for best absorption; Instruct patient to immediately report unusual tiredness, chest pain or other cardiac symptoms, upper right abdominal pain, yellowing of skin or eyes, or dark urine.

Dobutamine

ATC Code: C01CA07 Cardiac Therapy (Adrenergic and Dopaminergic Agents)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Avoid.

Indications and Dosage

• Cardiac decompensation: By i.v. infusion, 0.5mcg–2.5mcg/kg/min initially then maintenance 2mcg–20mcg/kg/min.

Off-label uses

None.

Contraindications

Hypersensitivity to dobutamin; Hypertrophic cardiomyopathy with outflow obstruction.

Cautions

Atrial fibrillation; Hypovolemia; Post myocardial infarction; Elderly.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%, inactivated when given orally.

Distribution Vd= 0.2L/kg.

Metabolism Metabolized by the liver and other tissues.

Elimination Excreted by urine with half-life of 2 minutes.

Dosage forms and trade names available in Iraq

Dobutamin Hcl 12.5mg/ml inj

Dobutamine-Hamlen (Siegfried Hameln Germany).

Drug interactions

Amitriptyline: Tricyclic antidepressants increase or decrease effects of sympathomimetics, by blocking reuptake of NE, or blocking uptake of indirect sympathomimetics into the adrenergic neuron.

Side effects

Common (more than 10%) None.

Less common (1-10%) Angina; Dyspnea; Eosinophilic myocarditis; Fever; Headache; Hypertension; Nausea; Palpation; Premature ventricular beats; Tachyarrhythmia.

Rare but serious (less than 1%) Cardiac dysrhythmia; Exacerbation of coronary arteriosclerosis; Hypokalemia; Injection site reactions; Syncope.

Patient educations

Instruct patient to report anginal pain, headache, leg cramps, and shortness of breath; Explain need for close observation and monitoring.

Docetaxel

ATC Code: L01CD02 Antineoplastic Agents (Taxanes)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Breast carcinoma: By i.v. injection, 60mg–100mg/m^2 given over 1 hr every 3weeks.
• Non–small cell lung carcinoma: By i.v. injection, 75mg/m^2 every 3 weeks.
• Prostate cancer: 75mg/m^2 every 3 weeks with concurrent administration of prednisone.
• Head and neck cancer: 75mg/m^2 every 3 weeks for 3–4 cycles, followed by radiation therapy.
• Gastric adenocarcinoma: 75mg/m^2 every 3 weeks.

Off-label uses

Bladder, esophageal, ovarian, small-cell lung carcinoma; Soft tissue carcinoma; Cervical cancer; Ewing's sarcoma; Osteosarcoma.

Contraindications

Hypersensitivity to docetaxel; Neutrophil count less than 1500 cells/mm^3.

Dosage forms and trade names available in Iraq

docetaxel 20mg (10mg/1ml) 2ml vial
DOCETAXEL PFIZER (Pfizer Ireland).

docetaxel 80mg (10mg/1ml) 8ml vial
DOCETAXEL PFIZER (Pfizer Ireland).

Cautions

Myelosuppression; Fluid retention; Pulmonary disease, Heart failure; Active infection.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Total bilirubin, ALT, AST more than 1.5 times with alkaline phosphatase more than 2.5 times, use of docetaxel not recommended.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=113L, 94-97%protein bound.
Metabolism Extensively metabolized by the liver.
Elimination Metabolites undergo fecal elimination with half-life of 11.1 hours.

Drug interactions

Deferiprone: deferiprone and docetaxel both increases toxicity of the other by pharmacodynamic synergism.

Side effects

Common (more than 10%) Alopecia; Anemia; Asthenia; Diarrhea; Fever; Fluid retention; Infections; Leukopenia; Myalgia; Nail changes; Nausea; Neutropenia; Sensory neuropathy; Skin reactions; Vomiting.
Less common (1-10%) Arthralgia; Thrombocytopenia.
Rare but serious (less than 1%) None.

Patient educations

Maintain strict oral hygiene; Hair loss is reversible, but new hair growth may have different color or texture; New hair growth resumes 2–3 months after last therapy dose.

Domperidone

ATC Code: A03FA03 Drugs for Functional Gastrointestinal Disorders (Propulsives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

D

Indications and Dosage

- Nausea and vomiting: 10 mg t.i.d., maximum 30 mg/day.
- Gastro-intestinal pain in palliative care: 10 mg t.i.d.

Off-label uses

Improve lactation in breast feeding women.

Contraindications

Hypersensitivity to domperidone; Cardiac disease [conditions where cardiac conduction is, or could be, impaired (in adults)]. Prolactin-releasing pituitary tumor (prolactinoma); Hypokalemia; Hypomagnesaemia; Hyperkalemia; CHF; Gastrointestinal Hemorrhage; Mechanical obstruction or perforation. Concomitant use with QT-prolonging drugs or potent CYP3A4 inhibitors.

Cautions

Breast cancer; Family history of coronary artery disease; High blood pressure; High blood cholesterol; Diabetes mellitus; Obesity; Smoking; Excessive alcohol consumption.

Dose adjustment in renal failure: Reduce frequency. (It is better to remove the following statement.

Dose adjustment in hepatic failure: In moderate to severe hepatic failure, use of domperidone is contraindicated.

Dosage forms and trade names available in Iraq

Domperidone 10 mg tablet
DOMPERISAM (SDI Iraq), **Motidon** (Pioneer IRAQ).

Domperidon oral susp. 10mg/10ml
Motilight (Alkindi IRAQ), **Domperidin** (Wadi Al-Rafidain IRAQ), **Motidon** (Pioneer IRAQ).

Pharmacokinetic parameters

Absorption F=15%, slightly delayed absorption with food.
Distribution Vd= Undetermined, 91-93% protein bound.
Metabolism Rapidly and extensively metabolized in the liver via N-dealkylation by CYP3A4 isoenzyme and via hydroxylation by CYP3A4, CYP1A2 and CYP2E1 isoenzymes.
Elimination Renal elimination is 31% with half-life of 7-9 hours.

Drug interactions

Acyclovir: The metabolism of domperidone can be decreased when combined with acyclovir.
Antiarrhythmics (dronedarone), Azole antifungals, Aprepitant, Calcium channel blockers (diltiazem, verapamil), Cobicistat, Crizotinib, HIV-protease inhibitors, Idelalisib, Imatinib, Macrolides (clarithromycin, erythromycin), Netupitant, Nilotinib, Sulfamethoxazole: increase the risk of QT-prolongation when given with domperidone.

Side effects

Agitation; Amenorrhea; Loss of libido; Anxiety; Breast pain or tenderness; Convulsions; Diarrhea; Dizziness; Elevated prolactin levels; Extrapyramidal side effects; Galactorrhea; Gynecomastia; Nervousness; Oculogyric crisis; Dry mouth; Pruritus; Serious ventricular arrhythmias; QT interval prolongation; Rash; Somnolence; Sudden cardiac death; Torsades de pointes; Transient intestinal cramps; Asthenia; Urticaria; Headache; Urinary retention.

Patient educations

Should be taken on an empty stomach. Take 15-30 min before meals; Domperidone may cause dizziness and somnolence, if affected, do not drive or operate machinery.

Donepezil

ATC Code: N06DA02 Psychoanaleptics (Anticholinesterases)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Alzheimer disease, dementia: 5mg daily at bedtime, may titrate to max of 10mg-23mg daily.

Off-label uses

Multi-infarct dementia.

Contraindications

Hypersensitivity to donepezil.

Cautions

Cardiovascular disease; Chronic obstructive pulmonary disease (COPD); Asthma; Sick sinus syndrome; Patients at risk for developing ulcers; Not indicated for children less than 2 years.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Donepezil Hcl 10mg tablet
  Dementil (Tabuk ksa).
- Donepezil Hcl 5mg tablet
  Dementile (Tabuk ksa).

Pharmacokinetic parameters

Absorption F=100%, food has no effect on absorption.

Distribution Vd=12L/kg, 96% protein bound.

Metabolism Extensive hepatic metabolism.

Elimination Renal elimination is 57% with a half-life of 70 hr.

Drug interactions

Dipyridamole: Dipyridamole may diminish the therapeutic effect of donepezil.

Haloperidol: Donepezil may enhance the QTc prolonging effect of haloperidol.

Ivabradine: Donepezil may enhance the bradycardic effect of ivabradine.

Side effects

Common (more than 10%) Accident; Diarrhea; Infection; Insomnia; Nausea.

Less common (1-10%) Abnormal dreams; Anorexia; Confusion; Cramping; Fatigue; Hallucinations; Headache; Hypertension; Syncope; Vomiting.

Rare (less than 1%) None.

Patient educations

Advise patient to take drug at bedtime with or without food; Instruct patient to allow orally disintegrating tablet to dissolve under tongue and then follow with a glass of water; Inform patient that drug may slow the heart rate, leading to fainting episodes; Instruct patient to immediately report signs or symptoms of GI ulcers (“coffee-ground” vomitus, black tarry stools, and abdominal pain), or irregular heartbeat.

Dopamine

ATC Code: C01CA04 Cardiac Therapy (Adrenergic and dopaminergic agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Dopamine inhibits lactation.

D

Indications and Dosage

• Cardiogenic shock (hemodynamic support): By i.v. infusion, 2–5 mcg/kg/min may gradually increase by 5mcg–10mcg/kg/min increments, (max 50mcg/kg/min).

Off-label uses

Symptomatic bradycardia or heart block unresponsive to atropine or cardiac pacing.

Contraindications

Hypersensitivity to dopamine; Pheochromocytoma; Ventricular fibrillation; Uncorrected tachyarrhythmias.

Cautions

Ischemic heart disease; Occlusive vascular disease; Hypovolemia; Ventricular arrhythmias; Post myocardial infarction; Hyperthyroidism.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Dopamine hydrochloride 40mg/1ml (5ml inj)
Dopamine Fresenius (Fresenius Kabi Austria).

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=1.8-2.45L/kg.

Metabolism Metabolized in liver, kidneys and plasma.

Elimination Renal elimination is 80% with half-life of 2 minutes.

Drug interactions

Amitriptyline: Tricyclic antidepressants increase or decrease effects of sympathomimetics, by blocking reuptake of NE, or blocking uptake of indirect sympathomimetics into the adrenergic neuron.

Olanzapine: Olanzapine decreases effects of dopamine by pharmacodynamic antagonism.

Risperidone: Risperidone decreases effects of dopamine by pharmacodynamic antagonism.

Side effects

Anginal pain; Anxiety; Atrial fibrillation (at very high doses); Azotemia; Bradycardia; Cardiac conduction; Abnormalities; Dilated pupils; Dyspnea; Ectopic beats; Gangrene of extremities has occurred when high doses were administered for prolonged periods or in patients with occlusive vascular disease receiving low doses of dopamine; Headache; Hypotension; Increased intraocular pressure; Nausea; Palpitation; Piloerection; Tachycardia; Vasoconstriction; Ventricular arrhythmia; Vomiting; Widened QRS complex.

Patient educations

Report tremors, seizures, rash, diarrhea, or other new symptoms.

ANGINET®

Valsartan

CO-ANGINET®

Valsartan / HCT

UNITED PHARMACEUTICALS part of MS pharma

ANGINET®
Valsartan

CO-ANGINET®
Valsartan / HCT

UNITED PHARMACEUTICALS part of MS pharma

Dorzolamide

ATC Code: S01EC03 Ophthalmologicals (Carbonic Anhydrase Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Ocular hypertension: Instill 1 drop in affected eye tid.

Off-label uses

None.

Contraindications

Hypersensitivity to dorzolamide; Hyperchloraemic acidosis.

Cautions

Chronic corneal defects; Renal calculi; Intra ocular surgery.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Dorzolamide is absorbed via the cornea and stroma.

Distribution Vd= Undetermined, 33%protein bound.

Metabolism Dorzolamide is metabolized to N-desethyldorzolamide.

Elimination Renal elimination is 80% with half-life of 120 days.

Dosage forms and trade names available in Iraq

Dorzolamide (as HCl) 2% eye drop
Dorzimid (PIONEER IRAQ).

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) Bitter taste; Discomfort; Ocular burning; Stinging; Superficial punctate keratitis; Ocular allergic reactions.

Less common (1-10%) Angioedema; Blurred vision; Bronchospasm; Dyspnea; Epistaxis; Ocular dryness; Ocular redness; Photophobia; Stevens-Johnson syndrome; Tearing; Toxic epidermal necrolysis.

Rare but serious (less than 1%) None.

Patient educations

Teach patient not to discontinue product abruptly; emphasize the importance of comply¬ing with dosage schedule, even if feeling better; if dose is missed take as soon as remembered; take at same time each day; Teach patient not to use OTC products (cough, cold, allergy) unless directed by pre¬scriber; also to avoid large amounts of caffeine; Emphasize the need to rise slowly to sitting or standing position to minimize orthostatic hypotension; Teach patient to notify prescriber of mouth sores, sore throat, fever, swelling of hands or feet, irregular heartbeat, chest pain; Caution patient to report excessive perspira¬tion, dehydration, vomiting, diarrhea; may lead to fall in blood pressure.

Doxazosin

ATC Code: C02CA04 Antihypertensives (Alpha-Adrenoreceptor Antagonists)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Benign prostatic hyperplasia: 4mg once daily, may titrate to 8mg daily.
• Hypertension: 4mg once daily (max 16mg daily).

Off-label uses

Expulsion of distal ureteral stone.

Contraindications

Hypersensitivity to doxazosin.

Cautions

Constipation; GI obstruction.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=65%, food increase AUC and Cmax.
Distribution Protein bound 98%.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 9% and fecal 63% with a half-life of 22 hours.

Dosage forms and trade names available in Iraq

- Doxazosin Mesylate 1mg tab
  Cardura (Pfizer Germany).
- Doxazosin Mesylate 4mg tab
  Cardura (Pfizer Germany).

Drug interactions

Duloxetine: Doxazosin may enhance the hypotensive effect of duloxetine.

Side effects

Common (more than 10%) Dizziness; Fatigue; Headache.
Less common (1-10%) Abdominal pain; Anxiety; Dyspnea; Edema; Hypotension; Nausea; Orthostatic hypotension (dose related); Palpitations; Rhinitis; Upper respiratory tract infection (URTI); Vertigo.
Rare (less than 1%) None.

Patient educations

Tell patient to swallow extended release tablets whole and not to chew, divide, cut, or crush them; Caution patient not to drive or perform other activities requiring alertness for 12 to 24 hours after first dose; Tell patient to move slowly when sitting up or standing, to avoid dizziness or light headedness from sudden blood pressure decrease; Advise patient to report episodes of dizziness or palpitations.

Doxorubicin

ATC Code: L01DB01 Antineoplastic Agents (Anthracyclines and Related Substances)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Indications and Dosage

• Kaposi's sarcoma: By i.v. infusion, 20mg/m^2 every 3 weeks infused over 30 min.
• Ovarian cancer: By i.v. infusion, 50mg/m^2 every 4 weeks.
• Multiple myeloma: By i.v. infusion, 30mg/m^2 every 3 weeks.

Off-label uses

Advanced or metastatic uterine sarcoma; Advanced soft tissue sarcomas; Cutaneous T-cell lymphomas; Endometrial carcinoma; Head and neck cancer; Hodgkin's lymphoma.

Contraindications

Hypersensitivity to doxorubicin; Myelosuppression; Recent myocardial infarction within 4–6 weeks; Severe arrhythmias; Severe myocardial insufficiency.

Dosage forms and trade names available in Iraq

Doxorubicin hydrochloride 10 mg/5ml vial
Doxorubicn „Ebewe" (EBEWE Austria).

Cautions

Cardiomyopathy; Patients who received radiation therapy; Preexisting myelosuppression; Severe Heart failure.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Serum bilirubin 1.2-3mg/dL: use 50% of doxorubicin dose; Serum bilirubin 3.1-5mg/dL: use 25% of doxorubicin dose; Severe hepatic failure: use of doxorubicin is contraindicated.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=809-1214L/m^2, 74-76% protein bound.
Metabolism Mostly metabolized by the liver by CYP2D6 and CYP3A4.
Elimination Renal elimination is 5% with half-life of 16.7 hours.

Drug interactions

Enzalutamide: Enzalutamide will decrease the level or effect of doxorubicin by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Alopecia; Anemia; Anorexia; CHF; Diarrhea; Fatigue; Leukopenia; Neutropenia; Pruritus; Vomiting.
Less common (1-10%) Cardiomyopathy.
Rare but serious (less than 1%) None.

Patient educations

Hair loss is reversible, but new hair growth may have different color, texture. New hair growth resumes 2–3 months after the last therapy dose.

Note

Doxorubicin can be indicated for breast cancer; bladder cancer, acute lymphocytic leukemia (ALL).

Doxycyclin

ATC Code: J01AA02 Antibacterials for Systemic Use (Tetracyclines)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

D

Indications and Dosage

Treatment of susceptible infections due to rickettsiae, brucellosis, chlamydia, cholera, malaria prophylaxis, nongonococcal urethritis, pelvic inflammatory disease, plague, primary and secondary syphilis: 100mg bid, (Max 200mg daily).

Off-label uses

Traveler's diarrhea; Pleural effusion.

Contraindications

Hypersensitivity to doxycyclin.

Cautions

History or predisposition to oral candidiasis; During tooth development in children; Avoid prolonged exposure to sunlight.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Doxycyclin 100mg tablet
Vibramycin (Pfizer France).

Pharmacokinetic parameters

Absorption F=100%, food has no effect on absorption.

Distribution Vd=0.75L/kg, 80% protein bound.

Metabolism Hepatic metabolism 50%.

Elimination Renal elimination is 35-45% with a half-life of 15-24 hr.

Drug interactions

Amoxicillin: Doxycycline decreases effects of amoxicillin by pharmacodynamic antagonism, doxycycline may interfere with the bactericidal action of penicillins, monitor for decreased therapeutic effects of penicillins if concomitantly used with a doxycycline.

Tretinoin: Doxycycline and tretinoin both increases toxicity of the other by unspecified interaction mechanism, both tretinoin and doxycycline can cause increased intracranial pressure.

Side effects

Anorexia; Dental discoloration; Diarrhea; Drug rash with eosinophilia and systemic symptoms; Dysphagia; Enterocolitis; Erythema multiform; Esophageal ulcer; Esophagitis; Exacerbation of systemic lupus erythematosus; Exfoliative dermatitis; Glossitis; Headache; Hemolytic anemia; Hepatotoxicity; Hypoglycemia; Intracranial hypertension; Nausea; Neutropenia; Pericarditis; Serum sickness; Skin hyperpigmentation; Thrombocytopenia; Urticaria; Vomiting.

Patient educations

Avoid unnecessary exposure to sunlight; Do not take with antacids, iron products; Complete full course of therapy; If GI upset occurs, may take with small amount food, however doxycyclin should be taken on an empty stomach.

Dulaglutide

ATC Code: A10BJ05 Drugs Used in Diabetes (Glucagon-Like Peptide1- (GLP1-) Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Diabetes mellitus (type 2): Indicated as once-weekly SC injection adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
• also to reduce risk of major adverse cardiovascular (CV) events (CV death, nonfatal MI, or nonfatal stroke) in adults with T2DM who have established CV disease or multiple CV risk factors; by subcutaneous injection, 0.75mg once weekly, may increase to 1.5mg once weekly if glycemic response inadequate

Off-label uses

None.

Contraindications

Hypersensitivity to dulaglutide; Personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2.

Dosage forms and trade names available in Iraq

Dulaglutide 0.75mg in 0.5 ml pfp
Trulicity (Eli lilly USA).
Dulaglutide 1.5mg in 0.5 ml pfp
Trulicity (Eli lilly USA).

Cautions

Patients with increased serum calcitonin; Thyroid nodules; Pancreatitis; Severe Gastrointestinal disease; Diabetic ketoacidosis; Type 1 diabetes.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=47-65%.
Distribution Vd=18L.
Metabolism Dulaglutide is degraded into its component amino acids by general protein catabolism pathways.
Elimination Half-life is 5 days.

Drug interactions

Phenobarbital: Dulaglutide slows gastric emptying and may impact absorption of concomitantly administered oral medications; be particularly cautious when coadministered with drugs that have a narrow therapeutic index.

Side effects

Common (more than 10%): Diarrhea; Increased amylase; Increased lipase; Nausea.
Less common (1-10%): Abdominal distension; Abdominal pain; AV block; Constipation; Decreased appetite; Dyspepsia; Eructation; Fatigue; Flatulence; Gastroesophageal reflux disease; Severe hypoglycemia; Sinus tachycardia; Vomiting.
Rare but serious (less than 1%): Urticaria; Systemic rash, Facial edema, Lip swelling; Injection site reactions; Pancreatitis.

Patient educations

Diabetes requires lifelong control, Diet and exercise are principal parts of treatment; do not skip or delay meals.

Duloxetine

ATC Code: N06AX21 Psychoanaleptics (Other Antidepressants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

D

Indications and Dosage

• Anxiety: Initially 30mg once daily, increased to 60mg once daily; maximum 120mg per day.
• Diabetic peripheral neuropathy pain, fibromyalgia, musculoskeletal pain: 60mg daily, may titrate to 120mg daily.
• Moderate to severe stress urinary incontinence; Adult (female): 40mg twice for 2-4 weeks, assessed after this period.

Dosage forms and trade names available in Iraq

Duloxetine 30 mg cap
CYMBALTA (Lilly Spain).
Duloxetine 60 mg cap
CYMBALTA (Lilly Spain).

Off-label uses

Urinary incontinence; Chemotherapy induced peripheral neuropathy.

Contraindications

Hypersensitivity to duloxetine; Narrow angle glaucoma.

Cautions

Hyponatremia; Seizure disorder; Conditions that slow gastric emptying; Urinary hesitancy and frequency; History of mania; Heavy alcohol use; Children; Bleeding disorders; Cardiac disease; Hypertension (avoid if uncontrolled).
Dose adjustment in renal failure: CrCl less than 30ml/min: avoid.
Dose adjustment in hepatic failure: Avoid.

Pharmacokinetic parameters

Absorption F=30-80%, food slow absorption.
Distribution Vd=1640L, 90% protein bound.
Metabolism Circulating metabolites are inactive pharmacologically; It is moderate CYP26D inhibitor.
Elimination Renal elimination is 70% with half-life of 8-17 hr.

Drug interactions

Metoprolol: Duloxetine increase the exposure to metoprolol with moderate effect.

Side effects

Common (more than 10%) Anxiety; Constipation;Diarrhea; Dizziness; Drowsiness;GIT discomfort;Muscle complaints;Nausea;Palpitations; Paraesthesia.
Less common (1-10%) Apathy; Arrhythmias;Dysphagia; Hepatic disorders. Hyperglycemia; Photosensitivity reaction; Postural hypotension;Suicidal behaviors;Syncope.
Rare (less than 1%) Angioedema; Hypertensive crisis; Hyponatremia; mania; Menopausal symptoms. Seizure; Serotonin syndrome; SIADH; Stevens Johnson syndrome.

Patient educations

Tell patient to take drug with full glass of water; Inform patient that drug may decrease ejaculatory volume; Explain that sexual side effects may not subside after treatment stopped.

Dutasteride

ATC Code: G04CB02 Urologicals (Testosterone-5-Alpha Reductase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Dutasteride not indicated for use in women.

Indications and Dosage

• Benign prostatic hyperplasia: 0.5mg once daily.

Off-label uses

Male pattern alopecia.

Contraindications

Hypersensitivity to dutasteride; other 5-alpha reductase inhibitors, soya or peanut; Women and children and adolescents; Patients with severe hepatic impairment.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Caution should be used in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the use of dutasteride is contraindicated

Dosage forms and trade names available in Iraq

Dutasteride 0.5mg Capsule
Dutasgaran (Biogaran France), **Aripsa** (Pharma Bavaria Spain), **Dutabit** (Aurobindo India).

Pharmacokinetic parameters

Absorption F=60%, minimal food effect.
Distribution Vd=300-500L.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is less than 1% with a half-life of 5 weeks.

Drug interactions

Clarithromycin: Clarithromycin will increase the level or effect of dutasteride by affecting hepatic enzyme CYP3A4 metabolism.
Diltiazem: Diltiazem will increase the level or effect of dutasteride by affecting hepatic enzyme CYP3A4 metabolism.
Rifampin: Rifampin will decrease the level or effect of dutasteride by affecting hepatic/intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) None.
Less common (1-10%) Breast disorders; Decreased libido; Ejaculation disorder; Gynecomastia; Impotence.
Rare (less than 1%) Dizziness.

Patient educations

Tell patient to take drug with full glass of water; The capsules should be swallowed whole and not chewed or opened as contact with the capsule contents may result in irritation of the oropharyngeal mucosa. The capsules may be taken with or without food.; Inform patient that drug decreases testosterone production in prostate; Tell patient to report dysuria and urinary urgency; Advise patient not to donate blood for at least 6 months after final dose; Inform patient that drug may decrease ejaculatory volume; Explain that sexual side effects eventually will subside.

Dydrogesterone

ATC Code: G03DB01 Sex Hormones and Modulators of The Genital System (Pregnadien Derivatives)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Dydrogesterone is not indicated during lactation.

D

Indications and Dosage

• Endometriosis, menstrual disorders, recurrent miscarriage: 10mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to dydrogesterone; Meningioma; Undiagnosed vaginal bleeding.

Cautions

Porphyria; Herpes gestationis; Otosclerosis; Severe pruritus; History of depression.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In sever hepatic failure use dydrogesterone is contraindicated.

Dosage forms and trade names available in Iraq

Dydrogesterone 10mg tablet

Duphaston (Abbott Netherland).

Pharmacokinetic parameters

Absorption F=28%.

Distribution Vd=1400L, 90%protein bound.

Metabolism Completely metabolized to 20α-dihydrodydrogesterone (DHD).

Elimination Renal elimination is 63% with half-life of 5-17 hours.

Drug interactions

Carbamazepine; Phenobarbital; Rifampicin: Dydrogesterone increased metabolism with concomitant use of CYP3A4 inducers.

Side effects

Common (more than 10%) Headache; Abdominal pain; Back pain; Breast pain and tenderness.

Less common (1-10%) Vaginal candidiasis; Depression, Nervousness; Migraine, Dizziness; Nausea, Vomiting, Flatulence; Postmenopausal spotting; Menorrhagia; Irregular menstruation; Dysmenorrhea; Pelvic pain; Cervical discharge; Peripheral edema; Increased weight.

Rare but serious (less than 1%) Influence on libido; Hypertension; Peripheral vascular disease; Varicose vein; Venous thromboembolism; Dyspepsia; Jaundice; Gall bladder disorder; Breast enlargement, Premenstrual syndrome; Decreased weight; Myocardial infarction; Angioedema, Vascular purpura

Patient educations

Dydrogesterone may cause mild somnolence or dizziness, if affected, do not drive or operate machinery.

Econazole

ATC Code: D01AC03 Antifungals For Dermatological Use (Imidazole And Triazole Derivatives)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding; Application to the nipple area should be avoided.

Dosage forms and trade names available in Iraq

- Econazole nitrate 1% cream
- Econazole Nitrate 150 mg vaginal ovule

Indications and Dosage

• Treatment of tinea pedis, tinea cruris, tinea corporis, tinea versicolor: Apply once daily to affected area for 2-4 weeks.

• Treatment of cutaneous candidiasis: Apply bid to affected area for 2 weeks.

Off-label uses

None.

Contraindications

Hypersensitivity to econazole.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Absorption through intact skin is minimal.

Distribution Undetermined.

Metabolism Undetermined.

Elimination Renal elimination is less than 1%.

Drug interactions

Warfarin: Econazole topical increases effects of warfarin by decreasing metabolism, most cases reported use of econazole under occlusive bandage, genital application, or application to large body surface area which may increase the systemic absorption.

Side effects

Common (more than 10%) None.

Less common (1-10%) Application site reaction; Burning and stinging sensations; Erythema.

Rare but serious (less than 1%) Pruritus.

Patient educations

Instruct to apply with glove to prevent further infection; not to cover with occlusive dressings; Teach patient that long term therapy may be needed to clear infection (2week-6months depending on organism); compliance is needed even after feeling better; Teach patient proper hygiene: hand washing technique, nail care, use of concomitant top agents if prescribed; Instruct patient to use medical asepsis (hand washing) before and after each application; to change socks and shoes once a day during treat¬ment of tinea pedis; Advise patient to report to health care pre¬scriber if infection persists or recurs; if blisters, burning, oozing, swelling occur; Caution patient to avoid alcohol because nausea, vomiting, hypertension may occur; Caution patient to use sunscreen or avoid direct sunlight to prevent photosensitivity.

Emicizumab

ATC Code: B02BX06 Antihemorrhagics (Other Systemic Hemostatics).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not yet known

Dosage forms and trade names available in Iraq

Emiclzumab 150mg / 1 ml vial
Hemlibra (La Roche Switzerland Japan).
Emiclzumab 30mg / 1 ml vial
Hemlibra (La Roche Switzerland Japan).

Indications and Dosage

Used for the prevention of bleeding in patients with Hemophilia A with Factor VIII inhibitors. Dosage is usually 1.5 to 3 mg/kg and is administered subcutaneously.

Off-label uses

None.

Contraindications

Hypersensitivity to Emicizumab or any of its components.

Cautions

In patients with a history of thrombotic microangiopathy or thrombotic events related to Hemlibra.

Dose adjustment in renal failure: No specific information is available

Dose adjustment in hepatic failure: No specific information is available.

Pharmacokinetic parameters

As a monoclonal antibody, Emicizumab has unique pharmacokinetics.

Drug interaction

No known interactions.

Side effects

Common (more than 10%): Injection site reactions; headache; joint pain.
Less common (1-10%): Fatigue; diarrhea; muscle pain.
Rare but serious (less than 1%): Serious blood clots (thrombotic events).

Patient educations

• Report any unusual bleeding; bruising; signs of an allergic reaction (rash; swelling; difficulty breathing) to your healthcare provider immediately.
• Emicizumab is administered via subcutaneous injection. Be sure to follow your healthcare provider's instructions for how to properly inject this medication.

Empagliflozin

ATC Code: A10BK03 Drugs Used in Diabetes (Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

• Diabetes mellitus (type 2): 10mg once daily in the morning, taken with or without food. If tolerated initially, dosing may increase up to 25mg.

Off-label uses

None.

Contraindications

Hypersensitivity to empagliflozin; End stage renal disease, Dialysis.

Cautions

Not recommended in type 1 diabetes; Diabetic ketoacidosis; Hypovolemia; Dehydration; Anemia; Elderly; Low systolic blood pressure; Hyperlipidemia; Genital mycotic infection.

Dose adjustment in renal failure: CrCl less than 45ml per minute, use of empagliflozin is contraindicated.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Empagliflozin 10mg tab
  Jardiance (Boehringer ingelheim Germany).
- Empagliflozin 25mg tab
  Jardiance (Boehringer ingelheim Germany).

Pharmacokinetic parameters

Absorption F=78%, food has no effect on absorption.

Distribution Vd=73.8L, 86.2%protein bound.

Metabolism Metabolized via glucuronidation by UGT2B7, UGT1A3, UGT1A8, and UGT1A9 to minor metabolites.

Elimination Renal elimination is 50% with half-life of 12.4 hours.

Drug interactions

Furosemide: Coadministration of empagliflozin with diuretics results in increased urine volume and frequency of voids, which might enhance the potential for volume depletion.

Side effects

Common (more than 10%) None.

Less common (1-10%) Arthralgia; Dyslipidemia; Female genital mycotic infections; Increased urination; Male genital mycotic infections; Nausea; Polydipsia; Upper respiratory tract infection; Urinary tract infection.

Rare but serious (less than 1%) Bacterial infection is necrotizing fasciitis of the perineum; Dehydration; Hypotension; Hypovolemia; Orthostatic hypotension.

Patient educations

Monitoring for empagliflozin includes (HbA1c) reading every 3 to 6 months; Renal function, blood pressure, lipid profile, and pregnancy test need require verification before initiation; Patients should be carefully monitored for hypoglycemia and hypotension if they are co-prescribed insulin, sulfonylureas, or diuretics.

Enalapril

ATC Code: C09AA02 Agents Acting on The Renin-Angiotensin System (ACE Inhibitors, Plain)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Heart failure: 2.5mg daily or bid, (max 40mg daily in divided doses).
• Hypertension: 5mg daily.
• Kidney disease, nondiabetic: 5mg daily, (max 20mg daily).

Off-label uses

Proteinuria in steroid-resistant nephrotic syndrome; Diabetic nephropathy; Hypertensive emergency.

Contraindications

Hypersensitivity to Enalapril; Angioedema.

Cautions

Hypertrophic cardiomyopathy with outflow tract obstruction; Severe aortic stenosis; Major surgery; Unstented unilateral or bilateral renal artery stenosis.

Dose adjustment in renal failure: CrCl less than 30ml/min: 2.5mg daily.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Enalapril maleate 5mg tablet
  SAFAPRIL (SAFA Iraq).
- Enalapril maleate 10mg tablet
  ENALAPRIL (melco-pharma Iraq).
- Enalapril maleate 20mg tablet
  RENITEC (MSD UK).

Pharmacokinetic parameters

Absorption F=60%, food has no effect on absorption.
Distribution Protein bound 50-60%.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 61% with a half-life of 1.3 hr.

Drug interactions

Alfuzosin: Enalapril may enhance the hypotensive effect of alfuzosin.
Allopurinol: angiotensin-converting enzyme inhibitors may enhance the potential for allergic or hypersensitivity reactions to allopurinol.
Duloxetine: Enalapril may enhance the hypotensive effect of duloxetine.

Side effects

Common (more than 10%): None.
Less common (1-10%): Chest pain; Cough; Dizziness; Headache; Hypotension; Rash.
Rare (less than 1%): None.

Patient educations

Inform patient that drug's full effect may not occur for several weeks; Advise patient to report persistent dry cough with nasal congestion; Tell patient to immediately report swelling of face, eye area, tongue, lips, hands, or feet; rash, hives, or severe itching; unexplained fever; unusual tiredness; yellowing of skin or eyes; abdominal pain; or easy bruising; Instruct patient to move slowly when sitting up or standing, to avoid dizziness or light-headedness from sudden blood pressure decrease.

Enoxaparin

ATC Code: B01AB05 Antithrombotic Agents (Heparin Group)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Prophylaxis in COVID-19 disease: 40mg s.c. once daily for 6-11 days.
• DVT prophylaxis, hip or knee replacement surgery: 20mg s.c. every 12 hours starting 12-24 hours postoperatively for 7-14 days.
• DVT treatment: 1mg/kg s.c. every 12 hours, initiate warfarin therapy as soon as possible and continue enoxaparin for at least 5 days and until target INR is reached.
• Unstable angina and non-Q-wave myocardial infarction: 1mg/kg s.c. every 12 hours for 2-8 days with aspirin 100mg daily.

Off-label uses

Gynecologic surgery; Management of venous thromboembolism during pregnancy; Percutaneous coronary intervention adjunctive therapy; Antiphospholipid antibody syndrome; Cerebral thromboembolism

Dosage forms and trade names available in Iraq

Enoxaparin sodium 2000 IU PFS
Clexane (sanofi France).
Enoxaparin sodium 4000 IU PFS
Clexane (sanofi France).
Enoxaparin sodium 6000 IU PFS
Clexane (sanofi France).
Enoxaparin sodium 8000 IU PFS
Clexane (sanofi France).

Contraindications

Hypersensitivity to enoxaparin; Thrombocytopenia; Active major bleeding.

Cautions

Bacterial endocarditis; Children; GI bleeding; Hemorrhagic stroke; History of bleeding disorder; Hypertension; Recent CNS surgery.
Dose adjustment in renal failure: CrCl less than 30ml/min: avoid use or reduce dose by 50%.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100% following subcutaneous dose.
Distribution Vd=4.3L.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 40% with a half-life of 7 hours.

Drug interactions

Ceftriaxone: it increases effects of enoxaparin by anticoagulation, cephalosporins may decrease prothrombin activity.
Anticoagulants, platelets inhibitors: may increase bleeding
Supplementation with anticoagulant effect (ex. feverfew, garlic, ginger, ginko biloba, ginseng, red clover, sweet clover, white willow & etc.): may increase effect on platelets or risk of bleeding

Side effects

Common (more than 10%) Anemia; Hemorrhage.
Less common (1-10%) Fever; Thrombocytopenia; Nausea; Ecchymosis.
Rare but serious (less than 1%) Atrial fibrillation; Pulmonary edema.

Entecavir

ATC Code: J05AF10 Antivirals FOR Systemic Use (Nucleoside and Nucleotide Reverse Transcriptase Inhibitors)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid; An alternative agent may be preferred.

Indications and Dosage

• Treatment of chronic HBV infection: 0.5mg-1mg once daily.

Off-label uses

HBV reinfection prophylaxis, Post–liver transplant, HIV/HBV coinfection.

Contraindications

Hypersensitivity to entecavir.

Cautions

Elderly patients; Children.

Dose adjustment in renal failure: CrCl 10-30ml/min: 0.15mg once daily; CrCl less than 10ml/min 0.05mg once daily.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Entecavir (as monohydrate) 0.05 mg/1ml oral solution
- Entecavir Monohydrate 0.5 mg tablet
- Entecavir monohydrate 1 mg tablet

Pharmacokinetic parameters

Absorption F=70%, entecavir take on an empty stomach at least 2 hr before or after a meal.

Distribution Protein bound 13%.

Metabolism Not metabolized.

Elimination Renal elimination is 62-73% with half-life of 128-149 hr.

Drug interactions

Cladribine: Entecavir undergo intracellular phosphorylation may diminish the therapeutic effect of cladribine, avoid combination.

Orlistat: Orlistat may decrease the serum concentration of entecavir.

Side effects

Common (more than 10%) None.

Less common (1-10%) Dizziness; Fatigue; Headache; Nausea.

Rare (less than 1%) Diarrhea; Dyspepsia; Insomnia; Somnolence; Vomiting.

Patient educations

Take medication at least 2 hours after a meal and 2 hours before the next meal; Avoid transmission of hepatitis B infection to others through sexual contact, blood contamination; Immediately report unusual muscle pain, abdominal pain with nausea and vomiting, cold feeling in extremities, dizziness (signs and symptoms signaling onset of lactic acidosis).

Enzalutamide

ATC Code: L02BB04 Endocrine Therapy (Anti-Androgens)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Enzalutamide is not indicated for use in female patients.

Indications and Dosage

•Metastatic castration resistant prostate cancer; Castration-resistant prostate cancer: 160mg given once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to enzalutamide.

Cautions

Seizure disorder; Brain injury with loss of consciousness; Transient ischemic attack within past 12 months; CVA; Brain metastases; Brain arteriovenous abnormality.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Enzalutamide 40mg capsule
Xtandi (Astellas pharma Netherland).

Pharmacokinetic parameters

Absorption F= 89.7%, food has no effect on absorption.
Distribution Vd=110 L, 95%protein bound.
Metabolism Extensively metabolized by the liver by CYP2C8 and CYP3A4 enzyme systems.
Elimination Renal elimination is 71% with half-life of 6 days; feces 14%

Drug interactions

Amiodarone: Enzalutamide will decrease the level or effect of amiodarone by affecting hepatic enzyme CYP3A4 metabolism.
Rifampicin (CYP2C8 inducers): may cause therapeutic failure by increasing the metabolism of enzalutamide
Warfarin: Enzalutamide will reduce the level of effect of warfarin by affecting the hepatic enzyme CYP2C9/10 metabolism.

Side effects

Common (more than 10%) Arthralgia; Back pain; Constipation; Decreased appetite; Decreased weight; Diarrhea; Dizziness; Dyspnea; Falls; Headache; Hot flush; Hypertension; Musculoskeletal pain; Peripheral edema; Upper respiratory tract infection.
Less common (1-10%) Anxiety; Dry skin; Epistaxis; Gynecomastia; Hematuria; Insomnia; Lower respiratory tract and lung infection; Mental impairment disorders; Muscular weakness; Musculoskeletal pain; Non-pathologic fractures; Paresthesia; Peripheral edema; Pollakiuria; Pruritus; Restless leg syndrome; Spinal cord compression.
Rare but serious (less than 1%) Decreased appetite; Decreased weight; Dizziness; Mental impairment disorders.

Patient educations

Sexually active men must wear condom during treatment and for 1 week after treatment due to potential risks to fetus; Women who are pregnant or are planning pregnancy may not touch medication without gloves; Dizziness, headache, muscle weakness, leg swelling should be reported; Immediately report fever or cough; Routine lab testing will occur during treatment.
Do not increase your dose or take this medication more often than prescribed.

Epirubicin

ATC Code: L01DB03 Antineoplastic Agents (Anthracyclines and Related Substances)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

•Breast cancer: By i.v. injection, 100mg/m², repeat every 21days for 6 cycles.

Off-label uses

None.

Contraindications

Hypersensitivity to epirubicin; Cardiomyopathy; Heart failure; Recent myocardial infarction; Severe arrhythmias; Severe myocardial insufficiency.

Cautions

Bone marrow depression; Neoplastic bone marrow infiltration; Neutropenic fever.

Dose adjustment in renal failure: Serum creatinine greater than 5mg/dL, decrease dose by 50%.

Dose adjustment in hepatic failure: Serum bilirubin 1.2-3mg/dL, use 50% of epirubicin dose; Serum bilirubin more than 3mg/dL, use 25% of epirubicin dose; Severe hepatic failure, use of epirubicin is not recommended.

Dosage forms and trade names available in Iraq

Epirubicin HCl 50 mg/25ml vial
Pharmorubicin (Pfizer Australia).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=23±7L/kg, 77%protein bound.
Metabolism Extensively and rapidly metabolized by the liver and other tissues.
Elimination Renal elimination is 20-27% with half-life of 35 hours.

Drug interactions

Deferiprone: deferiprone and epirubicin both increase toxicity of the other by pharmacodynamics synergism.
Trastuzumab: trastuzumab and epirubicin both increase toxicity of the other by unknown mechanism, trastuzumab may cause cardiomyopathy.

Side effects

Common (more than 10%) Black, tarry stools; bleeding, redness, or ulcers in the mouth or throat; chest pain; cough or hoarseness; fever or chills; lower back or side pain; pain or burning in the mouth or throat ; painful or difficult urination ; sore throat ; sores, ulcers, or white spots in the mouth or on the lips ; swollen glands ; trouble breathing ; unusual bleeding or bruising ;unusual tiredness or weakness
Less common (1-10%) Blood in the urine or stools; pinpoint red spots on the skin; red streaks along the injected vein
Rare but serious (less than 1%) Darkening or redness of the skin at the place of irradiation; fast or irregular heartbeat; joint pain; pain, redness, or warmth at the injection site; skin rash or itching; swelling of the abdomen or stomach, lower legs, and feet; swelling or tenderness of the lymph nodes, abdomen, side or lower back.

Patient educations

Inform patient that drug may cause tissue damage at injection site; Advise patient to avoid receiving live vaccines while taking this drug; Explain that drug will cause hair loss, but that hair should grow back within a few months after therapy; Advise female patient that drug may cause premature menopause or permanent cessation of menses.

داباكسوسين

Dapaxosin

DAPAGLIFLOZIN
(AS PROPANEDIOL) 5, 10MG

إعرف عدوك..احمي نفسك

Indications : Use to lower blood glucose in type 2diabetes , as monotherapy (if metformin inappropriate), Type 2 diabetes mellitus in combination with insulin or other antidiabetic drugs (if existing treatment fails to achieve adequate glycaemic control) .

ALSAIDALY
SCIENTIFIC BUREAU

SDI

Epoetin Alfa (Human Recombinant Erythropoietin)

ATC Code: B03XA02 Antianemic Preparations (Other Antianemic Preparations).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: It is unknown.

Dosage forms and trade names available in Iraq

- Epoetin alfa 10.000 IU injectable solution
  EPREX (Cilag AG Switzerland).
- Epoetin zeta 2000IU/0.6ml pfs
  Retacrit (Pfizer Europe Belgium).
- Epoetin zeta 4000IU/0.4ml pfs
  Retacrit (Pfizer Europe Belgium).

Indications and Dosage

Epoetin alfa is indicated for the treatment of anemia due to chronic kidney disease, anemia due to zidovudine in HIV patients, and anemia due to chemotherapy. Dosage is individualized based on the patient's hemoglobin level, generally starting at 50-100 Units/kg three times a week.

Off-label uses

Epoetin alfa may be used to reduce the need for transfusions following surgery.

Contraindications

In patients with uncontrolled hypertension or with known hypersensitivity to the drug.

Cautions

Epoetin alfa may increase the risk of serious cardiovascular events and death when targeting a hemoglobin level greater than 11 g/dL. Monitor blood pressure and hemoglobin regularly.

Dose adjustment in renal failure: Epoetin alfa is primarily used in patients with renal failure to treat anemia; dosing adjustments may be needed based on the patient's hemoglobin level.

Dose adjustment in hepatic failure: No guidelines have been established, but use with caution.

Pharmacokinetic parameters

Absorption F= Variable, dependent on route of administration.
Distribution Vd= Approximately 0.1 L/kg, minimal protein binding.
Metabolism Metabolized via the kidney and liver.
Elimination Excreted primarily by the kidney; half-life is approximately 4-13 hours.

Drug interaction

Epoetin alfa + Lenalidomide or Thalidomide: Increased risk of thrombosis.

Epoetin alfa + Antihypertensive agents: May require adjustment of antihypertensive medications due to fluctuating blood pressure.

Side effects

Common (more than 10%): Hypertension; headache; arthralgia; rash; nausea.
Less common (1-10%): Thrombosis; dizziness; vomiting; diarrhea.
Rare but serious (less than 1%): Severe hypertension; seizures; thrombotic events; pure red cell aplasia.

Patient education

1. Monitor your blood pressure regularly and inform your doctor if it's high.
2. Report any unusual bruising; bleeding or signs of a stroke or heart attack immediately.
3. Avoid activities that may increase your risk of bleeding or injury.

Eptacog Alfa

ATC Code: B02BD08 Antihemorrhagics (Blood Coagulation Factors).

Pregnancy category:
FDA A B **C** D X N
TGA A **B1** B2 B3 C D X N

Lactation: It's not yet known.

Indications and Dosage

Eptacog alfa, a recombinant Factor VIIa, is used for treatment of bleeding and prevention of surgical bleeding in patients with hemophilia A or B with inhibitors, congenital Factor VII deficiency, and Glanzmann's thrombasthenia with refractoriness to platelets. Dosage is weight-based and depends on the severity of the bleeding.

Off-label uses

Treatment of bleeding in patients with acquired hemophilia and other bleeding disorders.

Contraindications

In patients with known hypersensitivity to eptacog alfa or any of its components.

Dosage forms and trade names available in Iraq

Eptacog alfa recombinant coagulation factor VIIa
1 mg vial
NovoSeven (NovoNordisk Denmark).

Cautions

Eptacog alfa may increase the risk of serious thrombotic events, particularly in patients with a history of coronary heart disease, liver disease, or disseminated intravascular coagulation.
Dose adjustment in renal failure: Not typically required
Dose adjustment in hepatic failure: Not typically required.

Pharmacokinetic parameters

Absorption F= 100% following intravenous administration
Distribution Vd= Unknown, unlikely to be protein bound.
Metabolism Presumed to be similar to endogenous Factor VIIa (via the liver).
Elimination Primarily via the liver, half-life of approximately 2.3 hours.

Drug interaction

Eptacog alfa + Anticoagulants: May increase the risk of bleeding.
Eptacog alfa + Antiplatelet agents: May increase the risk of bleeding.

Side effects

Common (more than 10%): Injection site reactions; fever.
Less common (1-10%): Headache; dizziness; flushing; cough.
Rare but serious (less than 1%): Serious thrombotic events; hypersensitivity reactions; antibody development against Factor VIIa.

Patient education

1. Inform healthcare provider immediately of any signs of thrombosis, such as unexplained swelling and pain.
2. Report any signs of allergic reactions, including hives; difficulty breathing, and swelling of the face or throat.

Ergocalciferol

ATC Code: A11CC05 VITAMINS (Vitamin D And Analogues)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Treatment and prophylaxis of vitamin D deficiency: By i.m. injection or oral route, 600000 IU as a single dose once a year.

Off-label uses

Osteoporosis prevention.

Contraindications

Hypersensitivity to ergocalciferol; Hypercalcemia; Hypercalciuria; Calcium lithiasis; Hypervitaminosis D.

Cautions

Heart disease; Arteriosclerosis; Renal calculi; Hyperphosphatemia; Obese patients (BMI more than 30kg/m^2).

Dose adjustment in renal failure: Use with caution.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Ergocalciferol 600,000 IU 1.5ml ampoule
STEROGYL 15 "H" (DESMA Italy).

Pharmacokinetic parameters

Absorption F=55-99%.

Distribution Vd= Undetermined, 70-90%protein bound.

Metabolism Ergocalciferol converted to 25-hydroxyvitamin D by the action of CYP2R1 followed by the generation of the major circulating metabolite (1,25-dihydroxyvitamin D or calcitrol) by the activity of CYP27B1.

Elimination Half-life is 5-8 hours.

Drug interactions

Calcium carbonate: The concurrent use of vitamin D with calcium salts is generally beneficial, in some patients this combination may result in hypercalcemia.

Side effects

Arrhythmias; Confusion; Constipation; Dry mouth; Headache; Hypercalcemia; Lethargy; Metallic taste; Muscle or bone pain; Nausea; Sluggishness; Vomiting.

Patient educations

Adequate calcium intake should be maintained; Dietary phosphorus may need to be restricted (foods high in phosphorus include beans, dairy products, nuts, peas, whole-grain products); Oral formulations may cause hypersensitivity reactions; Avoid excessive doses; Report signs/symptoms of hypercalcemia (headache, weakness, drowsiness, nausea, vomiting, dry mouth, constipation, metallic taste, muscle or bone pain); Maintain adequate hydration; Avoid magnesium containing antacids in patients with renal failure.

Erlotinib

ATC Code: L01EB02 Antineoplastic Agents (Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitors)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid; Breastfeeding discontinues 2 weeks after the last dose.

Indications and Dosage

- Non–small cell lung cancer: 150mg daily.
- Pancreatic cancer: 100mg daily.

Off-label uses

Metastatic renal cell carcinoma.

Contraindications

Hypersensitivity to erlotinib.

Cautions

Cardiovascular disease; Peptic ulcer disease; Diverticular disease; Total serum bilirubin greater than 3 times upper limit of normal.

Dose adjustment in renal failure: In sever renal failure use of erlotinib is not recommended.

Dose adjustment in hepatic failure: Use with extreme caution, reduce starting dose to 75mg.

Dosage forms and trade names available in Iraq

Erlotinib150 mg tab

Tarceva (F. Hoffman – La Roche Switzerland).

Pharmacokinetic parameters

Absorption F=60%, food increase absorption.

Distribution Vd=232L, 93%protein bound.

Metabolism Mostly metabolized by the liver CYP3A4 enzyme system.

Elimination Renal elimination is 8% with half-life of 36 hours.

Drug interactions

Antacids: Antacids may decrease the serum concentration of erlotinib, separate the administration of erlotinib and any antacid by several hours in order to minimize the risk of a significant interaction.

Ciprofloxacin: Ciprofloxacin may increase the serum concentration of erlotinib, avoid use of this combination when possible. When the combination must be used, monitor the patient closely for the development of severe adverse reactions, and if such severe reactions occur, reduce the erlotinib dose (in 50mg decrements).

Side effects

Common (more than 10%) Abdominal pain; Anorexia; Conjunctivitis; Cough; Diarrhea; Dry skin; Dyspnea; Fatigue; Infection; Nausea; Pruritus; Rash; Stomatitis; Vomiting.

Less common (1-10%) Acne; Paronychia; Pneumonitis pulmonary infiltrate; Pulmonary fibrosis; Weight loss.

Rare but serious (less than 1%) Interstitial lung disease-like events.

Notes: Erlotinib tablets contain lactose and should not be administered to patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

Patient educations

Advise patient to seek immediate medical attention for severe or persistent diarrhea, nausea, vomiting, anorexia, severe rash, eye pain, eye irritation, or onset or worsening of unexplained shortness of breath or cough; Advise patient not to smoke while taking drug.

Ertugliflozin

ATC Code: A10BK04 Drugs Used in Diabetes (Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

• Diabetes mellitus (type 2): 5mg daily in the morning, (max 15mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to ertugliflozin; Diabetic ketoacidosis; Patients on hemodialysis.

Cautions

Genital mycotic infections; Hypotension; Pancreatitis; Caloric restriction; Dehydration; Alcohol abuse; Acute febrile illness; Pancreatic surgery; Peripheral vascular disease; Neuropathy; Diabetic foot ulcers; Hypovolemia; Chronic renal insufficiency; CHF; Uncircumcised males; Not recommended for treatment of type 1 diabetes mellitus; Temporarily discontinue therapy more than 4 days before surgery or any event that may precipitate ketoacidosis.

Dose adjustment in renal failure: CrCl 30-60ml per minute, use of ertugliflozin is not recommended; CrCl less than 30ml per minute, use of ertugliflozin is contraindicated.

Dose adjustment in hepatic failure: In sever hepatic failure use of ertugliflozin is not recommended.

Dosage forms and trade names available in Iraq

- Ertugliflozin 15mg tab
  Steglatro (Merk sharp & Dohme Netherlands).
- Ertugliflozin 5mg tab
  Steglatro (Merk sharp & Dohme Netherlands).

Pharmacokinetic parameters

Absorption F=70-90%.

Distribution Vd=85.5L, 94-96%protein bound.

Metabolism Extensively metabolized primarily by uridine diphosphate glucuronosyltransferases (UGT)1A9 and UGT2B7 via O-glucuronidation into inactive metabolites.

Elimination Renal elimination is 50% with half-life of 11-17 hours.

Drug interactions

Quinolones: Quinolones may enhance the hypoglycemic effect of ertugliflozin.

Side effects

Common (more than 10%) Female genital mycotic infections.

Less common (1-10%) Back pain; Headache; Increased urination; Male genital mycotic infections; Nasopharyngitis; Thirst; Urinary tract infections; Vaginal pruritus; Volume depletion; Weight decreased.

Rare but serious (less than 1%) None.

Patient educations

This drug may increase your risk of lower limb amputations; it is important to adhere with your routine preventive foot care.

Erythromycin

ATC Code: J01FA01 Antibacterials for Systemic Use (Macrolides)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Treatment of susceptible infections: 250mg–500mg tid, (max 2g daily).
• Treatment of acne vulgaris: Apply a thin layer of a 2% topical solution to the affected area bid.

Off-label uses

Chancroid; Campylobacter enteritis; Gastroparesis; Lyme disease; Preoperative gut sterilization.

Contraindications

Hypersensitivity to erythromycin; Prolonged QT interval; Uncorrected hypokalaemia; Hypomagnesaemia; Bradycardia.

Cautions

Elderly; Myasthenia gravis; Patients with prolonged QT intervals; Hypokalemia; Hypomagnesemia.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Erythromycin 125mg/5ml suspension
  Ritrom (Pioneer Iraq).
- Erythromycin 250mg/5ml suspension
  Ritrom (Pioneer Iraq).
- Erythromycin 250mg CAP
  ERYTHROMYCIN (SDI Iraq).

Pharmacokinetic parameters

Absorption F=18-45%.
Distribution Vd=0.64L/kg, 70-80%protein bound.
Metabolism Partially metabolized by the liver.
Elimination Renal elimination is 2-15% with half-life of 1.4-2 hours.

Drug interactions

Simvastatin: Erythromycin base will increase the level or effect of simvastatin by affecting hepatic enzyme CYP3A4 metabolism, increased risk for rhabdomyolysis with drugs that increase simvastatin systemic exposure.

Side effects

Abdominal pain; Cholestatic hepatitis; Confusion; Diarrhea; Dyspepsia; Fever; Flatulence; Hallucinations; Headache; Hearing loss; Hypertrophic pyloric stenosis; Hypotension; Interstitial nephritis; Nausea; Seizures; Pain; Pruritus; Pseudomembranous colitis; QT prolongation; Rash; Skin eruptions; Tinnitus; Torsades de pointes; Urticaria; Ventricular arrhythmias; Ventricular tachycardia; Vertigo; Vomiting.

Patient educations

Instruct patient to take with 240ml of water 1 hour before or 2 hours after meals; If drug causes GI upset, encourage patient to take it with food; Advise patient to immediately report irregular heartbeats, unusual tiredness, yellowing of skin or eyes, or signs and symptoms of new infection; Tell patient he'll undergo periodic blood tests to monitor liver function.

Escitalopram

ATC Code: N06AB10 Psychoanaleptics (Selective Serotonin Reuptake Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Depression, generalized anxiety disorder: 10mg daily (max 20mg daily).

Off-label uses

Seasonal affective disorder (SAD) in children and adolescents; Pervasive developmental disorders such as autism; Vasomotor symptoms associated with menopause.

Contraindications

Hypersensitivity to escitalopram.

Cautions

History of mania or seizures; Suicidal tendency; Elderly patients; Children.

Dose adjustment in renal failure: CrCl less than 20ml/min: Use cautiously.

Dose adjustment in hepatic failure: Max. 10mg once daily.

Dosage forms and trade names available in Iraq

- Escitalopram 10mg tab
  Cipralex (H.Lundbeck Denmark).
- Escitalopram 20mg tab
  Escitagaran (Biogaran Portugal).

Pharmacokinetic parameters

Absorption F=80%, food has no effect on absorption.
Distribution Vd=12L/kg, 56% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 10% with a half-life of 27-32 hr.

Drug interactions

Enoxaparin: Escitalopram may enhance the anticoagulant effect of enoxaparin, discontinue antiplatelet agents prior to initiating enoxaparin whenever possible. if concomitant administration is unavoidable, monitor closely for signs and symptoms of bleeding.

Selegiline: Selective serotonin reuptake inhibitors may enhance the serotonergic effect of selegiline this could result in serotonin syndrome.

Side effects

Common (more than 10%): Ejaculation disorder; Headache; Insomnia; Nausea; Somnolence.

Less common (1-10%): Anorgasmia; Constipation; Decreased appetite; Diarrhea; Fatigue; Flatulence; Flu-like syndrome; Indigestion; Lethargy; Libido decrease; Menstrual disorder; Neck/shoulder pain; Rhinitis; Sinusitis; Toothache; Vomiting; Weight gain; Xerostomia; Yawning.

Rare (less than 1%): None.

Patient educations

Advise patient to minimize gastrointestinal upset by eating small, frequent servings of food and drinking plenty of fluids; Inform patient that full drug effect may take up to 4 weeks; Caution him not to overuse drug or stop drug abruptly;

Esomeprazole

ATC Code: A02BC05 Drugs for Acid Related Disorders (Proton Pump Inhibitors)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• H. pylori GI infection: 40mg PO daily for 10 days in combination with amoxicillin 1000mg and clarithromycin 500mg bid.
• Erosive esophagitis without GERD, GERD and heartburn treatment: 20mg-40mg PO daily for 4-8 weeks.
• Treatment of GERD with erosive esophagitis, reduce risk of ulcer re-bleeding post procedures: 20mg-40mg PO daily for 4-8 weeks, if oral not possible or inappropriate, i.v. infusion, 20mg or 40mg once daily for up to 10 days, switch to oral once patient able to swallow.
• Risk reduction of NSAID-induced gastropathy: 20mg-40mg PO daily for up to 6 months.
• Zollinger-Ellison syndrome: 40mg bid up to 240mg/day.

Off-label uses

Gastritis, GERD in pediatric under 1 year for oral PPI, while i.v. are indicated for 1-month age.

Dosage forms and trade names available in Iraq

Esomeprazole 20mg tab.
Nexium (Astrazeneca Sweden).
Esomeprazole 40mg tab
Nexium (AstraZeneca Sweden).
Esomeprazole 40mg vial
Nexium (AstraZeneca Sweden).

Contraindications

Hypersensitivity to esomeprazole or other PPI and patient receiving rilpivirine containing products.

Cautions

Esomeprazole may increase risk of hip, wrist, spine fractures.
Dose adjustment in renal failure: mild to moderate not required, while sever not recommended.
Dose adjustment in hepatic failure: Max. 20mg daily.

Pharmacokinetic parameters

Absorption F=89-90%, food decrease AUC by 33-53%.
Distribution Vd=16L, 97% protein bound.
Metabolism Extensive hepatic metabolism by hepatic P450 enzyme.
Elimination Renal elimination is 80%, feces 20% with a half-life of 1.2-1.5 hour.

Drug interactions

Enzalutamide: Enzalutamide will decrease the level or effect of esomeprazole by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Headache.
Less common (1-10%) Abdominal pain; Constipation; Diarrhea; Dizziness; Flatulence; Nausea; Pruritus; Somnolence; Xerostomia.
Rare (less than 1%) Agranulocytosis; Pancytopenia; Blurred vision and others.

Patient educations

Take it at any time of the day with or without food; If swallowing capsules is difficult, open capsule and mix pellets with soft food without crushing; Swallow immediately without chewing.

Estradiol

ATC Code: G03CA03 Sex Hormones and Modulators Of The Genital System (Natural and Semisynthetic Estrogens, Plain)

Pregnancy category:

FDA A B C D **X** N

TGA A B1 B2 **B3** C D X N

Lactation: Discontinue breast-feeding; Estrogen use during lactation has been shown to decrease the quantity and quality of breast milk.

Dosage forms and trade names available in Iraq

Estradiol 2mg tablet

Estrofem (Novo Nordisk Denmark).

Indications and Dosage

• Menopause, moderate to severe abnormal vasomotor function, moderate to severe atrophic vulva or vagina: Orally, 1mg-2mg daily for 21 days followed by 7 days off, vaginally insert one 10mcg vaginal tablet daily for 2 weeks followed by one 10mcg insert twice weekly such as Tuesday and Friday.

• Breast cancer: 10mg tid for 3 months.

• Carcinoma of prostate: 1mg-2mg tid.

• Decreased estrogen level, secondary to hypogonadism, castration, or primary ovarian failure: 1mg-2mg daily.

• Postmenopausal osteoporosis prophylaxis: 0.5mg daily for 23 days followed by 5 days off.

Off-label uses

None.

Contraindications

Hypersensitivity to estradiol; Angioedema; Undiagnosed abnormal vaginal bleeding; Estrogen dependent cancer; Breast cancer; Thrombophlebitis or thromboembolic disorders.

Cautions

Diabetes mellitus; Endometriosis; Hyperlipidemias; Asthma; Epilepsy; Migraines; SLE; Hypertension; Hypocalcemia; Hypothyroidism; Cardiovascular disease; Obesity.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=40%, food has no effect on absorption.

Distribution Protein bound 98%.

Metabolism Extensive hepatic metabolism.

Elimination Renal elimination with a half-life of 21 hours.

Drug interactions

Hydrocortisone: Estrogen may increase the serum concentration of hydrocortisone.

Side effects

Abdominal cramping; Amenorrhea; Anxiety; Bloating; Breast enlargement; Depression; Dry mouth; Headache; Hypertension; Impotency; Influenza; Leukorrhea; Melasma; Muscle cramps; Nausea; Nervousness; Peripheral edema; Polydipsia; Pruritus; Rash; Skin irritation and redness at application site; Spotting; Swelling; Syncope; Toothache; Vaginal discomfort; vaginal erosion; vaginal ulceration; adherence of the vaginal ring to the vaginal wall; Vomiting.

Patient educations

Teach proper technique for use of vaginal tablet; Tell patient drug may cause loss of libido (in women) or erectile dysfunction (in men).

Etanercept

ATC Code: L04AB01 Immunosuppressants (Tumor Necrosis Factor Alpha (TNF-α) Inhibitors)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 C **D** X N

Lactation: Manufacturer advises avoid-present in milk in animal studies.

Indications and Dosage

• Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis: 25mg twice weekly alternatively 50mg once weekly, review treatment if no response within 12 weeks of initial dose.

• Plaque psoriasis: 50mg once weekly alternatively 50mg twice weekly for up to 12 weeks, followed by 50mg once weekly if required continue treatment for up to 24 weeks, continuous therapy beyond 24 weeks may be appropriate in some patients, discontinue if no response after 12 weeks.

Dosage forms and trade names available in Iraq

Etanercept 50mg PFS

Enbrel (Pfizer Belgium).

Off-label uses

Hidradenitis suppurativa, Necrobiosis lipoidica, Palmoplantar pustulosis, Sarcoidosis., Polyarteritis nodosa; Pyoderma gangrenosum, SAPHO syndrome.

Contraindications

Hypersensitivity to etanercept; Serious active infection or sepsis.

Cautions

History of recurrent infections; Diabetes; Heart failure Decreased left ventricular function; Hematologic abnormalities; Alcoholic hepatitis; Elderly; CNS demyelinating disorder; Active tuberculosis should be treated with standard treatment for at least 2 months before starting etanercept.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Caution in moderate to severe alcoholic hepatitis.

Pharmacokinetic parameters

Absorption F=70%.

Distribution Vd=1.78-3.39L/m2.

Metabolism Not metabolized.

Elimination Half-life of 102 hr.

Drug interactions

Cyclophosphamide: Etanercept may enhance the adverse effect of cyclophosphamide, an increased risk of solid cancer development may be present, avoid combination.

Side effects

Common (more than 10%) Cystitis ; fever; headache; Diarrhea; Infection; Injection site reactions; Non-upper respiratory infections; Rash; Upper respiratory infections.

Less common (1-10%) Diarrhea; Pruritus; Pyrexia; Rash; Urticaria.

Rare (less than 1%) None.

Patient educations

For more comfortable injection, leave prefilled syringe, auto injector, reconstituted vial at room temperature for around 15-30 minutes before injecting, also don't remove the needle cover while allowing to reach room temperature.

Etonogestrel

ATC Code: G03AC08 Sex Hormones and Modulators of The Genital System (Progestogens).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Not recommended during the first 6 weeks postpartum.

Dosage forms and trade names available in Iraq

Etonogestrel 68 mg for subdermal use

Implanon NXT (Organon Netherland).

Indications and Dosage

Used for the prevention of pregnancy for up to 3 years. The 68 mg implant is inserted subdermally in the upper arm by a healthcare provider.

Off-label uses

Treatment of heavy menstrual bleeding; dysmenorrhea; endometriosis.

Contraindications

Contraindicated in women who are pregnant or have a history of thromboembolic disorders, liver tumors or active liver disease, undiagnosed abnormal genital bleeding or known/suspected breast cancer.

Cautions

Should be removed if thrombosis or thromboembolism occurs, monitor for depression and discontinue if severe. The implant may be difficult to locate and remove.

Dose adjustment in renal failure: Not typically required.

Dose adjustment in hepatic failure: Use is contraindicated in active liver disease.

Pharmacokinetic parameters

Absorption F= 100% following subdermal implantation.

Distribution Vd= Unknown, 66% is protein bound.

Metabolism Primarily via the liver.

Elimination Predominantly in urine and feces, with a half-life of approximately 25 hours.

Drug interaction

Etonogestrel + Certain anticonvulsants (phenytoin, carbamazepine, etc.): May reduce contraceptive efficacy.

Etonogestrel + Antiretroviral agents: Some may decrease plasma etonogestrel concentrations, reducing efficacy.

Side effects

Common (more than 10%): Bleeding irregularities; headache; weight increase; acne; breast pain.

Less common (1-10%): Dizziness; abdominal pain; decreased libido; mood swings; hair loss.

Rare but serious (less than 1%): Ectopic pregnancies; thrombotic events; liver disease; severe depression.

Patient education

1. This contraceptive implant does not protect against sexually transmitted infections.
2. If you suspect that you may be pregnant, contact your healthcare provider immediately.
3. Report any significant changes in mood or depression to your healthcare provider.

Etoposide

ATC Code: L01CB01 Antineoplastic Agents (Podophyllotoxin Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Etoposide 100mg/5ml vial
Etoposid (Ebewe Austria).

Indications and Dosage

• Refractory testicular tumors: By i.v. injection, 50mg–100mg/m^2/day on days 1–5, or 100mg/m^2/day on days 1, 3, 5 every 3–4weeks for 3–4 courses.
• Small cell lung carcinoma: 35mg/m2/day for 4 consecutive days up to 50mg/m^2/day for 5 consecutive days every 3–4 weeks.

Off-label uses

Acute lymphocytic and acute nonlymphocytic leukemias; Ewing's and Kaposi's sarcoma; Hodgkin's and non-Hodgkin's lymphomas; Non-small cell lung carcinomas; Multiple myeloma; Myelodysplastic syndromes; Neuroblastoma; Osteosarcoma; Ovarian germ cell tumors; Primary brain tumors; Gestational trophoblastic tumors; Soft tissue sarcomas; Wilms tumor.

Contraindications

Hypersensitivity to etoposide.

Cautions

Myelosuppression; Elderly; Patients with low serum albumin.
Dose adjustment in renal failure: CrCl 15-50ml per minute, use 75% of etoposide dose; CrCl less than 15ml per use 50% of etoposide dose.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=50%.
Distribution Vd=18-29L, 97% protein bound.
Metabolism Metabolism by the liver.
Elimination Renal elimination is 45% with half-life of 4-11 hours.

Drug interactions

Enzalutamide: Enzalutamide will decrease the level or effect of etoposide by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%): Alopecia; Anemia; Anorexia; Diarrhea; Leukopenia; Nausea and Vomiting; Thrombocytopenia.
Less common (1-10%): Orthostatic hypotension; Pancytopenia; Peripheral neuropathy; Stomatitis.
Rare but serious (less than 1%): Asthenia; Fever; Hyperuricemia; Local soft tissue toxicity has been reported following extravasation; Malaise; Mucous membrane inflammation; Shivering.

Patient educations

Hair loss is reversible, but new hair growth may have different color, texture; Do not have immunizations without physician's approval; Avoid contact with those who have recently received live virus vaccine; Promptly report fever, sore throat, signs of local infection, numbness in extremities, yellowing of skin or eyes.

Etoricoxib

ATC Code: M01AH05 Antiinflammatory and Antirheumatic Products (Coxibs)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

• Osteoarthritis: 60mg once daily.
• Rheumatoid arthritis, ankylosing spondylitis: 90 mg once daily.
• Acute gouty arthritis: 120mg once daily for 8 days.
• Postoperative dental surgery pain: 90mg once daily for 3 days.

Off-label uses

None.

Contraindications

Hypersensitivity to etoricoxib; Active peptic ulceration; Gastrointestinal bleeding; Inflammatory bowel disease; Congestive heart failure; Uncontrolled hypertension; Ischemic heart disease; Peripheral arterial disease; Cerebrovascular disease; History of bronchospasm; Acute rhinitis; Nasal polyps; Angioneurotic edema; Urticaria.

Dosage forms and trade names available in Iraq

- Etoricoxib 60 mg tablet
  Painoxia (PIONEER IRAQ), **Orotix** (Pharma International Jordan).
- Etoricoxib 90 mg tablet
  Painoxia (PIONEER IRAQ), **Orotix** (Pharma International Jordan).
- Etoricoxib 120 mg tablet
  Painoxia (PIONEER IRAQ), **Orotix** (Pharma International Jordan).

Cautions

Ulceration; Gastrointestinal bleeding; Hyperlipidemia; Hypertension; Diabetes mellitus; Smoking; Heart failure; Cirrhosis; Left ventricular dysfunction; Pre-existing edema; Dehydration.
Dose adjustment in renal failure: CrCl less than 30ml per minute, use of etoricoxib is contraindicated.
Dose adjustment in hepatic failure: Mild hepatic failure max 60mg once daily; Moderate hepatic failure max 30mg once daily; Severe hepatic failure use of etoricoxib is contraindicated.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=120L, 92%protein bound.
Metabolism Hepatic metabolism primarily via CYP3A4.
Elimination Renal elimination is 70% with half-life of 22 hours.

Drug interactions

ACE inhibitor or angiotensin II antagonist: Etoricoxib concomitant use with ACE inhibitor or angiotensin II antagonist may further deteriorate renal function,
Acetylsalicylic acid: Etoricoxib may increase rate of gastrointestinal ulceration with concomitant low dose acetylsalicylic acid.

Side effects

Arrhythmia; Abdominal pain; Constipation; Diarrhoea; Dyspepsia; Flatulence; Fluid retention; Gastritis; Heartburn; Hypertension; Increased ALT or AST; Nausea; Oedema; Oesophagitis; Oral ulcer; Flu-like disease; Alveolar osteitis; Headache; Bronchospasm; Palpitations; Vomiting.

Patient educations

This drug may cause dizziness, vertigo or somnolence, if affected, do not drive or operate machinery.

Evening Primrose Oil

ATC Code: Not Assigned

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Evening primrose oil is generally considered safe during lactation.

Indications and Dosage

- Eczema, Atopic: 4-6 g PO daily.
- Mastalgia: 3-4 g PO daily.
- Premenstrual Syndrome: 2-4 g PO daily.
- Rheumatoid Arthritis: 540 mg-2.8 g PO daily.

Off-label uses

None.

Contraindications

Hypersensitivity to evening primrose oil or any component of the formulation.

Cautions

Bleeding disorders, concomitant anesthesia, schizophrenia, seizure disorder.

Dose adjustment in renal failure: No specific dose adjustment is typically required in renal failure.

Dose adjustment in hepatic failure: No specific dose adjustment is typically required in hepatic failure.

Dosage forms and trade names available in Iraq

Evening Primrose Oil 1gm soft gel capsules
Evening primrose oil soft gelatin (Vitane USA).

Pharmacokinetic parameters

Absorption Evening primrose oil is absorbed in the gastrointestinal tract.

Distribution Volume of distribution and protein binding information is not readily available.

Metabolism Metabolism of evening primrose oil occurs primarily in the liver.

Elimination The elimination half-life of evening primrose oil is not well-defined.

Drug interactions

- Evening primrose oil may potentiate the effects of anticoagulant medications, increasing the risk of bleeding. Caution is advised when used concomitantly.
- Concurrent use with phenothiazines (a class of antipsychotic medications) may increase the risk of seizures in susceptible individuals.
- Drugs used for anesthesia: Evening primrose oil interacts with drugs used for anesthesia before surgical operations, increasing the risk of convulsions.

Side effects

Common (more than 10%): Gastrointestinal upset (such as nausea, diarrhea), headache.

Less common (1-10%): Skin rash, bloating, gas.

Rare but serious (less than 1%): Allergic reactions, increased risk of bleeding in susceptible individuals.

Patient educations

- Inform your healthcare provider about any existing medical conditions or medications you are taking before using evening primrose oil, especially if you have a bleeding disorder or are taking anticoagulant medications.
- Discontinue use and seek medical attention if you experience any signs of allergic reaction, such as rash, itching, or difficulty breathing, after taking evening primrose oil.

Everolimus

ATC Code: L04AA18 Immunosuppressants (Selective Immunosuppressants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Everolimus 10mg Tab
Afinitor (Novartis Switzerland).

Indications and Dosage

• Renal carcinoma, neuroendocrine tumors: 10mg once daily.
• Renal transplant rejection prophylaxis: 0.75mg bid.
• Liver transplant rejection prophylaxis (begin at least 30 days post-transplant): Initially, 1mg bid, adjust dose at 4–5 days intervals based on serum concentration, tolerability, and response.
• Subependymal giant cell astrocytoma: 4.5mg/m2 once daily.

Off-label uses

Metastatic breast cancer in females; Relapsed or refractory Waldenström's macroglobulinemia; Treatment of progressive advanced carcinoid tumors.

Contraindications

Hypersensitivity to everolimus.

Cautions

Noninfectious pneumonitis; Viral, fungal, or bacterial infection; Oral ulceration; Mucositis; Hyperlipidemia.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: In mild hepatic failure reduce dose by 33%; In moderate to severe hepatic failure reduce dose by 50%.

Pharmacokinetic parameters

Absorption F=5%.
Distribution Vd=128-589L, 74%protein bound.
Metabolism Extensively metabolized in the liver by CYP3A4 isoenzyme to form 6 weak metabolites.
Elimination Renal elimination is 5% with half-life of 30 hours.

Drug interactions

Dexamethasone: Dexamethasone will decrease the level or effect of everolimus by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Anemia; Anorexia; Asthenia; Constipation; Cough; Decreased lymphocytes; Diarrhea; Dry skin; Dyspnea; Edema, Epistaxis; Fatigue; Headache; Menstrual irregularities; Nausea; Pneumonitis; Pruritus; Pyrexia; Rash; Stomatitis; Vomiting.
Less common (1-10%) CHF; Hemorrhage; Hypertension; Tachycardia.
Rare but serious (less than 1%) Abdominal hernia; Angioedema; Arterial thrombotic events; Ascites; Bile duct stenosis; Cholecystitis; Cholelithiasis; Cytomegalovirus; Deep vein thrombosis; Hypokalemia; Hypomagnesemia; Hypotension; Hypothyroidism; Osteoarthritis; Ovarian cyst; Pancreatitis; Phlebitis; Sepsis; Thrombotic microangiopathy.

Ezetimide

ATC Code: C10AX09 Lipid Modifying Agents (Other Lipid Modifying Agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Mixed hyperlipidemia: 10mg daily in combination with fenofibrate.
• Primary hypercholesterolemia: 10mg daily, alone or in combination with an HMG-CoA reductase inhibitor (statin).

Dosage forms and trade names available in Iraq

Ezetimibe 10 mg tab

Off-label uses

None.

Contraindications

Hypersensitivity to ezetimibe; Active hepatic disease or unexplained persistent elevations in serum transaminase.

Cautions

Skeletal muscle toxicity; Elderly patients; Children.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Avoid.

Pharmacokinetic parameters

Absorption F=variable, food has no effect on absorption.
Distribution Vd=105L, 90% protein bound.
Metabolism Intestinal and hepatic metabolism.
Elimination Renal elimination is 11% with a half-life of 9-30 hr.

Drug interactions

Cyclosporine: Cyclosporine and ezetimibe both increases effects of the other; Monitor for potential adverse effects of cyclosporine and ezetimibe if coadministered, especially in patients with severe renal impairment.
Fenofibrate: Fenofibrate increases levels of ezetimibe by unspecified interaction mechanism.
Gemfibrozil: Gemfibrozil increases levels of ezetimibe by enhancing gastrointestinal absorption.

Side effects

Common (more than 10%) None.
Less common (1-10%) Arthralgia; Cough; Diarrhea; Fatigue; Increased liver transaminases; Influenza; Pain in extremity; Sinusitis; Upper respiratory tract symptoms.
Rare (less than 1%) None.

Patient educations

Teach patient about the role of diet, exercise, and weight loss in lowering cholesterol levels; Instruct patient to immediately report unexplained muscle pain, tenderness, or weakness while taking ezetimibe; Advise female patient of childbearing age to use effective contraception while taking ezetimibe concurrently with a statin and if she becomes pregnant to stop taking ezetimibe and statin.

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Factor IX

ATC Code: B02BD04 Antihemorrhagics (Blood Coagulation Factors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: There is not enough data to determine

Dosage forms and trade names available in Iraq

Recombinant coagulation factor IX 250 IU VIAL
BENEFIX (PFIZER Belgium).

Recombinant coagulation Factor IX 500 IU VIAL
Refixia (Novo Nordisk Denmark).

Indications and Dosage

Nonacog alpha is indicated in hemophilia B (congenital Factor IX deficiency or Christmas disease) for the control and prevention of bleeding episodes, perioperative management, and routine prophylaxis. The dosage and duration of therapy depend on the severity of the Factor IX deficiency, the location and extent of bleeding, and the patient's clinical condition.

Off-label uses

None.

Contraindications

In patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product.

Cautions

The product may contain traces of hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Factor IX replacement therapy is administered by intravenous injection, and the absorption is essentially 100%.
Distribution Factor IX is distributed within the plasma compartment.
Metabolism Metabolized by the liver.
Elimination half-life is about 24 hours.

Drug interactions

No known significant interactions.

Side effects

Common (more than 10%) Headache, cough, fever.
Less common (1-10%) Hematoma, hemorrhage at the injection site.
Rare but serious (less than 1%) Hypersensitivity reactions including anaphylaxis, development of neutralizing antibodies (inhibitors) to Factor IX.

Patient educations

• Report any signs of allergic reaction (rash, hives, difficulty breathing, swelling around the mouth) to your healthcare provider immediately.
• Regular follow-ups with your healthcare provider are necessary to monitor for the development of Factor IX inhibitors.

Factor VIII

ATC Code: B02BD02 Antihemorrhagics (Blood Coagulation Factors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

Factor VIII 250 IU/ vial
Kogenate (Bayer USA), **Novo Eight** (Novo Nordisk Denmark).

Factor VIII 500 IU/ vial
Kogenate (Bayer USA).

Indications and Dosage

• Hemophilia A, Von Willebrand disease: By i.v. injection, number of Factor VIII IU required = (body weight in kg) x (desired Factor VIII increase % of normal) x 0.5.

Off-label uses

Treatment of disseminated intravascular coagulation.

Contraindications

Hypersensitivity to any component of product.

Cautions

Hepatic disease; Patients with blood types A, B, AB (progressive anemia, intravascular hemolysis may occur).

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Undetermined
Distribution Undetermined
Metabolism Undetermined
Elimination Undetermined

Drug interactions

There are no known significant interactions.

Side effects

Anaphylaxis; Blurred vision; Chills; Fever; Headache; Lethargy; Nausea; Somnolence; Stinging at infusion site; Tachycardia; Urticaria; Vomiting.

Patient educations

Report any signs of bleeding that doesn't stop , like nosebleeds; blood in urine or stool.
Store your medication probably.

Note

Dosage is highly individualized and is based on patient's weight, severity of bleeding, and coagulation studies.

Factor XIII

ATC Code: B02BD07 Antihemorrhagics (Blood Coagulation Factors).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: There is no data available.

Dosage forms and trade names available in Iraq

Human Plasma Coagulation Factor XIII 1250 IU VIAL
Fibrogammin (CLS Behring Germany).

Indications and Dosage

Factor XIII is used for the prevention and control of bleeding in patients with Factor XIII deficiency. The dosage is individualized based on the severity of the factor XIII deficiency and the patient's clinical condition.

Off-label uses

None.

Contraindications

In patients with known hypersensitivity to human plasma-derived products.

Cautions

In patients with a history of thrombosis or who are at risk of thrombosis.
Dose adjustment in renal failure: Not typically required.
Dose adjustment in hepatic failure: Not typically required.

Pharmacokinetic parameters

Absorption Factor XIII is administered by intravenous infusion.
Distribution Not available.
Metabolism Metabolized in the reticuloendothelial system.
Elimination Excreted in urine and bile; half-life is approximately 10-14 days.

Drug interactions

No specific interactions have been identified with Factor XIII.

Side effects

Common (more than 10%) N/A
Less common (1-10%) N/A
Rare but serious (less than 1%) Hypersensitivity or allergic reactions; thromboembolic events.

Patient educations

1. Factor XIII is used to control bleeding in patients with Factor XIII deficiency. It's administered as an infusion in a healthcare setting.
2. If you experience any side effects such as shortness of breath, hives, rash, or chest discomfort, inform your healthcare provider immediately.
3. Regular monitoring of your condition and blood tests will be needed while you are receiving this medication.

Famotidine

ATC Code: A02BA03 Drugs for Acid Related Disorders (H-2Receptor Antagonists)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

- Famotidine 20mg tab
  FAMOSAM (SDI Iraq).
- Famotidine 40mg tab

Indications and Dosage

• Acute duodenal ulcer, acute gastric ulcer: 20mg bid or 40mg once daily at night, (max 40mg daily).
• Gastroesophageal reflux disease: 20mg-40mg bid for up to 12 weeks, (max 80 mg daily).
• Indigestion: 20mg bid.

Off-label uses

H.pylori eradication; Risk reduction of duodenal ulcer recurrence; Stress ulcer prophylaxis in critically ill patients; Relief of gastritis.

Contraindications

Hypersensitivity to famotidine.

Cautions

Elderly; Thrombocytopenia.
Dose adjustment in renal failure: CrCl less than 50ml/min: reduce dose by 50%.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=40-45%, food has no effect on absorption.
Distribution Vd=1.3L/kg, 10-20% protein bound.
Metabolism Minimal hepatic metabolism.
Elimination Renal elimination is 60% with a half-life of 2.5-3.5 hr.

Drug interactions

Bosutinib: Famotidine will decrease the level or effect of bosutinib by increasing gastric pH.
Digoxin: Famotidine will increase the level or effect of digoxin by increasing gastric pH.
Itraconazole: Famotidine will decrease the level or effect of itraconazole by increasing gastric pH.
Risedronate: Famotidine will increase the level or effect of risedronate by increasing gastric pH.

Side effects

Common (more than 10%) None.
Less common (1-10%) Constipation; Diarrhea; Dizziness; Headache.
Rare (less than 1%) None.

Patient educations

May take without regard to meals, antacids; Report headache; Avoid excessive amounts of coffee, aspirin; Report persistent symptoms of heartburn, acid indigestion, sour stomach.

Febuxostat

ATC Code: M04AA03 Antigout Preparations (Preparations Inhibiting Uric Acid Production).

Pregnancy category:
FDA A B **C** D X N
TGA A **B1** B2 B3 C D X N

Lactation: There is no data on presence of febuxostat in human milk.

Indications and Dosage

• Chronic Gout: Initial dose: 40 mg PO qDay, may increase to 80 mg PO qDay after 2 wk if serum uric acid <6 mg/dL is not achieved.

Off-label uses

None.

Contraindications

Hypersensitivity to febuxostat or any component of the formulation, severe liver disease, concomitant use with azathioprine or mercaptopurine.

Cautions

patients with a history of cardiovascular disease, renal impairment, or liver impairment, Cancer, Lesch-Nyhan Syndrome.

Dose adjustment in renal failure:

• CrCl <30 mL/min: Not to exceed 40 mg/day.

Dose adjustment in hepatic failure:

• Child-Pugh class C: Data not available; use with caution.

Dosage forms and trade names available in Iraq

⃠ Febuxostat 80mg tablet

F

Pharmacokinetic parameters

Absorption 49%, Peak plasma concentration: ~1.6 mcg/mL (40-mg dose); 2.6 mcg/mL (80-mg dose), Peak plasma time: 1-1.5 hr .

Distribution Protein bound: 99.2%, Vd: 50 L

Metabolism it undergoes hepatic metabolism primarily via CYP1A2.

Elimination Half-life: 5-8 hr, Excretion: Feces (45%),urine (49%).

Drug interactions

• Concurrent use with azathioprine or mercaptopurine may increase the risk of severe myelosuppression. Close monitoring of blood counts is recommended.

• Concurrent use with xanthine oxidase inhibitors (e.g., allopurinol) may increase the risk of hypersensitivity reactions. Caution is advised when using these medications concomitantly.

Side effects

Common (more than 10%): Liver function abnormalities , diarrhea, headache.

Less common (1-10%): Nausea, rash, gout flare-up, Arthralgia.

Rare but serious (less than 1%): Severe hypersensitivity reactions, cardiovascular events (such as M.I or stroke), Deafness, tinnitus, vertigo, Eye disorders, Immune system disorders.

Patient educations

Report any signs of liver problems, such as jaundice or abdominal pain, to your healthcare provider promptly.

Fenofibrate

ATC Code: C10AB05 Lipid Modifying Agents (Fibrates)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage
• Hypercholesterolemia, mixed dyslipidemia, hypertriglyceridemia: 145mg-200mg daily.

Off-label uses
Polymetabolic syndrome X.

Contraindications
Hypersensitivity to fenofibrate; Gallbladder disease.

Cautions
Pancreatitis; Cholelithiasis; Children.
Dose adjustment in renal failure: Avoid.
Dose adjustment in hepatic failure: Contraindicated.

Pharmacokinetic parameters
Absorption F=60%, minimal food effect on absorption.
Distribution Vd=60L, 99% protein bound.
Metabolism Fenofibrate is prodrug that undergoes rapid hydrolysis at the ester bond to fenofibric acid. Fenofibric acid is glucuronidated in the liver.
Elimination Renal elimination is 60-93% with a half-life of 24 hr.

Dosage forms and trade names available in Iraq
Fenofibrate 145mg tablet
Lipanthyl (Abbott Ireland).
Fenofibrate 200 mg capsules
Lipanthyl (Abbott Ireland).

Drug interactions
Ezetimibe: Fenofibrate may increase the serum concentration of ezetimibe.
Warfarin: Fenofibrate may enhance the anticoagulant effect of vitamin k antagonists also fenofibrate may increase the serum concentration of warfarin.

Side effects
Common (more than 10%) Increased liver function tests.
Less common (1-10%) Abdominal pain; Back pain; Constipation; Creatine phosphokinase increased; Headache; Nausea; Respiratory disorder; Rhinitis.
Rare (less than 1%) None.

Patient educations
Instruct patient to take with meals for best effect; Remind patient that he still needs to follow a triglyceride lowering diet; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness; Advise patient to minimize GI upset by eating frequent, small servings of food and drinking plenty of fluids; Tell patient that drug may take up to 2 months to alter lipid values.

Fentanyl

ATC Code: N01AH01 Anesthetics (Opioid Anesthetics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Fentanyl should not be used unless there are no safer alternatives.

Dosage forms and trade names available in Iraq

- Fentanyl 100mcg sublingual tablet
  Abstral (Kyowa Kirin UK).
- Fentanyl 200mcg sublingual tablet
  Abstral (Kyowa Kirin UK).
- Fentanyl as citrate 50 mcg/ml (10ml Amp)
  FENTANYL HAMELN (Hameln Germany).
- Fentanyl as citrate 50 mcg/ml (2ml amp.)
  FENTANYL HAMELN (Hameln Germany).

Indications and Dosage

• Surgery premedication: By slow i.v. injection, 50mcg-100mcg prior to surgery.
• General anesthesia, minor surgical procedures: By i.v. injection 0.5mcg-2mcg/kg/dose.
• General anesthesia, major surgery: Initially i.v. injection, 2mcg-20mcg/kg/dose then maintenance i.v. infusion 1mcg-2mcg/kg/hour, discontinue infusion 30-60 min prior to end of surgery.

Off-label uses

Analgesia for severe pain.

Contraindications

Hypersensitivity to fentanyl; Acute or severe bronchial asthma; Paralytic ileus.

Cautions

Diabetes mellitus; Severe or chronic pulmonary or hepatic disease; Cardiovascular disease; CNS tumors; Adrenal insufficiency; Hypothyroidism; Alcoholism or drug abuse; Elderly patients.
Dose adjustment in renal failure: CrCl less than 10ml/min: reduce dose by 50%.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Not applicable.
Distribution Vd=6L/kg, 80-85% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 75% with a half-life of 20-24 hr.

Drug interactions

Selegiline: selegiline increases toxicity of fentanyl, severe and unpredictable potentiation by selegiline has been reported with fentanyl.

Side effects

Angina pectoris; Anorexia; Anxiety; Apnea; Application-site reaction; Asthenia; Back pain; Bradycardia; Bronchitis; Cardiac arrest; Constipation; Dry mouth; Dyspepsia; Dysphoria; Dyspnea; Euphoria; Fever; Hallucinations; Hemoptysis; Hiccups; Micturition disorder; ST-segment elevation; Syncope; Tremor; Upper respiratory tract infection; Urinary retention; Urticaria; Visual disturbances.

Fexofenadine

ATC Code: R06AX26 Antihistamines for Systemic Use (Other Antihistamines for Systemic Use)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 **B2** B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Seasonal allergic rhinitis, idiopathic urticaria: 120mg-180mg daily.

Off-label uses

Perennial allergic rhinitis.

Contraindications

Hypersensitivity to fexofenadine.

Cautions

Elderly patients.

Dose adjustment in renal failure: CrCl 10-50ml/min: 60mg daily; CrCl less than 10ml/min: 30mg daily.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Fexofenadine 120mg tablet
  Fexofenadine (Chanelle Ireland).
- Fexofenadine 180mg tablet
  Fexofenadine (Chanelle Ireland).

Pharmacokinetic parameters

Absorption F=not established, fexofenadine rapidly absorbed.

Distribution Vd=5.4-5.8L/kg.

Metabolism Little hepatic or extrahepatic metabolism.

Elimination Fecal elimination is 50% with a half-life of 14-18 hr.

Drug interactions

Bosutinib: Bosutinib increases levels of fexofenadine by P-glycoprotein efflux transporter.

Diazepam: Diazepam and fexofenadine both increases effects of the other by pharmacodynamic synergism, coadministration may potentiate the CNS-depressant effects of each drug.

Gabapentin: Gabapentin and fexofenadine. Either increases effects of the other by pharmacodynamic synergism. Modify Therapy/Monitor Closely. Coadministration of CNS depressants can result in serious, life-threatening, and fatal respiratory depression. Use lowest dose possible and monitor for respiratory depression and sedation.

Side effects

Common (more than 10%) Vomiting.

Less common (1-10%) Back pain; Cough; Diarrhea; Dizziness; Dysmenorrhea; Headache; Pain in extremity; Pyrexia; Rhinorrhea; Somnolence; Stomach discomfort; Upper respiratory tract infection.

Rare (less than 1%) None.

Patient educations

Avoid tasks that require alertness, motor skills until response to drug is established; Avoid alcohol during antihistamine therapy; Coffee, tea may help reduce drowsiness; Do not take with any fruit juices.

Fibrinogen

ATC Code: B02BB01 Antihemorrhagics (Fibrinogen).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: There are no data.

Dosage forms and trade names available in Iraq

Human fibrinogen 1g Vial.
Haemocomplettan (CSL Behring GmbH, Germany), **Fibryga** (Wien Austria).

F

Indications and Dosage

Fibrinogen is used in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. The dosage depends on the severity of the fibrinogen deficiency and on the patient's clinical condition.

Off-label uses

None.

Contraindications

Hypersensitivity to human fibrinogen or any components of the preparation.

Cautions

Thrombosis can occur if doses exceed 100 mg per kg of body weight when given to patients with dysfibrinogenemia and hypo dysfibrinogenemia.
Dose adjustment in renal failure: Not established as of my last update.
Dose adjustment in hepatic failure: Not established as of my last update.

Pharmacokinetic parameters

As a naturally occurring protein in the body, traditional pharmacokinetic measures like **absorption and elimination** don't apply in the same way. The body naturally produces and regulates fibrinogen levels.

Drug interacions

Other coagulation factor products: these could theoretically increase the risk of clotting.
Anticoagulants: these could theoretically decrease the effectiveness of fibrinogen.

Side effects

Common (more than 10%): Not established as of my last update.
Less common (1-10%): Not established as of my last update.
Rare but serious (less than 1%): Allergic reactions; thromboembolic events.

Patient Education

1. Fibrinogen is a critical protein for blood clotting.
2. Report any signs of allergic reactions (like rash; itching; swelling) or unusual clotting (like chest pain; trouble breathing; pain; swelling; warmth in the leg).

Filgrastim

ATC Code: L03AA02 Immunostimulants (Colony Stimulating Factors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Chemotherapy induced neutropenia: By i.v. or s.c injection, initially 5mcg/kg/day, may increase by 5mcg/kg for each chemotherapy cycle based on duration and severity of neutropenia, continue for up to 14 days or until absolute neutrophil count reaches 10000 cells/mm3.

• Bone marrow transplant: By i.v. or s.c injection, 10mcg/kg/day.

• Chronic neutropenia, congenital neutropenia: By i.v. or s.c injection, initially 6mcg/kg/dose bid.

•Radiation injury syndrome: By s.c injection, 10mcg/kg once daily, continue until absolute neutrophil count remains greater than 1000 cells/mm3 for 3 consecutive CBCs.

Dosage forms and trade names available in Iraq

Filgrastim 30 million units/ 0.5ml PFS
Nivestim (Pfizer Europe Belgium).

Off-label uses

Treatment of AIDS related neutropenia in patients receiving zidovudine; Anemia in myelodysplastic syndrome; Hepatitis C virus infection treatment associated neutropenia.

Contraindications

Hypersensitivity to filgrastim.

Cautions

Gout; Psoriasis; Neutrophil count greater than 50,000 cells/mm3; Sickle cell disease.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=62-71%.
Distribution Vd=0.15L/kg.
Metabolism Degraded systemically.
Elimination Mainly eliminated by neutrophil mediated clearance with half-life of 1.8-3.5 hours.

Drug interactions

Cyclophosphamide: filgrastim may enhance the adverse effect of cyclophosphamide, the risk of pulmonary toxicity may be enhanced.

Side effects

Common (more than 10%) Alopecia; Bone pain; Diarrhea; Fatigue; Fever; Nausea; Vomiting.
Less common (1-10%) Anorexia; Chest pain; Constipation; Cough; Dyspnea; Headache; Rash; Sore throat.
Rare but serious (less than 1%) Acute myeloid leukemia; Alveolar hemorrhage Glomerulonephritis; Myelodysplastic syndrome; Sickle cell crisis.

Patient educations

Report fever, severe bone pain, chest pain, palpitations, difficulty breathing.

Finasteride

ATC Code: G04CB01 Urologicals (Testosterone-5-Alpha Reductase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Finasteride is not indicated for use in females.

Indications and Dosage

- Benign prostatic hyperplasia: 5mg once daily.
- Male pattern alopecia: 1mg once daily.

Off-label uses

Acne in women; Hirsutism.

Contraindications

Hypersensitivity to finasteride.

Cautions

Obstructive uropathy; Increased risk of high grade prostate cancer; Decrease in serum prostate specific antigen (PSA) level; Women (not indicated); Children (not indicated).

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Finasteride 5 mg tab

Pharmacokinetic parameters

Absorption F=63%, minimal food effect on absorption.

Distribution Vd=76L, 90% protein bound.

Metabolism Hepatic metabolism less than 20%.

Elimination Renal elimination is 40% with a half-life of 6 hr.

Drug interactions

Clarithromycin: Clarithromycin will increase the level or effect of finasteride by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) None.

Less common (1-10%) Breast enlargement; Decrease libido; Ejaculation disorder; Erectile dysfunction.

Rare (less than 1%) Breast tenderness; Rash.

Patient educations

Tell patient may take drug with or without food; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness; Inform patient that he may experience erectile dysfunction and decreased ejaculate. Advise him to discuss these issues with prescriber; Tell patient he may need at least 6 months of therapy for BPH treatment and at least 3 months to see improvement in male-pattern baldness; Inform patient with BPH that he'll undergo periodic digital rectal exams; Instruct patient not to donate blood for at least 1 month after last dose.

Fingolimod

ATC Code: L04AA27 Immunosuppressants (Selective Immunosuppressants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Multiple sclerosis: 0.5mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to fingolimod; Sick sinus syndrome; Second degree or higher conduction block; Recent myocardial infarction; Unstable angina; Stroke; TIA.

Cautions

Bradycardia; Ischemic heart disease; Diabetes; Hypokalemia; Hypomagnesemia; History of syncope; Uveitis.

Dose adjustment in renal failure: In severe renal failure, use of fingolimod with caution.

Dose adjustment in hepatic failure: In severe hepatic failure, use of fingolimod with caution.

Dosage forms and trade names available in Iraq

Fingolimod 0.5mg cap
Melior (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=90-93%.
Distribution Vd=1200±260L, 99.7%protein bound.
Metabolism Metabolized mostly by the CYP450 4F2 enzyme system.
Elimination Renal elimination is 81% with half-life of 6-9 hours.

Drug interactions

Amiodarone: Fingolimod increases effects of amiodarone by pharmacodynamic synergism, due to increased risk of bradycardia, AV block, and torsade de pointes, concomitant use is contraindicated.
Other drugs: disopyramide; dofetilide; dronedarone ; ibutilide; procainamide; quinidine; sotalol; thioridazine; upadacitinib.

Side effects

Common (more than 10%) Abdominal pain; Cough; Diarrhea; Headache; Influenza viral infection; Nausea; Sinusitis.
Less common (1-10%) Actinic keratosis; Alopecia; Asthenia; Back pain; Basal cell carcinoma; Blurred vision; Bradycardia; Bronchitis; Depression; Dizziness; Dyspnea; Eye pain; Gastroenteritis; Herpes viral infections; Herpes zoster; Hypertension; Increased blood triglycerides; Leukopenia; Lymphopenia; Migraine; Pain in extremity; Paresthesia; Sinusitis; Skin papilloma; Tinea infections; Tinea versicolor; Weight decreased.
Rare but serious (less than 1%) Macular edema; Seizures.

Patient educations

Obtain regular eye examinations during and for 2 months following treatment; Use effective methods of contraception during and for 3 months following treatment; Treatment may increase risk of certain cancers; report new skin lesions, fever, chills, night sweats, generalized weakness, weight loss, or pain or swelling of the lymph nodes.

Flavoxate

ATC Code: G04BD02 Urologicals (Drugs for Urinary Frequency and Incontinence).

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Insufficient information, caution is recommended.

Dosage forms and trade names available in Iraq

Flavoxate Hydrochloride 200 mg tablet
Urispas (Recordati Ireland).

Indications and Dosage

Treat symptoms such as frequent or urgent urination, increased night-time urination, bladder pain, and incontinence. Typically, the dosage is one or two 200 mg tablets three or four times a day.

Off-label uses

None.

Contraindications

In patients who have any of the following obstructive conditions: pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, gastrointestinal hemorrhage, and obstructive uropathies of the lower urinary tract.

Cautions

Patients with bladder outlet obstruction and risks of urinary retention should be treated with caution.
Dose adjustment in renal failure: Not requird.
Dose adjustment in hepatic failure: Not requird.

Pharmacokinetic parameters

Absorption Rapidly absorbed from the GI tract.
Distribution Unknown.
Metabolism Extensively metabolized in the liver.
Elimination 57% to 60% of an orally administered dose is excreted in the urine within 24 hours primarily as the glucuronide conjugate.

Drug interaction

Flavoxate + Anticholinergic drugs: May increase the risk of side effects of anticholinergic drugs.
Flavoxate + Potassium Chloride: May increase the risk of gastrointestinal side effects of potassium chloride.

Side effects

Common (more than 10%): Dry mouth; blurred vision; dizziness; nausea.
Less common (1-10%): Headache; constipation; dyspepsia.
Rare but serious (less than 1%): Angioedema; anaphylactic reactions; difficulty breathing.

Patient education

1. This medication may cause dizziness or blurred vision. Avoid driving or operating machinery until you know how it affects you.
2. Report any severe side effects like difficulty breathing or swallowing to your doctor immediately.

Fluconazole

ATC Code: J02AC01 Antimycotics for Systemic Use (Triazole and Tetrazole Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

- Candidal vulvovaginitis: 150mg single dose.
- Systemic candidiasis: 400mg daily.
- Cryptococcal meningitis: 400mg-800mg daily for 8 weeks, then 200 mg daily for 6-12 months.
- Oropharyngeal candidiasis: 100mg-200mg daily for 7-14 days.

Dosage forms and trade names available in Iraq

Fluconazole 50mg cap
DIFLUCAN (Pfizer UK).

Fluconazole 150 mg cap
FLUCONAZ (SDI Iraq), **FLUCOZOL** (PIONEER IRAQ).

Off-label uses

Cryptococcal pneumonia; Candidal intertrigo; Onychomycosis due to dermatophyte; Tinea.

Contraindications

Hypersensitivity to fluconazole.

Cautions

Hypokalemia; Potentially proarrhythmic conditions.
Dose adjustment in renal failure: CrCl less than 50ml/min: reduce dose by 50%.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.
Distribution Vd=0.6L/kg, 11-12%protein bound.
Metabolism Partially hepatic metabolism.
Elimination Renal elimination is 80% with a half-life of 30 hr.

Drug interactions

Clopidogrel: Fluconazole (strong CYP2C19 inhibitor) may decrease serum concentrations of the active metabolites of clopidogrel, due to a risk for impaired clopidogrel effectiveness with such a combination, carefully consider the need for a strong CYP2C19 inhibitor in patients receiving clopidogrel, monitor patients closely for evidence of a diminished response to clopidogrel.

Side effects

Common (more than 10%) Headache.
Less common (1-10%) Abdominal pain; Diarrhea; Nausea; Rash; Vomiting.
Rare (less than 1%) None.

Patient educations

Teach patient how to recognize and immediately report signs and symptoms of allergic response; Urge patient to contact prescriber if rash occurs, to determine whether Stevens-Johnson syndrome is developing; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness; Advise patient to minimize gastrointestinal upset by eating frequent, small servings of food and drinking adequate fluids; Tell female patient to inform prescriber if she is pregnant or breastfeeding.

Anti Diabetic Line By Pioneer

Pioxiga
Dapagliflozin Propnediol
5mg 10ml

Sitavia
Sitagliptin
500mg 100ml

Pioryl
Glimepiride
1mg 2mg

Piophage
Metformin Hydrochloride
500mg 850mg 1000mg

PIONEER CO.
FOR PHARMACEUTICAL INDUSTRIES

Fludarabine

ATC Code: L01BB05 Antineoplastic Agents (Purine Analogues)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Chronic lymphocytic leukemia: By i.v. injection, 25mg/m^2 daily for 5 consecutive days, continue for up to 3 additional cycles, begin each course of treatment every 28 days.

Off-label uses

Acute myeloid leukemia; Acute myeloid leukemia; Follicular lymphoma; Mantle cell lymphoma; Non-Hodgkin lymphoma; Waldenström macroglobulinemia.

Dosage forms and trade names available in Iraq

Fludarabine phosphate 50mg/vial
Fludara (Baxter Oncology Germany).

Contraindications

Hypersensitivity to fludarabine.

Cautions

Renal insufficiency; Granulocytopenia; Seizure disorder; Spasticity; Peripheral neuropathy; Infection; Fever before administration; Immunodeficiency.

Dose adjustment in renal failure: CrCl 50-80ml per minute decrease dose to 20mg/m^2; CrCl 30-49ml per minute decrease dose to 15mg/m^2; CrCl less than 15ml per minute, use of fludarabine is not recommended.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=55%.

Distribution Vd=96.2±26.0L/m^2, 19-29% protein bound.

Metabolism Fludarabine phosphate is rapidly dephosphorylated in the serum to fludarabine.

Elimination Renal elimination is 40-60% with half-life of 20 hours.

Drug interactions

Natalizumab: Fludarabine may enhance the adverse effect of natalizumab, the risk of concurrent infection may be increased, avoid combination.

Side effects

Common (more than 10%) Anemia; Anorexia; Cough; Diaphoresis; Diarrhea; Dyspnea; Edema; Fatigue; Fever; Infection; Leukopenia (partly therapeutic); Malaise; Myalgia; Neutropenia; Objective weakness; Pain; Paresthesia; Pneumonia; Rash; Visual disturbances.

Less common (1-10%) Abdominal pain; Alopecia; Angina; Arrhythmia; Back pain; Constipation; DVT; Flu like syndrome; Headache; Hearing Loss; Malaise; Peripheral edema; Pharyngitis; Stomatitis.

Rare but serious (less than 1%) None.

Patient educations

Avoid crowds and exposure to infection; Maintain strict oral hygiene; Promptly report fever, sore throat, signs of local infection; bleeding from any site; Report bloody urine or stool, decreased urinary output, blindness, confusion, nerve pain, seizure activity, weakness.

Flucinolone Acetonide

ATC Code: D07AC04 Corticosteroids, Dermatological Preparations (Corticosteroids, Potent (Group III))

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Atopic dermatitis, psoriasis, seborrheic dermatitis: Apply topically as a thin film to the affected area tid.

Off-label uses

None.

Contraindications

Hypersensitivity to flucinolone.

Cautions

hypersensitivity to corticosteroids.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Flucinolone acetonide 0.025% ointment

Pharmacokinetic parameters

Absorption is determined by multiple factors, including the integrity of the skin barrier and the specific product formulation.

Distribution is managed through metabolic pathways similar to systemically administered corticosteroids.

Metabolism primarily metabolized in the liver, similar to other corticosteroids.

Elimination primarily excreted by the kidneys, with a smaller portion also being excreted in bile.

Drug interactions

There are no known significant interactions.

Side effects

Acneiform eruptions; Burning; Dryness; Erythema; Intracranial hypertension; Ketatosis pilaris; Papules; Pigmentation changes; Pustules; Skin atrophy; Striae; Telangiectasia.

Patient educations

Avoid use with occlusive dressing; Avoid contact with face (i.e. eyes, nose, mouth), axillae, or groin; Instruct patient on correct technique of flucinolone acetonide administration; Emphasize importance of avoiding the eyes; Apply missed doses as soon as remembered unless almost time for the next dose; Caution patient to use only as directed. Avoid using cosmetics, bandages, dressings, or other skin products over the treated area unless directed by health care professional; Advise parents of pediatric patients not to apply tight-fitting diapers or plastic pants on a child treated in the diaper area; these garments work as an occlusive dressing and may cause more of the drug to be absorbed; Caution women that medication should not be used extensively, in large amounts, or for protracted periods if they are pregnant or planning to become pregnant; Instruct patient to inform health care professional if symptoms of underlying disease return or worsen or if symptoms of infection develop.

Fluorometholone

ATC Code: S01BA04 Ophthalmologicals (Corticosteroids, Plain)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

Used to treat inflammation of the eye including inflammation of the cornea and conjunctiva. Typical dosage: 1-2 drops into the conjunctival sac of the affected eye(s) 2-4 times per day.

Off-label uses

None.

Contraindications

In most viral diseases of the cornea and conjunctiva; fungal diseases of ocular structures, acute untreated bacterial infections, and hypersensitivity to any component of the medication.

Cautions

In patients with glaucoma as prolonged use may result in glaucoma with optic nerve damage, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Flaorometholone 0.1% eye drop

F

Pharmacokinetic parameters

Absorption: Fluorometholone is minimally absorbed systemically after topical administration.

Distribution: Vd= Unknown, as the drug is minimally absorbed systemically.

Metabolism: Any absorbed drug would be expected to follow corticosteroid metabolism, but this is unlikely to be clinically significant.

Elimination: Any absorbed drug would be expected to be excreted in urine, but this is unlikely to be clinically significant.

Drug interactions

Fluorometholone + Nonsteroidal anti-inflammatory drugs (NSAIDs): May increase the risk of healing problems.

Fluorometholone + Other corticosteroids: Concurrent use with other corticosteroids may increase intraocular pressure or exacerbate infection.

Side effects

Common (more than 10%) Increased intraocular pressure; discomfort or minor burning/stinging upon instillation.

Less common (1-10%) Blurred vision; photophobia; conjunctival hyperemia.

Rare but serious (less than 1%) Secondary ocular infection; cataract formation; delayed wound healing; optic nerve damage.

Patient educations

1. Do not touch the tip of the dropper to any surface or your eye to avoid contamination.
2. Avoid using this medication longer than prescribed; it can lead to increased pressure in your eyes over time.
3. Inform your doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye.

Fluorouracil

ATC Code: L01BC02 Antineoplastic Agents (Pyrimidine Analogues)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

• Colon and rectum cancer: By i.v. injection, 400mg/m² on day 1, followed by 2400mg-3000mg/m² as a continuous i.v. infusion over 46 hr every 2 weeks.
• Breast cancer: By i.v. injection, 500mg or 600mg/m² on days 1 and 8 every 28 days for 6 cycles.
• Gastric cancer: 200mg-1000mg/m²/day as a continuous infusion over 24 hr.
• Pancreatic cancer: By i.v. injection, 400mg/m² on day 1, followed by 2400mg/m² as a continuous infusion over 46 hr every 2 weeks.

Off-label uses

Treatment of carcinoma of bladder, cervical, endometrial, head or neck, anal, esophageal, renal cell, unknown primary cancer.

Contraindications

Hypersensitivity to fluorouracil; Myelosuppression; Poor nutritional status; Potentially serious infections.

Dosage forms and trade names available in Iraq

Fluorouracil 500mg/10ml injection
5-Fluorouracil „Ebewe“ (EBEWE Pharma. Austria).

Fluorouracil 1000mg/20ml vial
5-Fluorouracil „Ebewe“ (EBEWE Pharma. Austria).

Fluorouracil 5% cream
Efudix (MEDA Pharma Germany).

Cautions

History of high dose pelvic irradiation; Palmar plantar erythrodysesthesia syndrome (hand and foot syndrome); Previous use of alkylating agents.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use with extreme caution.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=1.9L/kg, 8-12%protein bound.
Metabolism Metabolized by dihydropyrimidine dehydrogenase to a less toxic compound.
Elimination Excreted primarily in urine with half-life of 10-20 minutes.

Drug interactions

Covid-19 vaccine: Immunosuppressants may diminish the therapeutic effect of covid-19 vaccine.

Side effects

Common (more than 10%): None.
Less common (1-10%): Alopecia; Diarrhea; Hand-foot syndrome; Headache; Loss of appetite; Maculopapular eruption (pruritic); Mucositis; Myelosuppression; Nausea; Photosensitivity; Vomiting.
Rare but serious (less than 1%): Angina; Coronary arteriosclerosis; Darkening of veins; Gastrointestinal ulcer; Hyperbilirubinemia; Nystagmus; Ophthalmic findings; Thrombophlebitis.

Patient educations

Maintain strict oral hygiene; Report signs and symptoms of infection, unusual bleeding, visual changes, nausea, vomiting, diarrhea, chest pain, palpitations; Avoid sunlight; wear protective clothing, sunglasses, sunscreen.

Fluoxetine

ATC Code: N06AB03 Psychoanaleptics (Selective Serotonin Reuptake Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Fluoxetine 20mg cap

Indications and Dosage

• Depression: 20mg daily, may titrate to 80mg daily.
• Panic disorder: 10mg daily, may increase to 60mg daily.
• Premenstrual dysphoric disorder: 20mg daily for 14 days prior to expected start of menses.

Off-label uses

Treatment of fibromyalgia; post-traumatic stress disorder; Raynaud's phenomena; Social anxiety disorder; Selective mutism.

Contraindications

Hypersensitivity to fluoxetine.

Cautions

Seizure disorder; Cardiac dysfunction; Diabetes; Patients with risk factors for QT prolongation; Patients at high risk for suicide; Patients where weight loss is undesirable; Elderly; Acute narrow angle glaucoma or increased intraocular pressure.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use cautiously.

Pharmacokinetic parameters

Absorption F=100%, food has no effect on absorption.
Distribution Vd=12-43L/kg, 95% protein bound.
Metabolism Hepatic metabolism more than 90%.
Elimination Renal elimination is 60% with half-life of 1-4 days while (7-15) days for active metabolite.

Drug interactions

Citalopram: Citalopram may enhance the serotonergic effect of fluoxetine, this could result in serotonin syndrome, fluoxetine may increase the serum concentration of citalopram, limit citalopram dose to a maximum of 20mg/day.
Benzodiazepines: Half-life of Diazepam prolonged.
Carbamazepine: Elevated plasma anticonvulsant concentrations and possible toxicity.

Side effects

Common (more than 10%) Anorexia; Anxiety; Asthenia; Diarrhea; Headache; Insomnia; Nausea; Nervousness; Somnolence; Tremor; Weakness.
Less common (1-10%) Abnormal dreams; Abnormal vision; Chills; Constipation; Decreased libido; Dizziness; Dry mouth; Dyspepsia; Fever; Flatulence; Flu syndrome; Impotence; Palpitation; Rash; Urinary frequency; Vomiting.
Rare (less than 1%) Periods and Heavy bleeding; Weight gain.

Patient educations

Encourage patient to establish effective bedtime routine to minimize sleep disorders; Tell patient drug may take 4 weeks or longer to be fully effective; Instruct patient to contact prescriber if he develops worsening depression or has suicidal thoughts; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness.

Fluphenazine

ATC Code: N05AB02 Psycholeptics (Phenothiazines with Piperazine Structure)

Pregnancy category:
FDA A B C D X **N**
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Fluphenazine Decanoate 25mg/1ml amp

Indications and Dosage

• Psychosis: By i.m. or subcutaneous injection, 25mg every 2 weeks, after achieving steady state, effects of a single injection may last 4-6 weeks.

Off-label uses

None.

Contraindications

Hypersensitivity to fluphenazine; Severe CNS depression; Comatose states; Severe depression; Subcortical brain damage; Presence of blood dyscrasias or liver damage.

Cautions

Paralytic ileus; Decreased gastrointestinal motility; Xerostomia; Urinary retention; Benign prostatic hyperplasia; History of seizures; Brain damage; Alcohol withdrawal.

Dose adjustment in renal failure: Use with caution

Dose adjustment in hepatic failure: Use with caution

Pharmacokinetic parameters

Absorption F=35%.

Distribution Vd=216±61L.

Metabolism Metabolized in the liver by CYP2D6 isoenzyme.

Elimination Elimination half-life is 6.8-9.6 days.

Drug interactions

Indapamide: Fluphenazine and indapamide both increase QTc interval.

Side effects

Common (more than 10%) Akathisia; Anticholinergic effects; Confusion; Decreased gag reflex; Dyskinesia; Dystonia; Erectile dysfunction; Muscle stiffness; Neuroleptic malignant syndrome (NMS; infrequent but serious); Oligomenorrhea or amenorrhea; Parkinsonism; Sedation; Tardive dyskinesia; Weight gain.

Less common (1-10%) Agitation; Anorexia; Anxiety; Cerebral edema; Constipation; Depression; Dizziness; Dyspepsia; Euphoria; Headache; Ileus; Lens opacities (with prolonged use); Orthostatic hypotension (after IM injection); Poikilothermia; Restlessness; Tachycardia; Weakness.

Rare but serious (less than 1%) Blood dyscrasia; Cholestatic jaundice; Diarrhea; ECG changes; Ejaculatory disorder; Galactorrhea; Photosensitivity; Priapism; Pruritus; Seizure.

Patient educations

Patient teaching Tell patient not to stop taking drug suddenly, because serious adverse effects may occur; Advise patient to report urinary retention or constipation. Instruct patient to immediately report unusual bleeding; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration, alertness, and vision; Tell patient to avoid activities that can cause injury; Advise him to use soft toothbrush and electric razor to avoid gum and skin injury.

Flurbiprofen

ATC Code: M01AE15 Anti-inflammatory and Antirheumatic Products (Propionic Acid Derivatives)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

•Rheumatoid arthritis, osteoarthritis: 100mg bid or tid.

•Intraoperative miosis: Apply 1 drop every 30 min starting 2 hr before surgery for total of 4 doses.

Off-label uses

Dysmenorrhea pain.

Contraindications

Hypersensitivity to flurbiprofen; Active peptic ulcer; Chronic inflammation of gastrointestinal tract; Gastrointestinal bleeding or ulceration, Treatment of perioperative pain following CABG surgery.

Cautions

History of mild to moderate heart failure; Peripheral arterial disease; Hypertension; Hyperlipidemia; Diabetes mellitus; Smoking; SLE; Asthma; Edema; Hypovolemia; Dehydrated and debilitated patients; Elderly; Not for prolonged use.

Dose adjustment in renal failure: In severe renal failure, use of flurbiprofen is not recommended.

Dose adjustment in hepatic failure: Avoid use in severe hepatic failure.

Dosage forms and trade names available in Iraq

- Flurbiprofen 100mg tablet
- Flurbiprofen 0.03% eye drops

Pharmacokinetic parameters

Absorption F= 96%.

Distribution Vd=0.12L/kg, 99%protein bound.

Metabolism Hepatic cytochrome P450 2C9 plays an important role in the metabolism of flurbiprofen to its major metabolite, 4-hydroxy-flurbiprofen.

Elimination Renal elimination is 70% with half-life of 4.7-5.7 hours.

Drug interactions

Apixaban: Flurbiprofen and apixaban both decrease anticoagulation.

Side effects

Fibrosis; Increased bleeding tendency of ocular tissues in conjunction with ocular surgery; Irritation; May slow corneal wound healing; Mild ocular stinging; Miosis; Mydriasis; Ocular hyperemia.

Patient educations

Take drug with food or meals if gastrointestinal upset occurs; Take only the prescribed dosage; If using eyedrops, review proper administration; Avoid use during pregnancy, serious adverse effects could occur. Using barrier contraceptives is advised; Dizziness or drowsiness can occur (avoid driving or using dangerous machinery); Report sore throat, fever, rash, itching, weight gain, swelling in ankles or fingers, changes in vision, black or tarry stools, bleeding.

Fluticasone Propionate

ATC Code: R03BA05 Drugs for Obstructive Airway Diseases (Glucocorticoids).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Excreted into breast milk. However, systemic effects are considered unlikely due to the low serum levels.

Dosage forms and trade names available in Iraq

- Fluticasone propionate 0.005% Ointment
- Fluticasone propionate 50µg/dose suspension for nasal

Indications and Dosage

Used in the management of the nasal symptoms of seasonal and perennial allergic and non-allergic rhinitis in adults and pediatric patients aged 4 years and older. The recommended dose for adults is 2 sprays (50 mcg/spray) in each nostril once daily (total daily dose, 200 mcg).

F

Off-label uses

For nasal polyps.

Contraindications

Hypersensitivity to fluticasone propionate or any of its ingredients.

Cautions

In patients with recent nasal ulcers, nasal surgery, or nasal trauma.

Dose adjustment in renal failure: Not typically required

Dose adjustment in hepatic failure: Not typically required.

Pharmacokinetic parameters

Absorption Negligible systemic absorption.

Distribution It is assumed to remain in the nasal cavity.

Metabolism Minimal metabolism.

Elimination Primarily via the feces.

Drug interaction

Fluticasone + Ritonavir: Co-administration can significantly increase plasma concentrations of fluticasone, increasing the risk of systemic corticosteroid side-effects.

Fluticasone + Ketoconazole: Co-administration can increase plasma concentrations of fluticasone, increasing the risk of systemic corticosteroid side-effects.

Side effects

Common (more than 10%): Nosebleeds; nasal irritation.

Less common (1-10%): Headache; sore throat.

Rare but serious (less than 1%): Perforation of the nasal septum; glaucoma; cataracts.

Patient education

1. This medication is for use in the nose, avoid contact with the eyes.
2. Report any severe side effects like vision changes or signs of a severe allergic reaction to your doctor immediately.

Folic Acid

ATC Code: B03BB01 Antianemic Preparations (Folic Acid and Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

- Folic acid deficiency: 1mg-5mg once daily.
- Pregnancy prophylaxis: 0.4mg-1mg once daily.

Off-label uses

Methotrexate toxicity prophylaxis.

Contraindications

Hypersensitivity to folic acid.

Cautions

Anemias (aplastic; normocytic, pernicious) when anemia present with vitamin B12 deficiency.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Folic acid 400µg tablet
  folic acid (Dubai co. IRAQ), Folic acid (Al-Kindi IRAQ).
- Folic acid 1mg tab
  FOLIC ACID (SAFA IRAQ).
- Folic acid 5 mg tablet
  FOLIC ACID (Wadi Al-Rafidain IRAQ).

Pharmacokinetic parameters

Absorption F=76-93%, food has no effect on absorption.

Distribution Stored in the liver and most tissues.

Metabolism Folic acid metabolized in the liver to active metabolite, 5-methyltetrahydrofolate.

Elimination Renal elimination is 30%.

Drug interactions

Aspirin: Aspirin decreases levels of folic acid by inhibition of GI absorption.

Bumetanide: Bumetanide decreases levels of folic acid by increasing renal clearance.

Carbamazepine: Carbamazepine decreases levels of folic acid by unspecified interaction mechanism.

Conjugated estrogens: Conjugated estrogens decreases levels of folic acid by altering metabolism.

Metformin: Metformin decreases levels of folic acid by unspecified interaction mechanism.

Sulfamethoxazole: Sulfamethoxazole decreases levels of folic acid by inhibition of GI absorption.

Sulfasalazine: Sulfasalazine decreases levels of folic acid by inhibition of GI absorption.

Side effects

Bronchospasm; Erythema; Malaise; Pruritus; Rash; Slight flushing.

Patient educations

Eat foods rich in folic acid, including fruits, vegetables, organ meats.

Follitropin Alpha

ATC Code: G03GA05 Sex Hormones and Modulators of The Genital System (Gonadotropins)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Follitropin alpha (recombinant Follicle stimulating hormone) 75 I.U S.C. injection

GONAL-F (Merck-Serono Italy).

Indications and Dosage

• Ovulation induction: By subcutaneous injection, 75 IU daily, after 14 days, increase dose by increments of up to 37.5 IU, further dose increases, as necessary every 7 days, (max 300 IU daily).

• Assisted reproductive technologies: Initial dose on cycle day 2 or 3, 150 IU subcutaneously daily until sufficient follicular development, typically does not exceed 10 days.

• Male patients with hypogonadotropic hypogonadism: By subcutaneous injection, 150 IU 3 times per week, if azoospermia persists, may increase dose to 300 IU 3 times per week, may need to administer for up to 18 months for adequate response.

Off-label uses

None.

Contraindications

Hypersensitivity to follitropin alpha; Ovarian enlargement or cyst not due to polycystic ovarian disease; Gynecological hemorrhages of unknown etiology; Ovarian carcinoma; Uterine carcinoma; Tumor of the hypothalamus and pituitary gland; Primary ovarian failure; Malformation of sexual organs incompatible with pregnancy; Fibroid tumor of uterus incompatible with pregnancy.

Cautions

Follitropin alpha may result in multiple births; Ovarian hyperstimulation syndrome; Hypothyroidism; Hyperprolactinemia.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=66-76%.

Distribution Vd=8L.

Metabolism Undetermined.

Elimination Elimination via liver and kidneys with half-life of 35 hours.

Drug interactions

there are no known significant interactions.

Side effects

Common (more than 10%) Headache; Vascular disorders; Ovarian cysts; Injection site reactions; hematoma.

Less common (1-10%) Abdominal pain; Abdominal distension; Abdominal discomfort; Nausea; Vomiting; Diarrhea; Acne; Gynecomastia; varicocele; Weight gain.

Rare but serious (less than 1%) Thromboembolism; Exacerbation or aggravation of asthma.

Patient educations

A Patient education is not currently available for this monograph.

Fondaparinux Sodium

ATC Code: B01AX05 Antithrombotic Agents (Other Antithrombotic Agents)

Pregnancy category:
FDA A B C D X **N**
TGA A B1 B2 B3 **C** D X N

Lactation: No information is available.

Dosage forms and trade names available in Iraq

- Fondaparinux Sodium 2.5mg/0.5ml prefilled syringe
  Arixtra (Aspen Irland).
- Fondaparinux Sodium 7.5 mg/0.6ml pre-filled syringe
  Arixtra (Aspen Ireland).

Indications and Dosage

Fondaparinux is indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism, in patients undergoing hip fracture surgery, hip replacement surgery, knee replacement surgery, or abdominal surgery. Typical dosage for adult patients is 2.5 mg subcutaneously once daily.

Off-label uses

Treatment of heparin-induced thrombocytopenia (HIT).

Contraindications

In patients with severe renal impairment, bacterial endocarditis, major bleeding, or thrombocytopenia associated with positive tests for antiplatelet antibodies in the presence of fondaparinux.

Cautions

In elderly patients, patients with renal or hepatic impairment, or those at increased risk of bleeding.

Dose adjustment in renal failure: Avoid use in patients with a creatinine clearance <30 mL/min.

Dose adjustment in hepatic failure: Not typically required but use with caution.

Pharmacokinetic parameters

Absorption Bioavailability is nearly 100% following subcutaneous administration.

Distribution Vd = 7 to 11 L.

Metabolism Minimal metabolism.

Elimination Excreted unchanged in urine, with a half-life of approximately 17 to 21 hours.

Drug interaction

Fondaparinux + other anticoagulants: Increased risk of bleeding.

Fondaparinux + NSAIDs: Increased risk of bleeding.

Side effects

Common (more than 10%): Bleeding; anemia.

Less common (1-10%): Thrombocytopenia; wound complications.

Rare but serious (less than 1%): Serious bleeding (e.g., gastrointestinal; retroperitoneal).

Patient educations

1. Avoid activities that may increase your risk of bleeding.
2. Report any unusual bleeding, bruising, or signs of thrombocytopenia (e.g., purpura, petechiae) to your doctor immediately.

Fosfomycin

ATC Code: J01XX01 Antibacterials for Systemic Use (Other Antibacterials)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation:Fosfomycin crosses the placenta but Considered safe to use during breast-feeding.

Dosage forms and trade names available in Iraq

Fosfomycin 3g (granules sachet)
Berny Adult (So.Se. pharm Italy).

Indications and Dosage

Indicated for the treatment of uncomplicated urinary tract infections (UTIs) in women and bladder infections caused by susceptible strains of Escherichia coli and Enterococcus faecalis. Single dose of 3 g with 3-4 ounces (oz) of water.

Off-label uses

Treatment of multi-drug resistant bacterial infections:
2-3 g with 3-4 oz of water every 2-3 days for 3 doses
Prostatitis: 3 g with 3-4 oz of water per 2-3 days or 3 g per Day for 1 week followed by 3 g per 48hr for ≥6 weeks

Contraindications

Hypersensitivity to fosfomycin or any component of the formulation.

Cautions

Patients with a history of renal dysfunction or individuals with known seizure disorders, Patients with perinephric abscess or pyelonephritis

Dose adjustment in renal failure: Not required; however, efficacy may be decreased.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Bioavailability is approximately 37% after oral administration.

Distribution Vd = 136 L (intravenous)

Metabolism Not metabolized

Elimination Predominantly in urine (38% to 50% as unchanged drug), with a half-life of 5.7 hours.

Drug interaction

Fosfomycin + Metoclopramide: Decreased absorption of fosfomycin

Fosfomycin + Cholera Vaccine: Cholera Vaccine may decrease the effectiveness of Fosfomycin.

Side effects

Common (more than 10%): Diarrhea; headache; nausea; vaginitis.

Less common (1-10%): Dizziness; dyspepsia; abdominal pain.

Rare but serious (less than 1%): Hypersensitivity reactions, including angioedema and anaphylaxis; Clostridium difficile-associated diarrhea.

Patient educations

1. Take on an empty stomach at least 2-3 hours after a meal.
2. Mix granules with 3 to 4 ounces of water before consuming.
3. Report persistent or worsening symptoms of urinary tract infection, or new symptoms of diarrhea or hypersensitivity, to healthcare provider.

Fulvestrant

ATC Code: L02BA03 Antineoplastic and Immunomodulating Agents (Anti-Estrogens)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Its use during breastfeeding is not recommended as it may pass into breast milk.

Dosage forms and trade names available in Iraq

Fulvestrant 250mg pre-filled syringe
Faslodex (Astra Zeneca UK).

Indications and Dosage

Fulvestrant is indicated for the treatment of hormone receptor-positive metastatic advanced breast cancer in postmenopausal women who have not responded to other anti-estrogen medications. The dosage and administration regimen may vary based on the specific treatment plan. Usually 250 mg administered intramuscularly into the buttocks (gluteal area) on Days 1, 15, 29, and once monthly thereafter. After the initial dose, the maintenance dose of 500 mg is administered intramuscularly into the buttocks (gluteal area) once monthly.

Off-label uses

None.

Contraindications

Hypersensitivity to fulvestrant or any of its components; Pregnancy or breastfeeding; Severe hepatic impairment; previous thromboembolic events.

Cautions

Caution should be exercised in patients with a history of bleeding disorders or liver disease; As it may cause a reduction in platelet count, which can lead to an increased risk of bleeding;It may cause liver function abnormalities, so monitoring of liver function is necessary during treatment; Hypercalcemia; Peripheral Edema.
Dose adjustment in renal failure: Not typically required in renal failure.
Dose adjustment in hepatic failure: Not typically required in hepatic failure, but caution and monitoring are necessary due to potential liver function abnormalities.

Pharmacokinetic parameters

Absorption Fulvestrant is administered intramuscularly, and its absolute bioavailability is unknown.
Distribution (Vd) is high (3 to 5 L/kg), indicating extensive distribution into tissues. Fulvestrant is approximately 99% protein-bound, primarily to albumin.
Metabolism Fulvestrant is mainly metabolized in the liver by cytochrome P450 enzymes.
Elimination Excretion of fulvestrant occurs primarily through feces (about 90%) with a half-life of approximately 40 days.

Drug interactions

• Concurrent use of strong CYP3A4 inhibitors may increase fulvestrant levels, which could lead to an increased risk of side effects.
• Combination with other hormonal therapies like aromatase inhibitors or tamoxifen may reduce the efficacy of fulvestrant and should be avoided.

Side effects

Common (more than 10%): Injection site reactions (e.g., pain, swelling); Nausea; Headache.
Less common (1-10%): Fatigue; Hot flashes; Joint pain.
Rare but serious (less than 1%): Blood clotting disorders- Liver function abnormalities- Allergic reactions.

Furosemide

ATC Code: C03CA01 Diuretics (Sulfonamides, plain)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

• Edema related to heart failure, renal failure, hepatic failure: Initially, 20mg-80mg daily, (max 600mg daily).
• Hypertension: 40 mg bid.

Off-label uses

Hypercalcemia associated with cancer.

Contraindications

Hypersensitivity to furosemide; Anuria.

Cautions

Hepatic cirrhosis; Hepatic coma; Severe electrolyte depletion; Prediabetes; Diabetes; Systemic lupus erythematosus; Prostatic hyperplasia; Urinary stricture.
Dose adjustment in renal failure: Avoid use in oliguric states.
Dose adjustment in hepatic failure: Not required, decreased effect, increased sensitivity to hypokalemia and volume depletion in cirrhosis.

Dosage forms and trade names available in Iraq

- Furosemide 20 mg/2ml amp
  Piozex (PIONEER IRAQ).
- Furosemide 20mg/5ml oral Solution
  Fudesix (Help Greece).
- Furosemide 40 mg tab
  LASIMEX (SDI Iraq), Kinemide (Al-Kindi Iraq).

Pharmacokinetic parameters

Absorption F=47-70%, food may lower Cmax and Tmax.
Distribution Protein bound 91-99%.
Metabolism Minimal hepatic metabolism 10%.
Elimination Renal elimination is 60-90% with a half-life of 30-120 min.

Drug interactions

Aminoglycosides: Furosemide may enhance the adverse effect of aminoglycosides, nephrotoxicity and ototoxicity.
Allopurinol: Furosemide may enhance the adverse effect of allopurinol, furosemide may increase the concentration of oxypurinol, an active metabolite of allopurinol.

Side effects

Common (more than 10%) Hypokalemia, Hyperuricemia.
Less common (1-10%) None.
Rare (less than 1%) Skin reaction; Interstitial nephritis; Ototoxicity.

Patient educations

Instruct patient to take in morning with food (and second dose, if prescribed, in afternoon), to prevent Nocturia; Tell patient that drug may cause serious interactions with many common drugs, Instruct him to tell all prescribers he's taking it; Instruct patient to report signs and symptoms of ototoxicity (hearing loss, ringing in ears, vertigo) and other drug toxicities; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness; Instruct patient to move slowly when rising, to avoid dizziness from sudden blood pressure decrease; Encourage patient to discuss need for potassium and magnesium supplements with prescriber; Caution patient to avoid alcohol and herbs while taking this drug.

Fusidic Acid

ATC Code: N02AX02 Analgesics (Other Opioids)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Sodium Fusidate 2% ointment
  Fucisam (SDI Iraq).
- Sodium Fusidate 2% Cream
  Fucidin (Leo Ireland).
- Fusidic acid 1% eye drop

Indications and Dosage

• Treatment of primary and secondary skin infections caused by sensitive strains of Staphylococcus aureus, Streptococcus spp: Apply to the affected skin area tid or qid.

• Bacterial infections of the eye caused by susceptible organisms: Instill 1 drop into the eye bid. Treatment should be continued for 2 days after the eye appears normal.

Off-label uses

None.

Contraindications

Hypersensitivity to fusidic acid.

Cautions

Hepatic disease; Neonates.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Avoid.

Pharmacokinetic parameters

Absorption F=91% for oral fusidic acid, absorption through normal skin is neglected.

Distribution Vd=Undetermined, 97-99% protein bound.

Metabolism Absorbed fusidic acid is extensively metabolized.

Elimination Fusidic acid is excreted mainly in the bile with little excreted in the urine with half-life of 5-6 hours.

Drug interactions

Drug interactions with systemically administered drugs are considered minimal as the systemic absorption of topical fusidic acid is negligible.

Side effects

Common (more than 10%) None.

Less common (1-10%) Dermatitis; Eczema; Erythema; Pruritus; Rash.

Rare but serious (less than 1%) Angioedema; Application site irritation; Blister; Conjunctivitis; Urticaria.

Patient educations

Bacterial resistance among staphylococcus aureus has been reported to occur with the use of topical fusidic acid. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance. Extended or recurrent use may increase the risk of developing contact sensitization; Fusidic acid contains excipients may cause local skin reactions, irritation to the eyes and mucous membranes. Fucidin cream should therefore be used with care when applied in the proximity of the eyes.

Gabapentin

ATC Code: N02BF01 Analgesics (Gabapentinoids)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Partial seizure: Initially, 300mg tid, may titrate to 600mg tid, (max 2400mg-3600mg daily).
• Post-herpetic neuralgia: 300mg on day 1, 300mg bid on day 2, 300mg tid on day 3, may titrate dose to 600mg tid.

Off-label uses

Treatment of neuropathic pain; Diabetic peripheral neuropathy; Vasomotor symptoms; Fibromyalgia; Postoperative pain adjunct; Restless leg syndrome.

Contraindications

Hypersensitivity to gabapentin.

Cautions

Elderly; History of suicidal behavior; Substance abuse.
Dose adjustment in renal failure: CrCl 30-60ml/min: 400mg-1400mg bid; CrCl 15-29ml/min: 200mg-700mg once daily.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Gabapentin 100 mg cap
Gabapentin 300 mg cap
Nurona (Pharma International Jordan).
Gabapentin 400 mg cap
Nurona (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=27-60%, food has no effect on absorption.
Distribution Vd=58L, less than 3% protein bound.
Metabolism Not metabolized.
Elimination Renal elimination is 76-81% and 10-23% in feces with a half-life of 5-7 hr.

Drug interactions

Metoclopramide: Metoclopramide may enhance the CNS depressant effect of gabapentin.

Side effects

Common (more than 10%) Ataxia; Dizziness; Drowsiness; Fatigue; Somnolence.
Less common (1-10%) Constipation; Depression; Diplopia; Dry mouth; Dysarthria; Dyspepsia; Hyperkinesia; Nervousness; Peripheral edema; Pharyngitis; Pruritus; Rhinitis; Tremor; Vasodilation; Weight gain.
Rare (less than 1%) Abnormal vision; Anorexia; Arthralgia; Asthenia; Hypertension; Malaise; Paresthesia; Purpura; Vertigo.

Patient educations

Tell patient gabapentin may take with or without food and to take first dose at bedtime to reduce adverse effects; Caution patient not to stop taking drug suddenly, dosage must be tapered to minimize seizure risk; Advise patient not to drink alcohol while taking gabapentin.

SENERGY®

Amlodipine / Valsartan

SENERGY® PLUS

Amlodipine / Valsartan / Hydrochlorothiazide

Falling Down Blood Pressure

UNITED PHARMACEUTICALS part of MS pharma

Falling Down Blood Pressure

ENERGY®
Amlodipine / Valsartan

ENERGY® PLUS
Amlodipine / Valsartan / Hydrochlorothiazide

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Gadobutrol

ATC Code: V08CA09 Contrast Media (Paramagnetic Contrast Media).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N
Lactation: Insufficient data

Dosage forms and trade names available in Iraq

Gadobutrol 604.72mg/ml (1mmol/ml) injection
Gadovist (Bayer Germany).

Indications and Dosage

Indicated for intravenous use in magnetic resonance imaging (MRI) in adults and children to detect and visualize areas with disrupted blood-brain barrier and/or abnormal vascularity of the central nervous system.
Dose: 0.1 mmol/kg body weight (0.1 mL/kg body weight).

Off-label uses

Used for enhancement in MR angiography for diagnostic purposes.

Contraindications

Hypersensitivity to gadobutrol or any components of the product.

Cautions

Increased risk of nephrogenic systemic fibrosis in patients with renal impairment. Exercise caution in patients with a history of seizure disorder.
Dose adjustment in renal failure: Avoid use in patients with severe renal impairment (GFR <30 mL/min/1.73m^2) unless the diagnostic information is essential and not available with non-contrast MRI.
Dose adjustment in hepatic failure: Not typically required.

Pharmacokinetic parameters

Absorption N/A, administered intravenously
Distribution Vd = 200 mL/kg; no protein binding
Metabolism Not metabolized
Elimination Eliminated unchanged via glomerular filtration in kidneys with a half-life of approximately 1.8 hours.

Drug interaction

Gadobutrol + Metformin: Increased risk of Metformin-induced lactic acidosis in patients receiving gadobutrol due to the potential for decreased renal clearance of Metformin.
Gadobutrol + NSAIDs: Increased risk of Gadobutrol-induced renal toxicity.

Side effects

Common (more than 10%) Headache; nausea
Less common (1-10%) Dizziness; dysgeusia; feeling hot
Rare but serious (less than 1%) Hypersensitivity reactions including anaphylactic shock; nephrogenic systemic fibrosis; seizure.

Patient educations

1. Inform patients to report any allergic reaction experienced in the past with contrast agents.
2. Advise patients to remain well-hydrated before receiving gadobutrol.
3. Advise patients to report any immediate side-effects like rash, itching, or difficulty breathing.

Gadoteric Acid

ATC Code: V08CA02 Contrast Media (Paramagnetic Contrast Media).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: The manufacturer recommends that caution be used when giving gadoteridol to nursing women.

Dosage forms and trade names available in Iraq

Gadoteric acid 279.32mg (0.5mmol/ml) 20ml vial
Dotagraf (Bayer Germany).

Indications and Dosage

• **Central Nervous System:** 0.1 mmol/kg (0.2 mL/kg) administered as a rapid intravenous infusion (10 mL/min to 60 mL/min) or bolus (greater than 60 mL/min). In patients suspected of having poorly enhanced lesions, in the presence of negative or equivocal scans, a second dose of 0.2 mmol/kg (0.4 mL/kg) may be given up to 30 minutes after the first dose.
• **Extracranial and Extraspinal Tissues:** 0.1 mmol/kg (0.2 mL/kg) administered as a rapid intravenous infusion (10 mL/min to 60 mL/min) or bolus (greater than 60 mL/min).

Off-label uses

None.

Contraindications

Hypersensitivity to gadoteric acid or any component of the formulation, severe renal impairment (glomerular filtration rate < 30 mL/min/1.73 m^2), acute renal failure, Nephrogenic Systemic Fibrosis (NSF) (Black Box Warning)

Cautions

History of allergic reactions to contrast agents, severe cardiovascular disease, or conditions predisposing to renal impairment.
Dose adjustment in renal failure: Gadoteric acid is contraindicated .
Dose adjustment in hepatic failure: No specific dose adjustment is typically required in hepatic failure.

Pharmacokinetic parameters

Absorption Gadoteric acid is administered intravenously and is not absorbed systemically.
Distribution Vd: 179 mL/kg (females); 211 mL/kg (males); approximately 95% protein bound.
Metabolism Gadoteric acid is not metabolized.
Elimination primarily eliminated unchanged via the kidneys; Half-life: 1.4 hr (females); 2 hr (males); 5.1 hr (moderate renal impairment; 13.9 hr (severe renal impairment).

Drug interaction

• Concurrent use with nephrotoxic agents (e.g., NSAID, aminoglycosides) may increase the risk of renal toxicity, particularly in patients with pre-existing renal impairment.
• Concurrent use with other gadolinium-based contrast agents should be avoided due to the potential for additive adverse effects.

Side effects

Common (more than 10%): Injection site reactions (such as pain or warmth), headache, nausea.
Less common (1-10%): Dizziness, pruritus, rash, Back pain, transient increase in creatinine levels.
Rare but serious (less than 1%): Anaphylactic reactions, Respiratory distress.

Galsulfase

ATC Code: A16AB08 Other Alimentary Tract and Metabolism Products (Enzymes).

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: It is not yet known

Indications and Dosage

Indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome). Dosage: 1 mg/kg of body weight administered once weekly as an intravenous infusion.

Off-label uses

None.

Contraindications

None.

Cautions

Anaphylaxis and severe allergic reactions have been observed in patients during and up to 24 hours after infusion; use with caution in patients susceptible to fluid overload, or patients with an acute febrile or respiratory illness.

Dose adjustment in renal failure: Not typically required.

Dose adjustment in hepatic failure: Not typically required, as hepatic impairment is not expected to affect the pharmacokinetics of galsulfase.

Dosage forms and trade names available in Iraq

Galsulfase 1mg/ml (5-ml vial)
Naglazyme (BioMarin Pharmaceutical USA).

Pharmacokinetic parameters

Absorption Not applicable for this intravenously administered drug
Distribution Vd= not available
Metabolism Metabolized by peptides and proteins into smaller peptides and amino acids
Elimination Primarily eliminated through uptake into cells and metabolism. Exact excretion and half-life unknown.

Drug interaction

No known significant interactions.

Side effects

Common (more than 10%): Rash; pain; pruritus; headache; fever; urticaria; chills.
Less common (1-10%): Abdominal pain; diarrhea; nausea; vomiting.
Rare but serious (less than 1%): Anaphylaxis; severe allergic reactions.

Patient educations

This medication can cause severe allergic reactions. Seek immediate medical attention if you experience difficulty breathing, swelling of the face, or severe dizziness.

Ganciclovir

ATC Code: J05AB06 Antivirals for Systemic Use (Nucleosides and Nucleotides Excl. Reverse Transcriptase Inhibitors)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Dosage forms and trade names available in Iraq

Ganciclovir 1.5g/1g ophthalmic gel

Indications and Dosage

• Prevention of cytomegalovirus in transplant patients: By i.v. injection, 5mg/kg/dose bid for 7–14 days, then 5mg/kg/day as a single daily dose.
• Congenital cytomegalovirus: 6mg/kg/dose bid for 6 weeks (if HIV positive, longer duration may be considered).

Off-label uses

Cytomegalovirus retinitis.

Contraindications

Hypersensitivity to ganciclovir.

Cautions

Neutropenia; Thrombocytopenia; Absolute neutrophil count less than 500 cells/mm3; Platelet count less than 25,000 cells/mm3.
Dose adjustment in renal failure: CrCl 50-70ml per minute decrease dose to 2.5mg/kg every 24 hours; CrCl 10-49ml per minute decrease dose to 1.25mg/kg every 24 hours; CrCl less than 10ml per minute decrease dose to 0.625mg/kg three times per week.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=0.74 ±0.15L/kg, 1-2%protein bound.
Metabolism Little to no metabolism.
Elimination Renal elimination is 90% with half-life of 2.9 hours.

Drug interactions

Imipenem: Ganciclovir may enhance the adverse effect of imipenem. specifically, the risk of seizures may be increased, avoid concomitant use of these drugs unless the prospective benefits of therapy outweigh the risks.

Side effects

Common (more than 10%) Neutropenia; Thrombocytopenia.
Less common (1-10%) Anemia; Confusion; Headache; Nausea; Neuropathy; Paresthesia; Pruritus; Rash; Retinal detachment; Sepsis; Vomiting; Weakness.
Rare but serious (less than 1%) None.

Patient educations

Ganciclovir provides suppression, not cure, of cytomegalovirus (CMV); Frequent blood tests, eye exams are necessary during therapy due to toxic nature of drug; Report any new symptom promptly; May temporarily or permanently inhibit sperm production in men, suppress fertility in women; Barrier contraception should be used during and for 90 days after therapy due to mutagenic potential.

Ganirelix

ATC Code: H01CC01 Pituitary and Hypothalamic Hormones and Analogues (Anti-Gonadotropin-Releasing Hormones)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Indications and Dosage

• Female infertility: By subcutaneous injection, 0.25mg once daily during day 2 or 3 of cycle, continue treatment until day of chorionic gonadotropin administration.

Off-label uses

None.

Contraindications

Hypersensitivity to ganirelix; Postmenopausal women.

Cautions

Women with signs and symptoms of active allergic conditions.
Dose adjustment in renal failure: Avoid use in moderate to severe renal failure.
Dose adjustment in hepatic failure: Avoid use in moderate to severe hepatic failure.

Dosage forms and trade names available in Iraq

Ganirelix 0.25mg / 0.5ml pfs
Orgalutran (Merk Sharp & Dohme Netherland).

Pharmacokinetic parameters

Absorption F=91.1%.
Distribution Vd=43.7L, 81.9%protein bound.
Metabolism Metabolized via enzymatic hydrolysis to 2 primary metabolites (1-4 and 1-6 peptide).
Elimination Renal elimination is 22% with half-life of 16.2 hours.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Headache; Injection site reaction; Nausea; Ovarian hyperstimulation syndrome; Pelvic pain; Vaginal bleeding.
Rare but serious (less than 1%) Anaphylactoid reactions.

Patient educations

Inform patient about possible adverse reactions; Teach patient about duration of treatment and required monitoring procedures; Urge patient to tell prescriber if she is pregnant before starting drug.

Gatifloxacin

ATC Code: S01AE06 Antiinfectives (Fluoroquinolones)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Excretion in milk unknown, Caution is advised during lactation.

Dosage forms and trade names available in Iraq

Gatifloxacin5mg/5ml Eye Drop

Indications and Dosage

• **Bacterial Conjunctivitis:** depend on the concentration if 0.3%: Days 1-2: Instill 1 gtt to affected eye(s) q2hr while awake, up to 8 xday than on Days 3-7: Instill 1 gtt to affected eye(s) up to QID; If 0.5%: Day 1: Instill 1 gtt to affected eye(s) q2hr while awake, up to 8 xday than on Days 2-7: Instill 1 gtt BID-QID on Days 2-7.

Off-label uses

Blepharitis, Acute Meibomianitis, Dacryocystitis.

Contraindications

Known hypersensitivity to gatifloxacin or other fluoroquinolones.

Cautions

Use with caution in patients with a history of central nervous system disorders.
Dose adjustment in renal failure: Data not available.
Dose adjustment in hepatic failure: Data not available.

Pharmacokinetic parameters

Absorption Undetectable in the system.
Distribution Undetectable in the system.
Metabolism Undetectable in the system.
Elimination Undetectable in the system.

Drug interactions

• Concurrent use with other drugs that prolong the QT interval may increase the risk of serious cardiac arrhythmias.
• Gatifloxacin may enhance the effects of oral anticoagulants, necessitating monitoring and potential dosage adjustments.

Side effects

Common (more than 10%): None.
Less common (1-10%): Conjunctival irritation, Increase lacrimation, Keratitis, Papillary conjunctivitis, Conjunctival hemorrhage, Chemosis, Dry eye, Eye discharge, Eye irritation, Eye pain, Eyelid swelling, Red eye, Visual acuity decrease, Taste disturbance.
Rare but serious (less than 1%): peripheral neuropathy, severe allergic reactions.

Patient educations

Wash hands well before use. Shake the eye drops well before use. The head should be tilted slightly, the lower eyelid pulled, instill the number of drops specified by the doctor, then close your eyes for two minutes. It is prohibited to touch the tip of the dropper with the hand, and it is also prohibited to touch it directly with the eyes. Avoid using contact lenses during the treatment period.

Gefitinib

ATC Code: L01EB01 Antineoplastic Agents (Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitors).
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: It is unknown

Dosage forms and trade names available in Iraq

Gefitinib 250 mg tab
IRESSA (Astra Zeneca UK).

Indications and Dosage

Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. Dosage: 250 mg orally once daily with or without food.

Off-label uses

No official uses, but some studies suggest potential efficacy in other EGFR mutation-positive cancers.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Cautions

Diarrhea; skin reactions; interstitial lung disease and ocular disorders including corneal erosion; abnormal eyelash growth; keratitis.
Dose adjustment in renal failure: Not typically required.
Dose adjustment in hepatic failure: Not typically required.

Pharmacokinetic parameters

Absorption Bioavailability is 60%
Distribution Vd=1400 L, <90% protein bound
Metabolism Primarily metabolized in the liver by CYP3A4
Elimination Primarily fecal excretion with a half-life of 48 hours

Drug interaction

Rifampicin: a strong CYP3A4 inducer, can significantly decrease the plasma concentration of gefitinib.
Omeprazole: a proton pump inhibitor, can significantly reduce the bioavailability of gefitinib.

Side effects

Common (more than 10%): Diarrhea; rash; acne; dry skin; nausea; vomiting
Less common (1-10%): Stomatitis; anorexia; conjunctivitis
Rare but serious (less than 1%): Interstitial lung disease; severe hepatic impairment; severe bullous skin reactions; ocular disorders.

Patient educations

1. Report any new or worsening symptoms such as breathlessness; cough or fever which could indicate interstitial lung disease.
2. Avoid pregnancy while on this medication and for some time after the last dose due to risk of harm to the unborn baby.

Gelatin Polysuccinate

ATC Code: B05AA06 Blood Substitutes and Perfusion Solutions (Blood Substitutes and Plasma Protein Fractions).
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: No information available

Indications and Dosage

Gelatin polysuccinate is typically used as a plasma volume expander in the treatment of hypovolemia due to hemorrhage, surgery, or burns. Dosage is individualized based on patient condition and response.

Off-label uses

None.

Contraindications

Known hypersensitivity to the product, severe hyperhydration, and congestive heart failure.

Cautions

In patients with renal impairment, heart disease, and electrolyte abnormalities.
Dose adjustment in renal failure: Use with caution, may require dosage adjustment or discontinuation in case of severe renal impairment.
Dose adjustment in hepatic failure: No specific information available. Use with caution.

Dosage forms and trade names available in Iraq

Gelatin Polysuccinate 4% 500ml gel solution for infusion
Gelofusine (B.Braun Germany).

Pharmacokinetic parameters

Absorption As an infusion, gelatin polysuccinate is directly introduced into the bloodstream.
Distribution Expands intravascular volume.
Metabolism Not metabolized.
Elimination Excreted in urine with a half-life of approximately 3-4 hours.

Drug interaction

No significant interactions.

Side effects

Common (more than 10%): N/A
Less common (1-10%): N/A
Rare but serious (less than 1%): Hypersensitivity reactions, hyperhydration, electrolyte imbalance, renal impairment.

Patient educations

Inform healthcare provider if any adverse reactions occur during or after the infusion.

Gemcitabine

ATC Code: L01BC05 Antineoplastic Agents (Pyrimidine Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Gemcitabine 1g vial

Indications and Dosage

• Breast cancer: By i.v. injection, 1250mg/m² over 30 min on days 1 and 8 of each 21-day cycle.
• Non-small cell lung cancer: By i.v. injection, 1000mg/m² on days 1, 8, and 15, repeated every 28 days, or 1250mg/m² on days 1 and 8, repeat every 21 days.
• Pancreatic cancer: By i.v. injection, 1000mg/m² once weekly for up to 7 weeks.

Off-label uses

Treatment of biliary tract carcinoma; Bladder carcinoma; Hodgkin's lymphoma; Non-Hodgkin's lymphoma.

Contraindications

Hypersensitivity to gemcitabine.

Cautions

Concurrent radiation therapy; Impaired pulmonary function.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%, food has no effect on absorption.
Distribution Vd=50L/m² (following infusions lasting less than 70 minutes), 370L/m² (long infusions), 10% protein bound.
Metabolism Converted in cells to active tri-phosphate metabolites.
Elimination Renal elimination is 92-98% with half-life of 32-94 minutes.

Drug interactions

Covid-19 vaccine: Immunosuppressant may diminish the therapeutic effect of covid-19 vaccine.

Side effects

Common (more than 10%) Alopecia; Anemia; Constipation; Diarrhea; Dyspnea; Edema; Fever; Flu-like syndrome; Hematuria; Hemorrhage; Infection; Leukopenia; Neutropenia; Pain; Proteinuria; Rash; Thrombocytopenia.
Less common (1-10%) Bronchospasm; Creatinine increased; Injection site reactions; Paresthesia.
Rare but serious (less than 1%) Arrhythmias; Capillary leak syndrome; Cellulitis; Desquamation and bullous skin eruptions; Gangrene; Hepatic veno-occlusive disease; Pseudocellulitis; Pulmonary edema; Pulmonary fibrosis; Supraventricular arrhythmias; Thrombotic microangiopathy.

Patient educations

Avoid crowds, exposure to infection; Maintain strict oral hygiene; Promptly report fever, sore throat, signs of local infection, easy bruising, rash, yellowing of skin or eyes.

Gemifloxacin

ATC Code: J01MA15 Antibacterials for Systemic Use (Fluoroquinolones)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Acute bacterial exacerbation of chronic bronchitis: 320mg once daily for 5 days.
• Community acquired pneumonia: 320mg once daily for 7 days.

Off-label uses

None.

Contraindications

Hypersensitivity to gemifloxacin.

Cautions

Seizure; Myasthenia gravis; Rheumatoid arthritis; History of QT interval prolongation; Bradycardia; Acute myocardial ischemia; Uncorrected electrolyte disorders.
Dose adjustment in renal failure: CrCl less than 40ml per minute, decrease dose to 160mg once daily.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Gemifloxacin Mesylate 320mg tablet
Factive (LG chem Korea)

Pharmacokinetic parameters

Absorption F=71%.
Distribution Vd=1.66-12.12L/kg, 60-70%protein bound.
Metabolism Minimal hepatic metabolism.
Elimination Renal elimination is 36% with half-life of 7 hours.

Drug interactions

Ondansetron: Gemifloxacin and ondansetron both increase QTc interval, avoid with congenital long QT syndrome; ECG monitoring recommended with concomitant medications that prolong QT interval, electrolyte abnormalities, CHF, or bradyarrhythmias.
Tretinoin topical: Gemifloxacin increased photo toxicity of tretinoin topical.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Diarrhea; Dizziness; Headache; Nausea; Neutropenia; Platelets increased; Rash; Thrombocythemia; Transaminases increased; Vomiting.
Rare but serious (less than 1%) Peripheral neuropathy; Photosensitivity; Tendon rupture.

Patient educations

Instruct patient to take drug at same time each day, with or without food; Advise patient to take iron, vitamins, antacids, or sucralfate 3 hours before or 2 hours after gemifloxacin; Advise patient to stop taking drug and immediately report sudden severe pain in shoulder or hand.

Gentamicine

ATC Code: J01GB03 Antibacterials for Systemic Use (Aminoglycoside Antibacterials)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

Gentamicin 20mg/2ml amp
Piogent (PIONEER IRAQ).

Gentamicin as Sulphate 80mg/2ml amp
Piogent (PIONEER IRAQ).

Gentamicin 0.3% skin cream
GENIDINE (SDI Iraq).

Gentamicin sulphate 0.3% eye ointment
GENIDINE (SDI Iraq).

Gentamicin sulfate 3mg/ml 0.3% eye drop
Piogent (PIONEER IRAQ).

Indications and Dosage

• Acute pelvic, bone, intraabdominal, joint, respiratory tract, burn wound, postoperative, skin infections, complicated urinary tract infection, septicemia, meningitis: By i.v. or i.m. injection, 3mg-6mg/kg/day in divided doses every 8 hr or 4mg-7mg/kg once daily.
• Superficial eye infections: Apply thin strip to conjunctiva bid or tid.
• Superficial skin infections: Apply to the affected area tid or qid.

Off-label uses

Surgical (preoperative) prophylaxis.

Contraindications

Hypersensitivity to gentamicin.

Cautions

Elderly; Neonates due to renal insufficiency or immaturity; Neuromuscular disorders (potential for respiratory depression); Vestibular or cochlear impairment; Renal impairment; Hypocalcemia; Myasthenia gravis.
Dose adjustment in renal failure: CrCl 41-60ml per minute increase interval to every 36 hours; CrCl 20-40ml per minute increase interval to every 48 hours; CrCl less than 20ml per minute, monitor levels.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=79-100%.
Distribution Vd=0.2-0.3L/kg, 0-30%protein bound.
Metabolism Gentamicin undergoes little to no hepatic metabolism.
Elimination Renal elimination is 90% with half-life of 2-4 hours.

Drug interactions

Carboplatin: Gentamicin may enhance the ototoxic effect of carboplatin, especially with higher doses of carboplatin.

Side effects

Common (more than 10%) Ataxia; Gait instability; Nephrotoxicity; Neurotoxicity; Ototoxicity; Vertigo.
Less common (1-10%) Edema; Itching; Rash; Reddening of skin.
Rare but serious (less than 1%) Anorexia; Dyspnea; Enterocolitis; Headache; Increased salivation; Muscle cramps; Photosensitivity; Stinging; Thrombocytopenia; Vomiting; Weakness; Weight loss.

Patient educations

Discomfort may occur with i.m injection; Blurred vision, tearing may occur briefly after each ophthalmic dose; Report any hearing, visual, balance, urinary problems, even after therapy is completed.

Glibenclamide

ATC Code: A10BB01 Drugs Used in Diabetes (Sulfonylureas)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Diabetes mellitus (type 2): Initially, 1.25mg–5mg, may increase by 2.5mg/day at weekly intervals, maintenance 1.25mg–20mg/day as single or divided doses, (max 20mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to glibenclamide; Diabetic ketoacidosis with or without coma; Type 1 diabetes mellitus.

Cautions

Stress; Elderly; Debilitated patients; Malnourished; G6PD deficiency; Adrenal or pituitary insufficiency.
Dose adjustment in renal failure: CrCl less than 60ml per minute, use of glibenclamide is not recommended.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Glibenclamide 5mg tab
DAONEER (PioneerIraq).

Pharmacokinetic parameters

Absorption Readily absorbed from the gastrointestinal tract, time to peak plasma concentration 2-4 hours.
Distribution Vd=19.3-52.6L, 99.9%protein bound.
Metabolism Glibenclamide is metabolized mainly by CYP3A4.
Elimination Renal elimination is 50% with half-life of 4-13.4 hours.

Drug interactions

Beta-blockers: may enhance the hypoglycemic effect of glibenclamide, cardio selective beta-blockers (such as atenolol and metoprolol may be safer than nonselective beta-blockers, all beta-blockers appear to mask tachycardia as an initial symptom of hypoglycemia).

Side effects

Agranulocytosis; Angioedema; Arthralgia; Blurred vision; Bullous reactions; Cholestatic jaundice; Disulfiram-like reaction; Heartburn; Hemolytic anemia; Hypoglycemia; Hyponatremia; Nausea; Nocturia; Pancytopenia; Paresthesia; Photosensitivity reaction; Pruritus; Rash; Thrombocytopenia; Urticaria; Vasculitis; Vomiting; Weight gain.

Patient educations

Advise patient to take daily dose with breakfast; Inform patient that he may need supplemental insulin during times of stress or when he can't maintain adequate oral intake; Teach patient how to recognize signs and symptoms of hypoglycemia and hyperglycemia; Instruct patient to keep sugar source available at all times; Encourage patient to drink plenty of fluids; Stress importance of diet and exercise in helping to control diabetes.

Dermatology
medicines

Protection and care
for all skin problems

Dubai Pharmaceutical Industries

DUBAI

DuDermocalm cream

Calamine 8 % w/w - Glycerin 10% w/w - Camphor 0.1% w/w

- Used to relieve pain and itching associated with dermatitis and skin diseases, it gives a feeling of coldness when applied to the skin, reducing pain and discomfort.

DuNyslacort ointment

Nystatin - Gramicidin - Neomycin-Triamcinolone Acetonide.

- Inflammation of skin, itchy skin rashes, bacterial and fungal skin infection.

Flamaziburn cream

Silver sulfadiazine 1%

- It's used to prevent and treat wound infections in patients with second- and third-degree burns

Betason cream

Betamethasone BP 0.1%

- Skin irritation, eczema, psoriasis and other skin inflammation.

Betason ointment

Betamethasone BP 0.1%

- Skin irritation, eczema, psoriasis and other skin inflammation.

Tetracycline ointment

Tetracycline 3%

- It is used to treat or prevent skin infections, also used to treat acne and skin ulcers.

DERMOSAM ointment

Clobetasol propionate 0.05%.

- Used on the skin to treat swelling, itching, irritation and also soothing skin.

DERMOSAM CREAM

Clobetasol propionate 0.05%.

- Used on the skin to treat swelling, itching, irritation and also soothing skin.

Zinc oxide ointment

Zinc oxide 15%

- Treat and prevent diaper rash and other minor skin irritations(burns, cuts)

CELYOVEX

Cetrimide BP 0.5% w/w

- For small wounds, cuts, abrasions, scratches, minor burns and antiseptic to cleanse and kill bacteria

HYDROSONE CREAM

Hydrocortisone 1% (skin cream)

- Used to help relieve redness, itching, swelling, or other discomfort caused by skin or eye conditions

Fugizol cream

Clotrimazole 1%

- Treat skin infections caused by a fungus (yeast)

Gliclazide

ATC Code: A10BB09 Drugs Used in Diabetes (Sulfonylureas)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid; Theoretical possibility of hypoglycemia in the infant.

Indications and Dosage

• Diabetes mellitus (type 2): 40mg-320mg once daily or bid.

Off-label uses

None.

Contraindications

Hypersensitivity to gliclazide; Diabetic ketoacidosis with or without coma; Type 1 diabetes mellitus.

Cautions

Malnourished; Poorly compensated endocrine disorders; Severe vascular disease; Poor carbohydrate intake; Imbalanced diet; Trauma; Infection; Surgery; G6PD-deficiency.

Dose adjustment in renal failure: Use of gliclazide in severe renal failure is contraindicated.

Dose adjustment in hepatic failure: Use of gliclazide in severe hepatic failure is contraindicated.

Dosage forms and trade names available in Iraq

Gliclazide 60 mg tab
Diamicron MR (Servier France).

Pharmacokinetic parameters

Absorption F=97%.
Distribution Vd=19-30L, 95%protein bound.
Metabolism Hepatic by CYP2C9 and CYP2C19 to inactive metabolites.
Elimination Renal elimination is 60-70% with half-life of 10.4-16 hours.

Drug interactions

Warfarin: Gliclazide may enhance effect of warfarin.

Side effects

Anxiety; Arthralgia; Back pain; Constipation; Cough; Dyspepsia; Visual disturbances; Hemolytic anemia; Headache; Hypertension; Hypoglycemia; Increased serum creatinine; Jaundice; Hepatitis; Leucopenia; Nausea; Palpitations; Pancytopenia; Pharyngitis; Pruritus; Rash; Rhinitis; Stevens Johnson syndrome; Tachycardia; Thrombocytopenia; Toxic epidermal necrolysis; Urticaria.

Patient educations

Instruct patient to take gliclazide directed at the same time every day; Explain to patient that this medication does not cure diabetes and must be used in conjunction with a prescribed diet, exercise regimen, to prevent hypoglycemic and hyperglycemic events; Concurrent use of alcohol may cause a disulfiram-like reaction (abdominal cramps, nausea, flushing, headaches and hypoglycemia); Instruct patient to avoid sun exposure and to wear protective clothing and sunscreen when outdoors; Advise patient to carry sugar packets or candy; Insulin is the recommended method of controlling blood sugar during pregnancy.

Glimepiride

ATC Code: A10BB12 Drugs Used in Diabetes (Sulfonylureas)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Breastfeeding is not recommended during use of glimepiride.

Indications and Dosage

• Diabetes mellitus (type 2): 1mg-2mg daily, may titrate by 1mg-2mg every 1-2 weeks, (max 8mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to glimepiride; Diabetic coma or ketoacidosis.

Cautions

Cardiovascular disease; Impaired thyroid, pituitary, or adrenal function; Elderly patients.
Dose adjustment in renal failure: Initially, 1mg daily then titrate dose based on serum glucose levels.
Dose adjustment in hepatic failure: Avoid.

Dosage forms and trade names available in Iraq

- Glimepiride 1mg tab
  Amaryl (Sanofi Italy).
- Glimepiride 2mg tab
  Amaryl (Sanofi Italy).
- Glimepiride 3 mg tab
  Amaryl (Sanofi Italy).
- Glimepiride 4 mg tab
  Amaryl (Sanofi Italy).

Pharmacokinetic parameters

Absorption F=100%, food decrease absorption.
Distribution Vd=8.8L, more than 99% protein bound.
Metabolism Hepatic metabolism 90%.
Elimination Renal elimination is 60% with a half-life of 5-9 hr.

Drug interactions

Beta-blockers: Beta-blockers may enhance the hypoglycemic effect of glimepiride, cardio selective beta-blockers (such as atenolol and metoprolol may be safer than nonselective beta-blockers, all beta-blockers appear to mask tachycardia as an initial symptom of hypoglycemia).
Cimetidine: Cimetidine may increase the serum concentration of glimepiride.

Side effects

Common (more than 10%) Hypoglycemia.
Less common (1-10%) Asthenia; Dizziness; Headache; Nausea.
Rare (less than 1%) Agranulocytosis; Allergic skin reactions; Aplastic anemia; Cholestasis; Diarrhea; Disulfiram-like reactions; Erythema; Gastrointestinal pain; Hyponatremia; Jaundice; Leukopenia; Pancytopenia; Pruritus; Thrombocytopenia; Urticaria; Vomiting.

Patient educations

Instruct patient to self-monitor his blood glucose level as prescribed; Teach patient how to recognize signs and symptoms of hypoglycemia and hyperglycemia; Stress importance of diet and exercise to help control diabetes.

Glipizide

ATC Code: A10BB07 Drugs Used in Diabetes (Sulfonylureas)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Breastfeeding is not recommended during use of glipizide.

Indications and Dosage

• Diabetes mellitus: 5mg-10mg daily, (max 40mg daily divided bid).

Off-label uses

None.

Contraindications

Hypersensitivity to glipizide; Severe thyroid disease; Uncontrolled infection; Serious burns; Trauma; Diabetic ketoacidosis.

Cautions

Cardiovascular disease; Elderly patients.
Dose adjustment in renal failure: 2.5mg daily.
Dose adjustment in hepatic failure: 2.5mg daily.

Pharmacokinetic parameters

Absorption F=100%, food delay absorption by 40 min.
Distribution Vd=11L, 99% protein bound.
Metabolism Hepatic metabolism 80%.
Elimination Renal elimination is 70% with a half-life of 2-5 hr.

Dosage forms and trade names available in Iraq

Glipizide 5mg tablet
Glucotrol (Pfizer USA)

Drug interactions

Beta-blockers: Beta-blockers may enhance the hypoglycemic effect of glipizide, cardio selective beta-blockers (such as atenolol and metoprolol may be safer than nonselective beta-blockers, all beta-blockers appear to mask tachycardia as an initial symptom of hypoglycemia).
Warfarin: Glipizide may enhance the anticoagulant effect of vitamin k antagonists (warfarin). Warfarin may enhance the hypoglycemic effect of glipizide.

Side effects

Abdominal pain; Anxiety; Cholestatic jaundice and hepatitis occur rarely but may progress to liver failure; Constipation; Depression; Dermatologic reactions; Diarrhea; Dizziness; Drowsiness; Erythema; Flatulence; Headache; Heartburn; Hypoglycemia; Maculopapular eruptions; Morbilliform eruptions; Nausea; Nervousness; Syncope; Urticaria; Vomiting.

Patient educations

Advise patient to take daily dose with breakfast; Tell patient he may need supplemental insulin during times of stress or when he can't maintain adequate oral intake; Teach patient how to recognize signs and symptoms of hypoglycemia and hyperglycemia; Stress importance of diet and exercise to help control diabetes; Advise patient to keep sugar source at hand at all times in case of hypoglycemia; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness.

Glucagon

ATC Code: H04AA01 Pancreatic Hormones (Glycogenolytic Hormones)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Use cautiously during lactation; it is not well studied.

Dosage forms and trade names available in Iraq

Glucagon 1mg (1 IU) vial
GlucaGen (Novo Nordisk Denmark).

Indications and Dosage

• **Severe hypoglycemic reactions in patients with diabetes treated with insulin:** 1 mg (1 unit) IM/SC/IV if no IV for dextrose, repeat q15min once or twice; give dextrose as soon as it is available and if no response and administer supplemental carbohydrate to replete glycogen stores.

• **Diagnostic Aid:** during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract,To inhibit motility of stomach and small bowel: 0.2-0.5 mg IV over 1 min or 1 mg IM, To inhibit motility of colon: 0.5-0.75 mg IV over 1 min or 1-2 mg IM, Bolus doses >1 mg administered IV may cause nausea and vomiting and are not recommended

Off-label uses

For overdose of beta blockers or calcium channel blockers, Load: 50-150 mcg/kg IVP over 1 minute, THEN 3-5 mg/hr or 50-100 mcg/kg/hr IV; titrate infusion to achieve adequate clinical response.

Contraindications

Hypersensitivity, Pheochromocytoma, Insulinoma, Glucagonoma when used as diagnostic tool.

Cautions

Use with caution in patients with pheochromocytoma and cardiovascular disease, patients with diabetes mellitus.
Dose adjustment in renal failure: No specific dose adjustment is usually required in renal failure.
Dose adjustment in hepatic failure: No specific dose adjustment is usually required in hepatic failure.

Pharmacokinetic parameters

Absorption Rapid absorption after injection.
Distribution Large volume of distribution (Vd); minimal protein binding.
Metabolism Metabolized in the liver.
Elimination Primarily excreted in the urine with a half-life of about 10-20 minutes.

Drug interactions

• Beta-blockers may blunt the hyperglycemic effects of glucagon, potentially requiring higher doses for adequate response.

• The effects of glucagon may be enhanced when used concomitantly with anticholinergic drugs, leading to increased heart rate.

Side effects

Common (more than 10%): Nausea, vomiting. Hypoglycemia, Headache, Hyperglycemia.
Less common (1-10%): Hypertension, tachycardia. Injection site reaction, Abdominal pain, Injection site discomfort, Urticaria
Rare but serious (less than 1%): Allergic reactions, rebound hypoglycemia, Hypoglycemia coma.

Glucose

ATC Code: V06DC01 General Nutrients (Carbohydrates).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Considered safe; not known to pass into breast milk.

Indications and Dosage

It is primarily used for hydration and calorie provision. The dosage depends on the age, weight, clinical condition of the patient, and laboratory determinations.

Off-label uses

It can be used to dilute other intravenous medications.

Contraindications

Hypersensitivity to dextrose; hyperglycemia; intracranial hemorrhage.

Cautions

Caution should be used in patients with diabetes; renal or cardiac disease.

Dose adjustment in renal failure: Depends on the clinical scenario, hydration status and serum electrolyte levels.

Dose adjustment in hepatic failure: No specific adjustment guidelines, but should be used with caution.

Dosage forms and trade names available in Iraq

Dextrose 5.0 g/100ml 5% I.V inj. 500 ml **DEXTROSE** (SDI IRAQ), **Dextrose** (Pioneer Iraq).

Pharmacokinetic parameters

Absorption N/A, it's given intravenously.
Distribution Rapidly distributed throughout total body water, no protein binding.
Metabolism Rapidly metabolized to carbon dioxide and water.
Elimination N/A, metabolized to carbon dioxide and water.

Drug interactions

There are no major known drug interactions with Glucose 5% water solution.

Side effects

Common (more than 10%) Overhydration; electrolyte imbalance.
Less common (1-10%) Injection site reactions.
Rare but serious (less than 1%) Pulmonary edema; hypersensitivity reactions.

Patient educations

1. The solution is used for hydration and does not have any nutritional content.
2. If you notice any swelling; discomfort; or redness around the IV site, let your nurse or doctor know immediately.
3. The healthcare team will regularly monitor your blood sugar and electrolyte levels while you are receiving this treatment.

Glycerin

ATC Code: A06AX01 Drugs for Constipation (Other Drugs for Constipation).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Not known to interfere with breastfeeding.

Indications and Dosage

Glycerin suppositories are used to treat occasional constipation. Dosage is typically one suppository inserted into the rectum, usually once daily or as directed by a healthcare provider.

Off-label uses

None.

Contraindications

Hypersensitivity to glycerin, rectal fissures or rectal bleeding.

Cautions

Prolonged use may result in dependence. Not intended for long-term use.

Dose adjustment in renal failure: Not typically required.

Dose adjustment in hepatic failure: Not typically required.

Dosage forms and trade names available in Iraq

- Glycerin 900mg suppositories
- Glycerine 1800mg supp

Pharmacokinetic parameters

Glycerin suppositories work locally in the rectum to soften stools and stimulate bowel movements. They are not significantly absorbed into the bloodstream.

Drug interaction

No significant interactions.

Side effects

Common (more than 10%): Anal irritation.

Less common (1-10%): Abdominal cramps; diarrhea.

Rare but serious (less than 1%): Allergic reaction.

Patient educations

• Inform your healthcare provider if your condition does not improve or if it worsens.

• Avoid using this product for more than one week unless directed by your healthcare provider, as it may cause dependence.

Glyceryl Trinitrate

ATC Code: C01DA02 Vasodilators Used In Cardiac Diseases (Organic Nitrates)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Use with caution during lactation; benefits should be weighed against potential risks.

Indications and Dosage

Angina Pectoris (Prophylaxis): ER capsule: Initial 2.5-6.5 mg PO q6-8hr, Titrate up to effect dose until limited by side effect.

Off-label uses

None.

Contraindications

Hypersensitivity to nitroglycerin, severe anemia, increased intracranial pressure, acute MI.

Cautions

Use with caution in patients with hypotension, severe renal or hepatic impairment, and in those taking medications that may exacerbate hypotension.

Dose adjustment in renal failure:

• CrCl: 10-50 mg/min: Administer q24-72 hr.

• CrCl<10 mL/min: Administer q72-96 hr

Dose adjustment in hepatic failure: Use with caution in severe hepatic impairment; dose adjustments may be necessary.

Dosage forms and trade names available in Iraq

- Glyceryl trinitrate 1mg/ml Ampule
  Glyceryl trinitrate-Hameln (Hameln pharma GERMANY).
- Glyceryl trinitrate 400mcg/dose Sublingual Spray
  Angizal (Pharmaserve United Kingdom).
- Glyceryl trinitrate 500mcg Sublingual tab

Pharmacokinetic parameters

Absorption Rapid and complete when administered sublingually or intravenously.
Distribution Protein Bound: 11-60%, Vd: 3 L/kg.
Metabolism Metabolized in various tissues.
Elimination Metabolites are excreted in the urine; half-life is short, around 5.5-11 L/minutes.

Drug interaction

• Concomitant use with phosphodiesterase-5 (PDE-5) inhibitors (e.g., sildenafil) may potentiate the hypotensive effects of nitroglycerin, leading to severe hypotension.

• Combining nitroglycerin with antihypertensive medications may result in an additive hypotensive effect.

Side effects

Common (more than 10%): Headache, dizziness, flushing.
Less common (1-10%): Nausea, vomiting, palpitations, Xerostomia
Rare but serious (less than 1%): Methemoglobinemia, severe hypotension, paradoxical bradycardia, Syncope, Prolonged bleeding time, Exfoliative dermatitis, Unstable angina, Rebound hypertension.

Patient educations

• Be aware of potential side effects such as headache and dizziness; consult your healthcare provider if symptoms persist or worsen.

• Inform your healthcare provider of all medications you are taking, including over-the-counter drugs, to avoid potential interactions.

Glycine

ATC Code: B05CX03 Blood Substitutes and Perfusion Solutions (Other Irrigating Solutions).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Not expected to interfere with breastfeeding.

Indications and Dosage

Primarily used as an irrigation fluid during transurethral procedures. The volume and rate of irrigation depend on the type of procedure and the healthcare provider's judgment.

Off-label uses

None.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Cautions

Careful attention is necessary to avoid extravasation, which can lead to fluid overload and electrolyte imbalance.

Dose adjustment in renal failure: Not typically required; however, patients with renal impairment may be at greater risk for fluid and electrolyte imbalance.

Dose adjustment in hepatic failure: Not typically required; however, careful monitoring is needed to prevent fluid overload.

Dosage forms and trade names available in Iraq

Glycine irrigation sterile 1.5% (not for injection)

Pharmacokinetic parameters

Glycine irrigation fluid is used topically and not systemically absorbed in significant quantities.

Drug interaction

No significant interactions.

Side effects

Common (more than 10%): None reported.

Less common (1-10%): None reported.

Rare but serious (less than 1%): TURP syndrome (if absorbed systemically in large quantities during procedure); hyponatremia.

Patient educations

1. This solution is used for specific surgical procedures and is administered by healthcare professionals.
2. If you experience unusual symptoms after a procedure where this solution was used, contact your healthcare provider.
3. This solution is not meant for injection.

Golimumab

ATC Code: L04AB06 Immunosuppressants (Tumor Necrosis Factor Alpha (TNF-α) Inhibitors)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Use with caution during lactation; the benefits should be weighed against potential risks.

Dosage forms and trade names available in Iraq

Golimumab 50mg/0.5ml Prefilled Pen

Simponi (Janssen Switzerland).

Indications and Dosage

• **Psoriatic Arthritis:** Subcutaneous: 50 mg once a month, OR IV: 2 mg/kg over 30 minutes at weeks 0 and 4, then every 8 weeks thereafter.

• **Ulcerative Colitis:** Initial dose: 200 mg subcutaneously at week 0, followed by 100 mg at week 2, Maintenance dose: 100 mg subcutaneously every 4 weeks.

• **Rheumatoid Arthritis:** Subcutaneous: 50 mg once a month, OR IV: 2 mg/kg over 30 minutes at Weeks 0 and 4, then every 8 weeks thereafter.

• **Ankylosing Spondylitis:** Subcutaneous: 50 mg once a month, OR IV: 2 mg/kg over 30 minutes at weeks 0 and 4, then every 8 weeks thereafter.

• **Juvenile Idiopathic Arthritis:** IV: 80 mg/m^2 over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter

Off-label uses

Data not available.

Contraindications

Known hypersensitivity to golimumab or any component of the formulation.

Cautions

Use with caution in patients with a history of infections, particularly active tuberculosis, and in those with heart failure, Malignancy, Demyelinating disorders.

Dose adjustment in renal failure: Data not available.

Dose adjustment in hepatic failure: Data not available.

Pharmacokinetic parameters

Absorption Golimumab is administered subcutaneously, and its bioavailability is approximately 50-60%.

Distribution Large volume of distribution (Vd); high affinity for tissues.

Metabolism Metabolized into smaller peptides, but the metabolism pathway is not well-defined.

Elimination Primarily excreted in the feces; half-life is approximately 2 weeks.

Drug interactions

• Concurrent use with other immunosuppressive agents may increase the risk of infections.

• Golimumab may interfere with the effectiveness of live vaccines.

Side effects

Common (more than 10%): Upper respiratory tract infections, injection site reactions.

Less common (1-10%): Hypertension, headache, gastrointestinal symptoms, Paresthesia

Rare but serious (less than 1%): Serious infections, hypersensitivity reactions, and liver function abnormalities, Leukemia

Goserelin Acetate

ATC Code: L02AE03 Endocrine Therapy (Gonadotropin Releasing Hormone Analogues)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Not recommended during lactation, and breastfeeding should be avoided during treatment.

Dosage forms and trade names available in Iraq

Goserelin acetate 3.6mg prefilled syring
Zoladex (AstraZeneca United Kingdom).
Goserelin acetate 10.8mg prefilled syring
Zoladex LA (AstraZeneca United Kingdom).

Indications and Dosage

• **Prostate Cancer:** Monthly implant: 3.6 mg SC q28days, 3-months implant: 10.8 mg SC q12week, Stage B2-C: Total of 4 doses, Advanced prostate cancer: Treat long-term
• **Breast Cancer:** 3.6 mg implant SC q28days, Treat long-term
• **Endometriosis:** including pain relief and reduction of endometriotic lesions for duration of therapy, 3.6 mg implant SC q28days x 6 months

Off-label uses

No data available.

Contraindications

Known hypersensitivity to goserelin or other GnRH agonists, pregnancy, breastfeeding, undiagnosed abnormal vaginal bleeding.

Cautions

Caution is advised in patients with a history of heart disease or risk factors for cardiovascular disease, Hypercalcemia, Hyperglycemia and diabetes, Depression.
Dose adjustment in renal failure: No specific dose adjustment is typically required in renal failure.
Dose adjustment in hepatic failure: Dose adjustment not necessary.

Pharmacokinetic parameters

Absorption Goserelin is administered as a subcutaneous implant or injection, resulting in sustained release.
Distribution Vd: 44.1 L (Male); 20.3 L (female); Protein bound: 27%
Metabolism Metabolized in tissues.
Elimination Mainly excreted in urine (90%) and feces; half-life is approximately 2-4 hours.

Drug interactions

• Concomitant use with other hormonal therapies may affect the efficacy of goserelin.
• Medications that alter hepatic enzyme activity may impact the metabolism of goserelin, potentially affecting its effectiveness.

Side effects

Common (more than 10%): Hot flashes, decreased libido, erectile dysfunction (in males).
Less common (1-10%): Fatigue, mood swings, injection site reactions.
Rare but serious (less than 1%): Osteoporosis, cardiovascular events, allergic reactions.

Patient educations

• Report any unusual side effects or symptoms promptly, especially if they affect mood, bone health, or cardiovascular function.
• If planning a pregnancy or currently breastfeeding, discuss the potential risks with your healthcare provider, and use effective contraception during treatment.

Granisetron

ATC Code: A04AA02 Antiemetics and Antinauseants (Serotonin (5HT3) Antagonists)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Granisetron Hydrochloride 1mg/ml ampoule
Grani-Denk (Denk Pharma Germany).

Indications and Dosage

• Prevention of chemotherapy induced nausea and vomiting: By i.v. injection, 10mcg/kg/dose within 30 min of chemotherapy, (max 1mg per dose).
• Postoperative nausea and vomiting: 0.35mg–3mg (5mcg–20mcg/kg) given at end of surgery.

Off-label uses

None.

Contraindications

Hypersensitivity to granisetron.

Cautions

Congenital QT prolongation; Electrolyte abnormalities; Following abdominal surgery; Hepatic disease.
Dose adjustment in renal failure: Granisetron was not affected in patients with CrCl less than 30ml per minute who received a single 40mcg/kg i.v. dose.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=2-4L/kg, 65%protein bound.
Metabolism Mostly metabolized by the liver.
Elimination Renal elimination is 12% with half-life of 10-12 hours.

Drug interactions

Amitriptyline: Granisetron and amitriptyline both increases toxicity of the other by serotonin levels.
Clomipramine: Granisetron and clomipramine both increases toxicity of the other by serotonin levels.
Fluoxetine: Granisetron and fluoxetine both increases toxicity of the other by serotonin levels.

Side effects

Common (more than 10%) Headache.
Less common (1-10%) Asthenia; Somnolence; Sedation; Drowsiness; Constipation; Diarrhea.
Rare but serious (less than 1%) Administration site reactions; Bradycardia; Chest pain; Erythema; Fatigue; Malaise; Pain; Palpitations.

Patient educations

Advise patient to avoid direct exposure to sunlight; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness; Advise patient to minimize GI upset by eating frequent, small servings of healthy food.

Haloperidol

ATC Code: N05AD01 Psycholeptics (Butyrophenone Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Haloperidol 5mg/1ml ampoule

Indications and Dosage

• Treatment of psychotic disorders: By i.m. injection, initially 100mg once every 28 days, (max 300mg every 28 days).
• Treatment of patients with schizophrenia.

Off-label uses

Treatment of non-schizophrenic psychosis; Alcohol dependence; Psychosis and agitation related to alzheimer's dementia; Emergency sedation of severely agitated and psychotic patients.

Contraindications

Hypersensitivity to haloperidol; CNS depression; Coma; Parkinson's disease; Severe cardiac disease. patients with dementia-related psychosis.

Cautions

Cardiovascular disease; History of seizures; Prolonged QT syndrome; Hypothyroidism; Thyrotoxicosis; Hypokalemia; Hypomagnesemia; EEG abnormalities; Narrow angle glaucoma; Elderly, patients at risk for pneumonia; Decreased GI motility; Urinary retention; Visual disturbances; Myelosuppression; Orthostatic hypotension; Cerebrovascular disease.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=40-75%.
Distribution Vd=9.5-21.7L/kg, 92%protein bound.
Metabolism Mostly metabolized by the liver.
Elimination Renal elimination is 30% with half-life of 21-24 hours.

Drug interactions

Amiodarone: Amiodarone and haloperidol both increase QTc interval.

Side effects

Common (more than 10%) Akathisia; Anticholinergic effects; Dystonia; Erectile dysfunction; Muscle stiffness; Oligomenorrhea or amenorrhea; Parkinsonism; Sedation; Tardive dyskinesia; Weight gain.
Less common (1-10%) Agitation, anxiety, cerebral edema, depression, dizziness, euphoria, headache, insomnia, poikilothermia, restlessness, weakness, confusion; Anorexia, constipation, dyspepsia, ileus, decreased gag reflex; Lens opacities (prolonged use); Orthostatic hypotension (after i.m. injection); Tachycardia.
Rare but serious (less than 1%) Blood dyscrasia; Cholestatic jaundice; Diarrhea; ECG changes; Ejaculatory disorder; Galactorrhea; Photosensitivity; Priapism; Pruritus; Seizure.

Patient educations

Full therapeutic effect may take up to 6 weeks; Do not abruptly withdraw from long term drug therapy; Sugarless gum, sips of water may relieve dry mouth; Drowsiness generally subsides during continued therapy; Avoid alcohol; Avoid exposure to sunlight, overheating, dehydration (increased risk of heatstroke).

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Suitable for children from 1 to 10 years

The balanced nutrition to catch up growth

Primasure Total provides a complete and balanced nutrition to your child

- **28 vitamins** and **minerals** to support your child's growth and development
- **DHA** or **Omega 3** to help your child's brain development and boost concentration
- **Antioxydants** to boost immunity
- **Prebiotics** to avoid hard stools

1-8 years → 2 cups / day

9-10 years → 3 cups / day

Heparin

ATC Code: B01AB01 Antithrombotic Agents (Heparin Group)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Catheter patency / Heparin flush for intravenous & arterial catheter: IV injection 50 – 100 IU as required
• Acute coronary syndrome: By i.v. infusion, 60 IU/kg bolus (max 4000 IU), then 12 IU/kg/hr (max 1000 IU/hr).
• Treatment of DVT: By i.v. infusion, 80 IU/kg bolus (max 5000 IU), then 18 IU/kg/hr adjusted according to aPTT.
• Thromboembolic prophylaxis: By subcutaneous injection, 5000 IU bid or tid.
• Hypertrophic and keloid scars, post-surgical scars: Apply a thin layer of the gel over the affected area and gently massage it till complete penetration bid or tid.

Off-label uses

ST elevation myocardial infarction; Non-ST elevation myocardial infarction; Unstable angina; Anticoagulant used during percutaneous coronary intervention.

Dosage forms and trade names available in Iraq

Heparin sodium 5000 IU/1ml (25000 I.U/5ml vial)
HEPARIN LEO (Leo pharma Denmark).

Contraindications

patients with a history of heparin-induced thrombocytopenia, uncontrolled active bleeding, and hypersensitivity to heparin. Concomitant use with other oral anticoagulants & antiplatelet drugs (increase the risk of hemorrhage). Concomitant use with estradiol, estrogen derivatives, and progesterone derivatives (increased risk of thromboembolic events)

Cautions

risk factors of bleeding (hemophilia, severe hypertension, intracranial hemorrhage, infective endocarditis, active tuberculosis, ulcerative lesions of the gastrointestinal tract, threatened abortion, menorrhagia, or advanced hepatic or renal disease). surgery of the brain, spinal cord, or eye; and in patients who are undergoing lumbar puncture or regional anesthetic block.
Dose adjustment in renal failure: Use with caution.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=30-70%.
Distribution Vd=0.05-0.1L/kg, very high protein bound.
Metabolism Metabolism by Liver and the reticulo-endothelial system.
Elimination Probably removed by the reticuloendothelial system (lymph nodes, spleen) with half-life of 1-2 hours.

Drug interactions

barbiturates (decreased effect of heparin by increasing metabolism), most 2nd and 3rd generation cephalosporins (increased level or effect of heparin), macrolides including azithromycin and clarithromycin (increased level or effect of heparin by decreasing metabolism). All of which use alternative
Azithromycin: Azithromycin increases effects of heparin by decreasing metabolism.

Side effects

bleeding, reversible alopecia, osteoporosis with long-term use, thrombocytopenia, injection site ulcer, increased liver transaminases, mild pain, hypersensitivity, and anaphylaxis.

Hexetidine

ATC Code: A01AB12 Stomatological Preparations (Antiinfectives and Antiseptics for Local Oral Treatment).

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Not expected to interfere with breastfeeding

Indications and Dosage

Used as a local antimicrobial for gingivitis, stomatitis, and other oral mucosal diseases. Usual dosage is rinsing with 10-15ml for about 30 seconds, twice daily.

Off-label uses

For general oral hygiene or bad breath (halitosis).

Contraindications

Hypersensitivity to hexetidine or any component of the formulation.

Cautions

Should not be swallowed. Long-term use is not recommended without medical advice.

Dose adjustment in renal failure: Not required, as it is not systemically absorbed.

Dose adjustment in hepatic failure: Not required, as it is not systemically absorbed.

Dosage forms and trade names available in Iraq

Hexetidine 0.1% (200ml) mouth wash

Pharmacokinetic parameters

Not applicable as hexetidine is not significantly absorbed systemically.

Drug interaction

There are no significant interactions with hexetidine mouthwash.

Side effects

Common (more than 10%): Slight burning sensation in the mouth.

Less common (1-10%): Taste alteration; skin irritation (in case of contact).

Rare but serious (less than 1%): Allergic reactions.

Patient educations

1. Rinse your mouth with 10-15ml of Hexetidine mouthwash for 30 seconds twice daily.
2. Avoid swallowing the mouthwash; spit it out after use.
3. If irritation occurs or symptoms persist, stop using and consult your dentist or doctor.

Homatropine

ATC Code: S01FA05 Homatropine (Anticholinergics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available.

Dosage forms and trade names available in Iraq

Homatropine Methyl bromide 2mg/ml Oral Drop **ANTISPASMIN** (SDI Iraq), **AntiSpasdain** (Wadi Al-Rafidain Iraq).

Indications and Dosage

• Infant colic: 0.5mg-1mg qid.

Off-label uses

None.

Contraindications

Hypersensitivity to homatropine.

Cautions

Down syndrome; Keratoconus.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Undetermined.
Distribution Undetermined.
Metabolism Undetermined.
Elimination Undetermined.

Drug interactions

There are no known significant interactions.

Side effects

Eczematoid dermatitis; Edema; Exudate; Follicular conjunctivitis; Increased IOP; Vascular congestion.

Patient educations

Tell patient drug may cause drowsiness; Caution him to avoid driving and other hazardous activities until CNS effects are known; Inform patient that prolonged use may lead to physical or psychological dependence; Caution patient to avoid alcohol during therapy; Instruct patient to move slowly when sitting up or standing, to avoid dizziness from sudden blood pressure decrease.

Human Chorionic Gonadotropin

ATC Code: G03GA01 Sex Hormones and Modulators Of The Genital System (Gonadotropins)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: discontinuation breastfeeding.

Indications and Dosage

• **Ovulation induction:** By i.m. injection, 5000 IU to 10,000 IU once 1 day following the last dose of menotropins.
• **Hypogonadism male:** By i.m. injection, 500IU-1000 IU 3 times a week for 3 weeks, then 500 IU-1000 IU 2 times a week for 3 weeks.

Dosage forms and trade names available in Iraq

Chorionic 5000 I.U. powder for injection
Choriomon (IBSA Institut Switzerland).

Off-label uses

None.

Contraindications

Hypersensitivity to chorionic gonadotrophin; Precocious puberty; Prostatic carcinoma; Androgenic dependent neoplasm.

Cautions

Cardiac disease; Epilepsy; Migraine; Asthma.
Dose adjustment in renal failure: Use with caution in patients with renal impairment; Chorionic gonadotrophin may cause fluid retention.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=40%.
Distribution Vd=21.4L.
Metabolism Undetermined.
Elimination Renal elimination is 10% with half-life of 4 hours.

Drug interactions

None significant.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Injection site inflammation; Nausea; Ovarian cyst; Ovarian hyperstimulation; Vomiting.
Rare but serious (less than 1%) Albuminuria; Back pain; Breast pain; Cardiac arrhythmia; Cervical lesion; Cough; Dizziness; Emotional lability; Genial herpes; Hyperglycemia; Pruritus; Urinary tract infection; Vaginal hemorrhage; Vaginitis.

Patient educations

Chorionic gonadotrophin can only be given i.m; Prepare a calendar with a treatment schedule. If you will be giving chorionic gonadotrophin at home, learn proper administration and disposal of needles and syringes; Report pain at injection site, severe headache, restlessness, swelling of ankles or fingers, difficulty breathing, severe abdominal pain.

Human Normal Immunoglobulin

ATC Code: J06BA02 Immune Sera and Immunoglobulins (Immunoglobulins, Normal Human).

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: IVIG is likely excreted in breast milk, but the risk is considered low.

Dosage forms and trade names available in Iraq

- Human normal Immunoglobulin 2.5g/25ml vial **Kiovig** (Takeda Belgium).
- Human normal immunoglobulin 2.5g/50ml vial **Intratect** (Biotest pharma Germany).
- Human normal Immunoglobulin 10g/100ml vial **Intratect** (Biotest pharma Germany).
- Human normal immunoglobulin 10g/200ml vial **Kiovig** (Takeda Belgium).
- Human normal immunoglobulin 50g/L vial **Biseko** (Biotest pharma Germany).

Indications and Dosage

IVIG is used in a variety of conditions including immune deficiencies, inflammatory and autoimmune diseases. Dosage is highly variable and depends on the specific condition being treated.

Off-label uses

Conditions like Kawasaki disease, Guillain-Barre syndrome, and multiple sclerosis.

Contraindications

Hypersensitivity to human immunoglobulin, especially in very rare cases of IgA deficiency when the patient has antibodies against IgA.

Cautions

In patients with renal impairment, a history of cardiac or vascular disease, or thrombotic episodes.

Dose adjustment in renal failure: Required; use with caution.

Dose adjustment in hepatic failure: Not usually required but use with caution.

Pharmacokinetic parameters

Absorption Not applicable for IV medication.

Distribution Rapidly distributed between plasma and extravascular fluid, after approximately 3-5 days equilibrium is reached.

Metabolism Metabolized in the reticuloendothelial system.

Elimination IVIG has a half-life of about 21-28 days.

Drug interaction

Live attenuated vaccines (e.g., MMR): Immunoglobulin can impair the efficacy of live attenuated vaccines. It is recommended to administer these vaccines at least 3 months after immunoglobulin treatment.

Drugs that impact renal function (e.g., NSAIDs, ACE inhibitors): Concurrent use may increase the risk of renal dysfunction.

Side effects

Common (more than 10%): Headache; flushing; chills; myalgia; fever.

Less common (1-10%): Nausea; vomiting; allergic reactions.

Rare but serious (less than 1%): Thrombotic events; kidney dysfunction; severe allergic reactions.

Patient educations

1. Report any adverse reactions such as rash, shortness of breath, or edema.
2. Stay hydrated before and after your infusion to decrease the chance of side effects.
3. Do not get any live vaccines for at least 3 months after receiving IVIG.

Human Tetanus Immunoglobulin

ATC Code: J06BB02 Immune Sera and Immunoglobulins (Specific Immunoglobulins)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Limited data suggest the drug does not represent a significant risk to the baby.

Dosage forms and trade names available in Iraq

Antitetanus immunoglobulin 250IU/1ml PFS
Tetagam®P (CSL Behring Germany).

Indications and Dosage

The anti-tetanus immunoglobulin is used for post-exposure prophylaxis and treatment of tetanus. The usual dose for adults is 250-500 units IM for prophylaxis and 3,000 to 6,000 units IM for treatment. For children, the dose is usually determined by weight.

Off-label uses

None.

Contraindications

In people who have had an allergic reaction to the product or any of its constituents.

Cautions

In patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.
Dose adjustment in renal failure: No specific guidelines have been provided.
Dose adjustment in hepatic failure: No specific guidelines have been provided.

Pharmacokinetic parameters

As a large protein molecule, it is not easily absorbed, nor is it easily distributed or metabolized. It is slowly catabolized, and its half-life is usually 3 to 5 weeks.

Drug interaction

Vaccines (Live): Immune Globulins may diminish the therapeutic effect of Vaccines (Live).
Sodium-containing solutions: May increase risk of sodium overload.

Side effects

Common (more than 10%) Local reactions, including pain, tenderness, muscle stiffness, or warmth at the injection site.
Less common (1-10%) Fever, headache, allergic reactions.
Rare but serious (less than 1%) Severe allergic reactions.

Patient educations

It's typically given as an injection in your muscle. You may have temporary soreness or swelling at the injection site.

Note

If you experience symptoms like high fever, difficulty breathing, or facial swelling, seek immediate medical attention.

Hydralazine

ATC Code: C02DB02 Antihypertensives (Hydrazinophthalazine Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Small amounts of hydralazine pass into breast milk, but the risk of adverse effects on the nursing infant is minimal.

Dosage forms and trade names available in Iraq

Hydralazine 20mg amp
Apresoline (Bag healthcare GERMANY).

Indications and Dosage

Hydralazine is indicated for the treatment of high blood pressure. Dosage is individualized based on the patient's response to the medication, usually starting at 10mg four times daily, which may be increased to a maximum of 200mg per day.

Off-label uses

Hydralazine may be used in the management of hypertensive crises.

Contraindications

In patients with known hypersensitivity to hydralazine, coronary artery disease, mitral valvular rheumatic heart disease, and in patients with tachycardia and heart failure.

Cautions

In patients with renal or hepatic impairment, systemic lupus erythematosus, and stroke.
Dose adjustment in renal failure: reduction may be necessary
Dose adjustment in hepatic failure: reduction may be necessary

Pharmacokinetic parameters

Absorption Hydralazine is rapidly absorbed following oral administration but undergoes extensive first-pass metabolism.
Distribution Vd= 2.2 L/kg; protein binding is minimal
Metabolism Hydralazine is primarily metabolized by acetylation.
Elimination Mostly excreted as metabolites in the urine; half-life is approximately 3-7 hours (varies significantly due to genetic polymorphism in acetylation).

Drug interaction

Beta-blockers: Hydralazine may increase the hypotensive effect of beta-blockers.
MAO inhibitors: MAO inhibitors can potentiate the action of hydralazine leading to severe hypotension.

Side effects

Common (more than 10%): Headache, anorexia, nausea, vomiting, diarrhea, palpitations, tachycardia
Less common (1-10%): Angina pectoris, hypotension, peripheral neuritis
Rare but serious (less than 1%): Drug-induced lupus erythematosus, heart failure, hepatotoxicity

Patient education

1. Hydralazine is used to lower high blood pressure. It should be taken as directed by your healthcare provider.
2. Notify your healthcare provider if you experience rapid heart rate, chest pain, or other severe side effects.
3. Regular monitoring of your blood pressure and kidney function will be required while on this medication.

Hydrochlorothiazide

ATC Code: C03AA03 Diuretics (Thiazides, Plain)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Edema: 25mg-100mg daily in single or divided doses.
• Hypertension: Initially, 12.5mg-25mg daily, may titrate to 50mg-100mg daily in single or divided doses.

Off-label uses

Treatment of calcium nephrolithiasis.

Contraindications

Hypersensitivity to hydrochlorothiazide; Anuria.

Cautions

Fluid or electrolyte imbalances; Gout; Systemic lupus erythematosus; Hyperparathyroidism; Glucose tolerance abnormalities; Bipolar disorder; Elderly patients.

Dose adjustment in renal failure: Contraindicated.

Dose adjustment in hepatic failure: Contraindicated.

Dosage forms and trade names available in Iraq

- Hydrochlorothiazide 25mg tab
- Hydrochlorothiazide 50 mg tablet

Urozide (Pioneer Iraq).

Pharmacokinetic parameters

Absorption F=60-80%.
Distribution Vd=3.6-7.8L/kg, 40%protein bound.
Metabolism Not metabolized.
Elimination Renal elimination is 50-70% with a half-life of 10-12 hr.

Drug interactions

Allopurinol: Thiazide diuretics may enhance the potential for allergic or hypersensitivity reactions to allopurinol, thiazide diuretics may increase the serum concentration of allopurinol also thiazide diuretics may increase the concentration of oxypurinol, an active metabolite of allopurinol.
Lithium: Hydrochlorothiazide slows down the body's removal of lithium, which may cause high levels of lithium in the body, which can lead to serious side effects.

Side effects

Anaphylaxis; Anorexia; Confusion; Disorder of hematopoietic structure; Dizziness; Epigastric distress; Fatigue; Headache; Hepatotoxicity; Hypercalcemia; Hypercholesterolemia; Hyperglycemia; Hyperlipidemia; Hyperuricemia; Hypokalemia; Hypomagnesemia; Hypotension; Interstitial nephritis; Metabolic acidosis; Muscle weakness or cramps; Nausea; Necrotizing angiitis; Pancreatitis; Phototoxicity; Pneumonitis; Pulmonary edema; Purpura; Rash; Respiratory distress; Stevens-Johnson syndrome; Toxic epidermal necrolysis; Vertigo; Vomiting; Xanthopsia.

Patient educations

Advise patient to take with food or milk if gastrointestinal upset occurs; Tell patient to take early in day to avoid nighttime urination; Tell patient to weigh himself daily, at same time on same scale and wearing same clothes; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness.

Hydrocortisone

ATC Code: H02AB09 Corticosteroids for Systemic Use (Glucocorticoids)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding in single dose.

Indications and Dosage

• Inflammation: By i.v. or i.m. injection, 100mg-500mg per dose qid.
• Status asthmaticus: Initially by i.v. injection, 1mg-2mg/kg qid, maintenance dose 0.5mg-1mg/kg qid.
• Skin disorders, corticosteroid responsive, atopic dermatitis: Apply thin layer topically to affected area once daily to bid.
• Ocular inflammation: Apply thin ribbon of ointment to conjunctival sac of affected eye every 3-4 hr depending on severity.

Off-label uses

COVID-19; Acute adrenal crisis; Phlebitis; Stomatitis.

Contraindications

Hypersensitivity to hydrocortisone; Systemic fungal infections.

Dosage forms and trade names available in Iraq

Hydrocortisone 100 mg vial
SOLU-CORTEF (Pfizer Belgium).
Hydrocortisone 1% Cream
HYDRO Skin (Wadi Al-Rafidain Iraq).
Hydrocortisone 2.5% Cream
HYDRO Skin (Wadi Al-Rafidain Iraq).
Hydrocortisone acetate 1% eye oint
HYDROCORTISONE (SDI Iraq).

Cautions

Hypertension; Osteoporosis; Glaucoma; GI disease; Hypothyroidism; Cirrhosis; Thromboembolic disorders; Myasthenia gravis; Heart failure.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=96% (oral); F=100% (injection).
Distribution Vd=34L, 90% protein bound.
Metabolism Hydrocortisone metabolized in tissues and liver.
Elimination Renal elimination (mainly), fecal elimination (minimally) with a half-life of 1-2 hr.

Drug interactions

Clarithromycin: Clarithromycin will increase the level or effect of hydrocortisone by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Aggression anxiety blurred vision burning, dry, or itching eyes decrease in the amount of urine discharge, excessive tearing dizziness dry mouth ear congestion fast, slow, pounding.
Less common (1-10%) Backache bloody, black, or tarry stools cough or hoarseness darkening of the skin decrease in height decreased vision diarrhea eye pain eye tearing facial hair growth in females fainting fever or chills flushed, dry skin.
Rare (less than 1%) None.

Patient educations

Advise patient to discontinue topical drug and notify prescriber if local irritation occurs; Instruct patient to eat small, frequent meals and to take antacids as needed to minimize gastrointestinal upset; Caution patient not to stop taking drug abruptly; In long-term use, instruct patient to have regular eye exams.

Hydroquinone

ATC Code: D11AX11 Other Dermatological Preparations (Other Dermatologicals)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Hyperpigmentation: Apply to the affected area bid.

Off-label uses

None.

Contraindications

Hypersensitivity to hydroquinone.

Cautions

Rash; Itching.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=45±11%.

Distribution Undetermined.

Metabolism Undetermined.

Elimination Undetermined.

Dosage forms and trade names available in Iraq

Hydroquinone 2% cream

Hydroquinone (Wadi Al-RafidainIraq).

Hydroquinone 4% cream

Hydroquinone (Wadi Al-RafidainIraq).

Drug interactions

There are no known significant interactions.

Side effects

Dermatitis; Dryness; Erythema; Inflammatory reaction; Mild skin irritation and sensitization (burning, stinging).

Patient educations

Avoid unnecessary exposure to sunlight; Test for skin sensitivity prior to use; Hydroquinone is a topical depigmentating agent that produces a reversible depigmentation of the skin by inhibiting enzymatic oxidation of tyrosine to 3,4 dihydroxyphenylalanine and suppressing melanocyte metabolic processes.

Hydroxocobalamin

ATC Code: B03BA03 Antianemic Preparations (Vitamin B12 (Cyanocobalamin and Analogues))

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Considered safe during breastfeeding as vitamin B12 is a normal component of breast milk.

Dosage forms and trade names available in Iraq

Hydroxocobalamin 1000mcg/1ml amp

Pio-Vit B12 (Pioneer Iraq).

Indications and Dosage

Treatment of pernicious anemia and the prevention and treatment of vitamin B12 deficiency. Usual dosage is 1000mcg intramuscularly, with frequency of dosing depending on the severity of the deficiency.

Off-label uses

Treatment of cyanide poisoning due to its ability to bind cyanide and form cyanocobalamin, which is excreted in urine; Vasoplegic syndrome.

Contraindications

In patients with known hypersensitivity to cobalt, cobalamin or any other component of the formulation.

Cautions

In patients with Leber's disease as it may cause severe and swift optic atrophy.

Dose adjustment in renal failure: No adjustment needed.

Dose adjustment in hepatic failure: No adjustment needed.

Pharmacokinetic parameters

Absorption Intramuscular injection bypasses absorption phase, delivering the drug directly into systemic circulation.

Distribution Binds to specific plasma proteins called transcobalamins; stored in the liver.

Metabolism Minimal metabolism.

Elimination Primarily excreted in the urine, with a half-life of approximately 6 days (variable).

Drug interaction

Chloramphenicol: May interfere with the hematologic response to vitamin B12 therapy in pernicious anemia.

Colchicine, aminosalicylic acid, and alcohol: These may decrease the absorption of Vitamin B12.

Side effects

Common (more than 10%): Injection site reactions.

Less common (1-10%): Headache, nausea, dizziness.

Rare but serious (less than 1%): Hypersensitivity reactions, including anaphylactic shock and death (very rare).

Patient educations

1. This medication is usually given as an injection at your doctor's office, a hospital, or a clinic.
2. Notify your healthcare provider immediately if you experience any signs of an allergic reaction, such as rash, itching, or difficulty breathing.
3. Keep all medical and laboratory appointments to monitor your response to this medication.

Hydroxychloroquine Sulfate

ATC Code: P01BA02 Antiparasitic Products, Insecticides and Repellents (Aminoquinolines)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Small amounts of it can pass into breast milk, but it's not enough to harm the baby.

Dosage forms and trade names available in Iraq

- Hydroxychloroquine Sulfate 200mg tablet **Plaquendin** (Alkindi Iraq), **Plaquneer** (PIONEER IRAQ).

Indications and Dosage

• Malaria prophylaxis: 400 mg orally once per week, starting 2 weeks before exposure and continuing for 4 weeks after leaving the endemic area.
• Rheumatoid Arthritis: 400-600 mg orally once or twice daily.
• Systemic Lupus Erythematosus: 200 to 400 mg orally once or twice daily.

Off-label uses

Some early studies suggested potential use in COVID-19, but evidence has not demonstrated effectiveness for this use.

Contraindications

Known hypersensitivity to hydroxychloroquine, 4-aminoquinoline compounds, or any component of the formulation.

Cautions

In patients with pre-existing auditory damage, hepatic disease, psoriasis, seizure disorder, or porphyria. Long-term therapy requires periodic eye examinations due to risk of retinopathy.
Dose adjustment in renal failure: Dose reduction may be required; dosing recommendations are not specific.
Dose adjustment in hepatic failure: Use with caution; dosing recommendations are not specific

Pharmacokinetic parameters

Absorption Well absorbed from the GI tract.
Distribution Large volume of distribution due to high tissue affinity.
Metabolism Partial hepatic metabolism to active de-ethylated metabolites.
Elimination Primarily renal elimination of metabolites, very long elimination half-life (up to 50 days).

Drug Interactions

Digoxin: Hydroxychloroquine may increase serum concentrations of digoxin.
Antidiabetes drugs: Hydroxychloroquine may enhance the hypoglycemic effect of antidiabetes drugs.

Side effects

Common (more than 10%): Nausea; diarrhea; stomach cramps; and vomiting.
Less common (1-10%): Headache; dizziness; ringing in ears; nervousness.
Rare but serious (less than 1%): Serious eye problems; heart problems such as heart failure and issues with the electrical system in the heart; liver problems.

Patient Education

1. Take with food or milk to decrease gastrointestinal side effects.
2. This medication may make you dizzy. Alcohol or marijuana can make you dizzier. Do not drive, use machinery, or do anything that needs alertness until you can do it safely.
3. Regular eye exams are recommended while taking this medication.

Hydroxyprogesterone

ATC Code: G03DA03 Sex Hormones and Modulators of The Genital System (Pregnen (4) Derivatives)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding; There is no indication of hydroxyprogesterone after delivery.

Indications and Dosage

• Prevention of preterm delivery: By i.m. injection, 250mg once weekly from 16 weeks of pregnancy until week 37.

Off-label uses

None.

Contraindications

Hypersensitivity to hydroxyprogesterone; Current or history of thromboembolic disorders; Breast cancer or hormone sensitive cancer; Undiagnosed abnormal vaginal bleeding unrelated to pregnancy; Cholestatic jaundice of pregnancy; Liver tumors; Active liver disease; Uncontrolled hypertension.

Dosage forms and trade names available in Iraq

Hydroxyprogesterone caproate 250mg/1ml ampoule

Primolut Depot (Bayer Germany).

Cautions

Physical examination is advised prior to starting therapy; Mental depression; diabetes; Discontinue treatment upon signs of thromboembolic and thrombotic disorders; Discontinue treatment if unexplained, sudden or gradual, partial or complete loss of vision; Asthma; Seizure disorders; Migraine; Cardiac dysfunction.

Dose adjustment in renal failure: Use with caution.

Dose adjustment in hepatic failure: Use of hydroxyprogesterone in severe hepatic failure is contraindicated.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=Undetermined, extensively bound to plasma proteins.

Metabolism Extensively metabolized by the liver.

Elimination Elimination half-life is 7.8 days.

Drug interactions

Erythromycin: Erythromycin will increase the level or effect of hydroxyprogesterone by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Injection site pain; Urticaria; Diarrhea; nausea.

Less common (1-10%) Diarrhea; Injection site nodule; Pruritus.

Rare but serious (less than 1%) Cervical dilation; Decreased glucose tolerance; Depression; Dyspnea; Fluid retention; Headache; Hot flashes; Hypertension; Jaundice; Rash; Vaginal bleeding; Vomiting.

Patient educations

Mark your calendar for weekly injections; The injections must be given each week until the 37th week of pregnancy or until deliver the baby, whichever comes first.

Hydroxyurea

ATC Code: L01XX05 Antineoplastic Agents (Other Antineoplastic Agents)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding as it is excreted in breast milk.

Indications and Dosage

• Skin; Head and neck cancer: 15mg/kg/day.
• Sickle cell anemia: Initially, 15mg/kg once daily, may increase by 5mg/kg/day every 12 weeks, (max 35mg/kg/day).
• Chronic myeloid leukemia (CML): Adult dose: 20-30 mg/kg/day orally, as a single dose or in divided doses
• Polycythemia vera: Adult dose: 15 mg/kg/day orally, as a single dose
• Essential thrombocythemia: Adult dose: 15 mg/kg/day orally, as a single dose

Dosage forms and trade names available in Iraq

Hydroxyurea 500mg cap
Cytodrox (Cipla India), **Hydroxyurea Medac** (Medac Germany).

H

Off-label uses

Cervical cancer, Psoriasis.

Contraindications

Hypersensitivity to HYDROXYUREA or any of its components; Severe bone marrow suppression ; Severe renal or hepatic impairment.

Cautions

it may cause myelosuppression, which lead to a decrease in blood cell counts, requiring regular monitoring; Renal and hepatic impairment; Avoidance of live vaccines; Previous irradiation therapy.
Dose adjustment in renal failure: Creatinine clearance (CrCl) 30-80 mL/min: Reduce initial dose to 50% of the normal dose ; CrCl <30 mL/min: Reduce initial dose to 30% of the normal dose
Dose adjustment in hepatic failure: Limited data available, use with caution and monitoring for toxicity.

Pharmacokinetic parameters

Absorption Rapid and almost complete (F=80-100%), food has no significant effect on absorption
Distribution Vd=25-30 L, minimal protein binding
Metabolism Limited hepatic metabolism, partially metabolized to urea and carbon dioxide.
Elimination Renal elimination (50-60% unchanged), with a half-life of 2-4 hours.

Drug interactions

• Concomitant use of didanosine (a medication used to treat HIV) may increase the risk of pancreatitis and peripheral neuropathy.
• Combining it with other myelosuppressive agents may lead to an increased bone marrow suppression and hematologic toxicity.

Side effects

Common (more than 10%): Bone marrow suppression (anemia, leukopenia,etc.); Gastrointestinal symptoms (nausea, vomiting, etc.) ; Anorexia.
Less common (1-10%): Skin changes (e.g., hyperpigmentation, rash) ; Alopecia ; Elevated liver enzymes.
Rare but serious (less than 1%) Secondary leukemia (with long-term use) or myelodysplastic syndrome ; Severe skin reactions (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis); Pulmonary fibrosis.

Hyoscine

ATC Code: A03BB01 Drugs For Functional Gastrointestinal Disorders (Belladonna Alkaloids, Semisynthetic)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 **B2** B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Hyoscine Butyl bromide 10mg tab
  SPASMOSAM (SDI Iraq), **Spasmodain** (Wadi Al-Rafidain Iraq), **SPASMOTAB** (Al-Kindi Iraq), **PiOCINE** (Pioneer Iraq).
- Hyoscine Butylbromide 20 mg/ml amp
  PiOCINE (Pioneer Iraq).
- Hyoscine Butylbromide 5mg/5ml Syrup
  Spasmo-kindi (Al-Kindi Iraq), **SPASMOSAM** (SDI Iraq), **PiOCINE** (Pioneer Iraq), **Spasmodain** (Wadi Al-Rafidain Iraq).

Indications and Dosage

Symptomatic relief of gastro-intestinal or genito-urinary disorders characterized by smooth muscle spasm, Irritable bowel syndrome, Acute spasm (Spasm in diagnostic procedures), Excessive respiratory secretions and, Bowel colic in palliative care: 10-20 mg t.i.d.

Off-label uses

Motion sickness.

Contraindications

Hypersensitivity to hyoscine; Myasthenia gravis; Narrow angle glaucoma; Tachycardia; Megacolon.

Cautions

Angina; Gastro-oesophageal reflux disease; Acute myocardial infarction; Conditions characterized by tachycardia (including Hyperthyroidism; Cardiac insufficiency; Cardiac surgery); Coronary artery disease; Hypertension; Open angle glaucoma; Pyrexia; Down's syndrome; Pyloric obstruction; Intestinal obstruction; Urinary bladder neck obstruction; Paralytic ileus; Gastrointestinal tract stenotic lesions; Prostatic hypertrophy; Urinary retention; Seizure; Psychosis.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=13%, the absolute bioavailability is low because of first pass metabolism.

Distribution Vd=141.3±1.6L, 30% protein bound.

Metabolism Primarily metabolized in the liver.

Elimination Renal elimination is 2% with half-life of 65 minutes.

Drug interactions

Antacids: Antacids may reduce absorption of hyoscine, resulting in decreased therapeutic effectiveness; doses of antacids should be spaced)2-3(hr. apart from doses of hyoscine.

Potassium chloride: Potassium chloride concurrent with hyoscine may increase severity of potassium chloride induced gastrointestinal lesions.

Patient educations

Take as prescribed, 30-60 minutes before meals; Avoid excessive dosage; Avoid hot environments; Avoid alcohol; wear sunglasses; impotence (reversible); difficulty urinating (empty bladder before taking drug).

Hypromellose

ATC Code: S01KA02 Ophthalmologicals (Viscoelastic Substances)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not known but given that it is not a drug and is generally considered safe, it is likely to be safe during lactation.

Dosage forms and trade names available in Iraq

- Hydroxypropyl methylcellulose 3mg/ml eye drop
- Hydroxypropyl Methylcellulose 1.60mg/0.5ml eye drop

ARTELAC (Dr. Gerhard Mann Chem-Pharm Germany).

Indications and Dosage

Varies depending on the specific product containing HPMC. For example, in eye drops, it is typically used as needed for relief of dry eyes.

Off-label uses

As an excipient, HPMC is used in a wide variety of drug formulations and is not subject to off-label use regulations.

Contraindications

Hypersensitivity to HPMC.

Cautions

None.

Dose adjustment in renal failure: Not applicable, as HPMC is not a drug and is not metabolized in the same way as drugs.

Dose adjustment in hepatic failure: Not applicable, as HPMC is not a drug and is not metabolized in the same way as drugs.

Pharmacokinetic parameters

Not applicable, as HPMC is not a drug and does not have pharmacokinetic parameters.

Drug interactions

As HPMC is not a drug, it does not typically interact with drugs.

Side effects

Common (more than 10%) None, generally.

Less common (1-10%) Some individuals may experience mild eye irritation if using eye drops containing HPMC.

Rare but serious (less than 1%) Hypersensitivity reactions are possible but very rare.

Patient educations

1. HPMC is used as an ingredient in various medications and products, including eye drops.
2. If using eye drops containing HPMC, follow the instructions provided by your healthcare provider.
3. If you experience any unusual or severe reactions, contact your healthcare provider immediately.

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Menstrual

Ibandronic Acid

ATC Code: M05BA06 Drugs for Treatment of Bone Diseases (Bisphosphonates)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Postmenopausal osteoporosis: 150mg once monthly.

Off-label uses

Hypercalcemia of malignancy; Reduces bone pain and skeletal complications from metastatic bone disease due to breast cancer.

Contraindications

Hypersensitivity to ibandronic acid; Hypocalcemia; Inability to stand or sit upright for at least 60 min; Esophageal stricture or achalasia.

Cautions

Barrett's esophagus; Smoking; Dysphagia; Gastritis; Duodenitis; Gasterointestinal ulcers; Patients who develop jaw osteonecrosis (ONJ) during therapy.

Dose adjustment in renal failure: CrCl less than 30ml/min: avoid.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Ibandronic acid (as sodium monohydrate) 150mg tab

Pharmacokinetic parameters

Absorption F=1%, food reduce absorption take 60 min prior to meal.
Distribution Vd=90L, 85-99% protein bound.
Metabolism Not metabolized.
Elimination Renal elimination is 50% with a half-life of 37-157 hours.

Drug interactions

• Supplements containing calcium, magnesium, iron or Aluminium
• Acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (NSAIDs) (including ibuprofen, diclofenac sodium and naproxen).

Side effects

Common (more than 10%) Headache; Rash; Back pain; Bronchitis; Dyspepsia; Upper respiratory infection.
Less common (1-10%) Asthenia; Diarrhea; Dizziness; Myalgia; Pneumonia; Tooth disorder; Urinary tract infection.
Rare (less than 1%) inflammation of the of the bowel duodenum causing stomach pain; hives.

Patient educations

After swallowing monthly Ibandronic acid tablet in the morning with a full glass of water (at least 180ml of water), wait for 1 hour before taking any other medication, including indigestion tablets, calcium supplements, or vitamin, do not take Ibandronic acid with food, choose one day of the month that will be easy to remember, swallow tablet whole — do not chew it, crush it or let it dissolve in the mouth, do not lie down for the next hour (60 minutes) after taken the tablet. While being treated, you should maintain good oral hygiene and receive routine dental check-ups. Contact dentist immediately if there are any problems with the mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw. A healthy lifestyle will help the patient to get the most benefit from the treatment like eating diet rich in calcium and vitamin D, walking or any other weight-bearing exercise, not smoking; and not drinking too much alcohol.

Ibrutinib

ATC Code: L01EL01 Antineoplastic Agents (Bruton's Tyrosine Kinase (BTK) Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Breastfeeding is not recommended while taking ibrutinib.

Dosage forms and trade names available in Iraq

Ibrutinib 140mg capsule
Imbruvica (Janssen cilag Belgium).

Indications and Dosage

Used to treat various types of leukemia and lymphoma including Mantle Cell Lymphoma (MCL), Chronic Lymphocytic Leukemia (CLL), and Waldenström's macroglobulinemia. The typical dosage is 560 mg orally once daily for MCL, and 420 mg orally once daily for CLL and Waldenström's macroglobulinemia.

Off-label uses

Treatment of Graft-versus-Host Disease (GVHD).

Contraindications

Hypersensitivity to ibrutinib or any component of the formulation.

Cautions

Hemorrhage, infections, cytopenias, cardiac arrhythmias, hypertension, and secondary primary malignancies have been observed.

Dose adjustment in renal failure: Not necessary for patients with mild to moderate renal impairment. The effect of severe renal impairment or dialysis on ibrutinib pharmacokinetics has not been evaluated.

Dose adjustment in hepatic failure: Ibrutinib is metabolized in the liver. So should be used with caution and adjustments are needed for varying degrees of hepatic impairment.

Pharmacokinetic parameters

Absorption Rapidly absorbed from the GI tract.
Distribution 95% protein bound.
Metabolism Primarily metabolized by the liver via CYP3A.
Elimination Eliminated primarily in the feces.

Drug interaction

Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole): Concurrent use may increase ibrutinib levels. Dose adjustment of ibrutinib may be required.

Strong CYP3A inducers (e.g., rifampin, carbamazepine): Concurrent use may decrease ibrutinib levels, reducing its efficacy.

Side effects

Common (more than 10%): Diarrhea, fatigue, cough, nausea, and rash.
Less common (1-10%): Fever, upper respiratory tract infection, anemia, bruising, and muscle spasms.
Rare but serious (less than 1%): Serious bleeding events, major cardiac events, renal failure, and liver failure.

Patient educations

• Take ibrutinib at approximately the same time each day with a glass of water.
• Do not open, break, or chew the capsules. Avoid grapefruit and Seville oranges during treatment; these can significantly increase blood concentrations of the drug.

Ibuprofen

ATC Code: M01AE01 Antiinflammatory and Antirheumatic Products (Propionic Acid Derivatives)

Pregnancy category:

FDA A B **C** **D** X N

TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Ibuprofen 100mg/5ml syrup
  Profedin (SDI Iraq), **profedad** (Wadi Al-Rafidain Iraq), **Profepain** (Almansour Iraq), **KINPROFEN** (Al-Kindi Iraq).
- Ibuprofen 200mg tab
  Profedain (Wadi Al-Rafidain Iraq), **PROFEDIN** (SDI Iraq), **Piofen** (PIONEER IRAQ),
- Ibuprofen 400mg tab
  Piofen (PIONEER IRAQ), **Profedain** (Wadi Al-Rafidain Iraq), **PAINPROOF** (Al- Kindi Iraq).
- Ibuprofen 600mg Sachets

Indications and Dosage

• Fever, Pain: 200mg-400mg qid or prn, (max 1200mg daily).

•Osteoarthritis or rheumatoid arthritis: 1200mg-3200mg daily in 3-4 divided doses.

• Topical analgesic and anti-inflammatory for backache, pain of non-serious arthritic conditions, muscular pain, sprains, strains, sports injuries and neuralgia: Apply the gel as a thin layer over the affected area tid.

Off-label uses

Treatment of cystic fibrosis; Pericarditis; Juvenile idiopathic arthritis; Migraine and tension headaches.

Contraindications

Hypersensitivity to ibuprofen; Perioperative use in coronary artery bypass graft surgery.

Cautions

Severe cardiovascular; Hepatic disease; GI disease; Asthma; Chronic alcohol use; Elderly patients; Children.

Dose adjustment in renal failure: Avoid

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%, food has minimal effect on absorption.

Distribution Vd=0.1L/kg, 99% protein bound.

Metabolism hepatic metabolism 20%.

Elimination Renal elimination is 45-80% with a half-life of 1.8-2.2 hr.

Drug interactions

Captopril: Ibuprofen may diminish the antihypertensive effect of captopril. The mechanism of these interactions is likely related to the ability of ibuprofen to reduce the synthesis of vasodilating renal prostaglandins.

Side effects

Common (more than 10%): None.

Less common (1-10%): Constipation; Dizziness; Edema; Epigastric pain; Fluid retention; Headache; Heartburn; Nausea; Rash; Tinnitus; Vomiting.

Rare (less than 1%): Agranulocytosis; Erythema multiforme; Exfoliative dermatitis; Hemolytic anemia; Neutropenia; Thrombocytopenia.

Patient educations

If GI upset occurs, take with food, milk, antacids.

Idursulfase

ATC Code: A16AB09 Other Alimentary Tract and Metabolism Products (Enzymes)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: There is no information available

Dosage forms and trade names available in Iraq

Idursulfase 2mg/ml injection
Elaprase (Shire Human USA).

Indications and Dosage

Indicated for patients with Hunter syndrome (Mucopolysaccharidosis II). The recommended dosage is 0.5 mg/kg of body weight administered once weekly as an intravenous infusion.

Off-label uses

None.

Contraindications

Severe hypersensitivity to idursulfase or any of the excipients of the product.

Cautions

In patients with acute febrile or respiratory illness. Sleep apnea is common in MPS II patients and antihistamine pretreatment may increase the risk of apneic episodes.
Dose adjustment in renal failure: No adjustment guidelines have been provided.
Dose adjustment in hepatic failure: No adjustment guidelines have been provided.

Pharmacokinetic parameters

Absorption Intravenous administration, bypassing absorption processes.
Distribution Predominantly to the liver.
Metabolism Presumably degraded by proteases.
Elimination Unknown, half-life is approximately 1.5 to 2.5 hours.

Drug interaction

there are no known significant interactions.

Side effects

Common (more than 10%): Headache, pruritus, rash, fever, cough, and urticaria.
Less common (1-10%): Hypertension, abdominal pain, arthralgia.
Rare but serious (less than 1%): Severe hypersensitivity reactions, risk of acute respiratory complications.

Patient education

1. Inform patients about the signs and symptoms of anaphylaxis and have immediate access to emergency medical support.
2. Do not drive or operate heavy machinery until you know how idursulfase affects you.
3. Keep all your medical and laboratory appointments for regular monitoring.

Ifosfamide

ATC Code: L01AA06 Antineoplastic Agents (Nitrogen Mustard Analogues)

Pregnancy category:
FDA A B C D X **N**
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Germ cell testicular carcinoma: By i.v. injection, 1200mg/m^2/day for 5 consecutive days, repeat every 3 weeks.

Off-label uses

Small cell lung cancer; Non-small cell lung cancer; Ovarian cancer; Cervical cancer; Bladder cancer; Soft tissue sarcomas; Hodgkin's, non-Hodgkin's lymphomas; Osteosarcoma; Ewing's sarcoma.

Dosage forms and trade names available in Iraq

Ifosfamide 2g injection
HOLOXAN (Baxter Oncology Germany).

Contraindications

Hypersensitivity to Ifosfamide; Urinary outflow obstruction.

Cautions

Compromised bone marrow reserve; Active urinary tract infection; Preexisting cardiac disease; Prior radiation therapy; Avoid use in patients with WBCs less than 2,000 cells/mm^3 and platelets less than 50,000 cells/mm^3.

Dose adjustment in renal failure: CrCl 30-60ml per minute reduce dosage to 75% of normal dose; CrCl 10-30ml per minute reduce dosage to 50% of normal dose; CrCl less than 10ml per minute use of Ifosfamide is not recommended.

Dose adjustment in hepatic failure: Bilirubin more than 3mg/dL reduce dosage to 25% of normal dose.

Pharmacokinetic parameters

Absorption F=90-100%.
Distribution Vd=33L.
Metabolism Metabolized by the liver to active antineoplastic compounds.
Elimination Renal elimination is 12-18% with half-life of 15 hours.

Drug interactions

Tacrolimus: Ifosfamide and tacrolimus both increases effects of the other by immunosuppressive effects, risk of infection.

Side effects

Common (more than 10%) Alopecia; CNS toxicity; Hematuria; Leukopenia; Metabolic acidosis; Nausea; Neurotoxicity; Thrombocytopenia; Vomiting.
Less common (1-10%) Infection; Nephrotoxicity.
Rare but serious (less than 1%) None.

Patient educations

Alopecia is reversible, but new hair growth may have a different color or texture; Drink plenty of fluids (protects against cystitis); Do not have immunizations without physician's approval (drug lowers resistance); Avoid contact with those who have recently received live virus vaccine; Avoid crowds, those with infections; Report unusual bleeding, fever, chills, sore throat, joint pain, sores in mouth or on lips, yellowing skin or eyes.

Imatinib

ATC Code: L01EA01 Antineoplastic Agents (BCR-ABL Tyrosine Kinase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

- Imatinib 100mg cap
  Avatib (Aspen Poland).
- Imatinib 400mg cap
  Glivec (Novartis Switzerland).

Indications and Dosage

• Philadelphia chromosome positive chronic myeloid leukemia (chronic phase): 400mg once daily, may increase to 600mg daily, (max 800mg daily).
• Philadelphia chromosome positive chronic myeloid leukemia (accelerated phase): 600mg once daily, may increase to 400mg bid.
•Philadelphia chromosome positive acute lymphoblastic leukemia: 600mg once daily.
• Gastrointestinal stromal tumors: 400mg once daily for 3 years.
• Aggressive systemic mastocytosis with eosinophilia: Initially, 100mg once daily, may increase up to 400mg daily.
• Dermatofibrosarcoma protuberans: 400mg bid.

Off-label uses

Treatment of desmoid tumors; Post-stem cell transplant; Follow up treatment in recurrent chronic myeloid leukemia; Treatment of advanced or metastatic melanoma.

Contraindications

Hypersensitivity to imatinib.

Cautions

Thyroidectomy patients; Hypothyroidism; Gastric surgery; Heart failure; Hypertension; Pulmonary disease.
Dose adjustment in renal failure: CrCl 20-39ml per minute max dose 400mg daily; CrCl less than 20ml per minute max dose 100mg daily.
Dose adjustment in hepatic failure: In severe hepatic failure, reduce dosage to 75% of normal dose.

Pharmacokinetic parameters

Absorption F=98%.
Distribution Vd=347±62L, 95%protein bound.
Metabolism Mostly metabolized by the CYP3A4 enzyme system to N-demethyl imatinib.
Elimination Renal elimination is 5% with half-life of 18-40 hours.

Drug interactions

Codeine: Imatinib may increase serum concentrations of the active metabolites of codeine.

Side effects

Common (more than 10%) malaise.
Less common (1-10%) nausea, vomiting, headache and diarrhea.
Rare but serious (less than 1%) severe renal failure, Hepatic necrosis; Hepatic failure; Tumor lysis syndrome; Gastrointestinal perforation.

Imiglucerase

ATC Code: A16AB02 Other Alimentary Tract and Metabolism Products (Enzymes)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available.

Dosage forms and trade names available in Iraq

Imiglucerase I.V infusion 400 unit/vial.
Cerezyme (Genzyme Ireland)

Indications and Dosage

• Gaucher's disease: By i.v. infusion, 2.5 IU/kg infused over 1-2 hr 3 times a week up to 60 IU/kg/week.

Off-label uses

None.

Contraindications

Hypersensitivity to imiglucerase.

Cautions

Patient with respiratory symptoms in the absence of fever.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=0.09-0.15L/kg.
Metabolism Undetermined.
Elimination Half-life is 3.6-10.4 minutes.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) None.
Less common (1-10%) Backache; Chills; Dizziness; Fatigue; Fever; Headache; Hypersensitivity with infusion; Nausea, abdominal pain, vomiting, diarrhea; Rash; Tachycardia.
Rare but serious (less than 1%) Burning; Discomfort; Pneumonia; Pruritus; Pulmonary hypertension; Sterile abscess at site of venipuncture; Swelling.

Patient educations

A Patient education is not currently available for this monograph.

Note

It is recommended to administer the diluted solution through an in-line low protein-binding 0.2 µm filter to remove any protein particles. This will not lead to any loss of imiglucerase activity. It is recommended that the diluted solution be administered within 3 hours. The product diluted in 0.9% sodium chloride intravenous solution will retain chemical stability if stored up to 24 hours at 2°C and 8°C under protection from light; but microbiological safety will depend on the reconstitution and dilution having been performed aseptically; Imiglucerase contains no preservatives. Any unused product or waste material should be disposed of in accordance with local requirements.

Imiquimod

ATC Code: D06BB10 Antibiotics and Chemotherapeutics for Dermatological Use (Antivirals)

Pregnancy category:

FDA A B **C** D X N

TGA A **B1** B2 B3 C D X N

Lactation: There is no information available; Caution is advised

Dosage forms and trade names available in Iraq

Imiquimod 5% cream

Aldara (MEDA Pharma Germany).

Indications and Dosage

• Actinic Keratosis: Apply 5% cream once daily to the affected area, up to a maximum single dose of 1 sachet. Treatment duration is typically 16 weeks.

• Superficial Basal Cell Carcinoma: Apply 5% cream once daily 5 times per week (e.g., Monday to Friday) for 6 weeks.

• External Genital Warts: Apply 5% cream once daily at bedtime, 3 times per week for up to 16 weeks.

Off-label uses

It may be used for other skin conditions such as molluscum contagiosum, cutaneous metastases of melanoma, and others

Contraindications

Individuals who have a history of hypersensitivity to the drug.

Cautions

Avoid contact with eyes, lips, and nostrils. If the cream comes into contact with these areas, rinse thoroughly with water. Do not use on broken, wounded, or burned skin.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Minimal systemic absorption.

Distribution Unknown.

Metabolism Mainly hepatic.

Elimination Mainly renal, with a half-life of approximately 37 hours.

Drug interaction

No specific interactions have been identified for this medication.

Side effects

Common (more than 10%): Skin redness, erosion, edema, itching, burning.

Less common (1-10%): Headache, insomnia, diarrhea, nausea.

Rare but serious (less than 1%): Allergic reactions, severe local inflammatory reactions, possible exacerbation of autoimmune conditions.

Patient educations

1. The cream is for external use only. Do not use it in your eyes, nose, or mouth.
2. Wash your hands before and after applying the cream.
3. Discontinue use and contact your healthcare provider if severe local skin reaction occurs.

Indapamide

ATC Code: C03BA11 Diuretics (Sulfonamides, plain)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Indapamide 1.5 mg tablet
  NATRILIX SR (Servier France).

Indications and Dosage

• Edema: Initially, 1.5mg daily, may increase to 4.5mg daily after 1 week.

•Essential Hypertension: Initially, 1.5mg, may increase to 3mg daily after 4 weeks or 4.5mg daily after additional 4 weeks (maximum 5mg / day). 1.5mg orally (once daily) has been reported to be the most effective agent in significantly lowering systolic blood pressure within 2-3 months of treatment initiation.

Off-label uses

Calcium nephrolithiasis.

Contraindications

Hypersensitivity to indapamide; hypersensitivity to sulfonamides due to cross- sensitivity; Anuria.

Cautions

Gout; Prediabetes; Diabetes; Elderly; Severe hyponatremia; Elevated serum cholesterol acute porphyrias.

Dose adjustment in renal failure: Use with caution.

Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=100%, food has no effect on absorption.

Distribution Vd=25-60L, 76-79%protein bound.

Metabolism Extensive metabolism in the liver.

Elimination Renal elimination is 60-70% with half-life of 13.9-18 hours.

Drug interactions

Moxifloxacin: Indapamide and moxifloxacin both increase QTc interval and risk for hyperkalemia complicated by arrhythmia, and facilitate adverse effects of concomitant digitalis.

Side effects

Common (more than 10%) hypersensitivity; electrolyte disturbances; increament of blood cholesterol; hyperuricemia precipitating gout.

Less common (1-10%) Anorexia; Blurred vision; Dizziness; Drowsiness; Electrolyte abnormalities; Fatigue; Flushing; Headache; Hypotension; Lethargy; Lightheadedness; Malaise; Nausea; Nocturia; Palpation; Polyuria; Pruritus; Rash; Restlessness; Rhinnorhea; Vertigo; Weakness.

Rare but serious (less than 1%) Cutaneous vasculitis; Eye Disorders: Choroidal effusion, acute myopia, and angle-closure glaucoma; Glycosuria; Pancreatitis; angioedema; hemolytic anemia; vertigo; arrhythemias; hepatic disorders; renal failure.

Patient educations

Expect increased frequency, volume of urination (diminishes with long-term use); To reduce hypotensive effect, go slowly from lying to standing; Eat foods high in potassium such as whole grains (cereals), legumes, meat, bananas, apricots, orange juice, potatoes (white, sweet), raisins; Take early in the day to avoid nocturia.

Indomethacin

ATC Code: M01AB01 Anti-inflammatory and Antirheumatic Products (Acetic Acid Derivatives and Related Substances)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Compatible with breastfeeding.

Indications and Dosage

• Pain, ankylosing spondylitis, osteoarthritis, rheumatoid arthritis: 25mg-50mg bid-tid, (max 200mg daily bid).
• Morning stiffness: One suppository to be inserted once at night or bid.

Off-label uses

Prevention of preterm labor; Bartter's syndrome; Pericarditis.

Contraindications

Hypersensitivity to indomethacin; Active GI bleeding.

Cautions

Severe cardiovascular disease; History of ulcer disease; Elderly patients; Children.
Dose adjustment in renal failure: CrCl less than 10ml/min: use cautiously.
Dose adjustment in hepatic failure: Use cautiously.

Dosage forms and trade names available in Iraq

Indomethacin 25mg capsule
Indomethacin 100mg suppositories

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.
Distribution Vd=0.34-1.57L/kg, 99% protein bound.
Metabolism Hepatic metabolism 40%.
Elimination Renal elimination is 60% with a half-life of 4.5 hr.

Drug interactions

Methotrexate: Nonsteroidal anti-inflammatory agents may increase the serum concentration of methotrexate, alternative anti-inflammatory therapy should be considered whenever possible, especially if the patient is receiving higher, antineoplastic doses of methotrexate.
Combining indomethacin with **ACE inhibitors**, AR blockers, or beta blockers can diminish their effectiveness.
Indomethacin may decrease the excretion rate of **Sulbactam** which could result in a higher serum level. The risk or severity of hypoglycemia can be increased when Indomethacin is combined with Sulfadiazine.

Side effects

Common (more than 10%) Elevated liver function test values; Headache; Jaundice; Transient renal insufficiency.
Less common (1-10%) Abnormal pain; Constipation; Depression; Diarrhea; Dizziness; Dyspepsia; Epigastric pain; Fatigue; Indigestion; Nausea; Somnolence; Tinnitus; Vertigo.
Rare (less than 1%) Acute interstitial nephritis with hematuria/proteinuria; Acute respiratory distress; Agranulocytosis; Angioedema; Aplastic anemia; Asthma; Bone marrow depression; Congestive heart failure; Hemolytic anemia; Leukopenia; Macular and morbilliform eruptions; Pulmonary edema; Thrombocytopenia; Thrombocytopenic purpura; Ulcerative stomatitis; Urticaria.

Patient educations

Tell patient to take with food, full glass of water, or antacid to reduce gastrointestinal upset; Advise patient not to open or crush capsules; Inform breastfeeding patient that indomethacin enters breast milk and may cause seizures in infant; Advise her to use a different infant feeding method during therapy.

Infliximab

ATC Code: L04AB02 Immunosuppressants (Tumor Necrosis Factor Alpha (TNF-α) Inhibitors)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 **C** D X N

Lactation: Breastfeeding discontinue 6 months after the last dose.

Dosage forms and trade names available in Iraq

Infliximab 100 mg vial

Remicade (JANSSEN-Cilag Switzerland), **Ixifi** (Pfizer Belgium).

Indications and Dosage

•Rheumatoid Arthritis in combination with methotrexate: By i.v. infusion, 3mg/kg followed by additional doses at 2 and 6 weeks after first infusion, then every 8 weeks thereafter.

•Crohn's disease (≥6 years), ulcerative colitis: By i.v. infusion, 5mg/kg followed by additional doses at 2 and 6 weeks after first infusion, then every 8 weeks thereafter.

•Ankylosing spondylitis: By i.v. infusion, 5mg/kg followed by additional doses at 2 and 6 weeks after first infusion, then every 6 weeks thereafter.

•Psoriatic arthritis; Chronic severe plaque Psoriasis (can be used with or without methotrexate): By i.v. infusion, 5mg/kg followed by additional doses at 2 and 6 weeks after first infusion, then every 8 weeks thereafter.

Off-label uses

•Behçet's disease; Noninfectious Uveitis; Sarcoidosis; Idiopathic pulmonary fibrosis; SAPHO syndrome; Severe hidradenitis suppurativa; Systemic lupus erythematosus.

Contraindications

Hypersensitivity to infliximab; Moderate to severe heart failure; Sepsis; Serious active infection.

Cautions

Hematologic abnormalities; COPD; CNS demyelinating disorders; Seizures; Mild heart failure; History of recurrent infections; Diabetes; Tuberculosis; Elderly; Chronic hepatitis B virus infection.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=3-6L.

Metabolism Undetermined.

Elimination Half-life is 9.5 days.

Drug interactions

Azathioprine: Azathioprine and infliximab both increase immunosuppressive effects and risk of infection.

Side effects

Common (more than 10%) Abdominal pain; Headache; Infusion related reaction; Nausea.

Less common (1-10%) Arthralgia; Back pain; Bacterial & Viral infection; Dyspnea; Hypertension; Leukopenia; Neutropenia; Pruritus; Rash.

Rare but serious (less than 1%) None.

Patient educations

Report symptoms of infection such as body aches, chills, cough, fatigue, fever; Avoid those with active infection.

Influenza Vaccine

ATC Code: J07BB Vaccines (Influenza Vaccines)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Influenza vaccine can be given to nursing mothers.

Dosage forms and trade names available in Iraq

Trivalent Influenza vaccine 0.5ml pre-filled syringe
INFLUAVAC (Abbott Netherlands).

Quadrivalent Influenza vaccine 0.5ml pre-filled syringe
Vaxigrip Tetra (Sanofi FRANCE).

Indications and Dosage

The vaccine is used for the prevention of influenza in individuals aged 6 months and older. The typical dosage is a single 0.5 mL dose given intramuscularly annually. For some children aged 6 months to 8 years, two doses given at least 4 weeks apart may be needed.

Off-label uses

None.

Contraindications

Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including egg protein.

Cautions

Use caution in individuals with a history of Guillain-Barré Syndrome within 6 weeks of a previous influenza vaccination.

Dose adjustment in renal failure: Not typically required.

Dose adjustment in hepatic failure: Not typically required.

Pharmacokinetic parameters

As vaccines work by stimulating the body's immune response, pharmacokinetic parameters such as **absorption, distribution, metabolism, and elimination** are not applicable.

Drug interaction

Immunosuppressants: May decrease the immunologic effect of the influenza vaccine.

Intranasal Influenza Virus Vaccine Live: May decrease the effectiveness of the influenza vaccine.

Side effects

Common (more than 10%): Soreness, redness, or swelling at the injection site, headache, muscle aches, fever.

Less common (1-10%): Nausea, fatigue.

Rare but serious (less than 1%): Allergic reactions, Guillain-Barre Syndrome.

Patient educations

1. Influenza vaccine does not cause flu as it contains inactivated virus or a recombinant influenza vaccine.
2. Side effects usually occur soon after vaccination and are generally mild and go away on their own within a few days.
3. If you have a history of severe allergic reaction to a previous dose of flu vaccine or any part of flu vaccine, you should not get a flu vaccine.

Chronic Disease Medications Line By Pioneer

Cloxaban
Rivaroxaban
10mg 15mg 20mg

Plavineer
Clopidogrel
75mg

Rosva
Rosuvastatin
10mg 20mg 40mg

Candasart-plus
Candesartan Cilexetil/ Hydrochlorothiazide
8mg 16mg 12.5 mg

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PiONEER CO.
FOR PHARMACEUTICAL INDUSTRIES

Interferon

ATC Code: L03AB01 Antineoplastic and Immunomodulating Agents (Interferons)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C **D** X N

Lactation: No known effects.

Indications and Dosage

• Interferon Alpha Indications include certain types of cancers (such as melanoma, leukemia, lymphoma) and viral infections (such as Hep B, Hep C). Dosage depends on the specific condition, patient's health status and response to therapy.

• Interferon beta-1b is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. The usual dose is 250 micrograms (8 million IU) injected under the skin every other day.

Dosage forms and trade names available in Iraq

- Interferon alfa PFP
  Intron-A (Bayer Schering (Schering) Irland).
- Interferon beta 44µg (12millionIU/0.5ml) PFS
  Rebif (Merck Serono SWITZERLAND).
- interferon beta 30µg (6million IU/0.5ml) PFS
  Avonex (FUJIFILM Diosynth Biotechnologies Denmark).
- interferon beta (8 million IU/1ml) PFS
  BETAFERON (BOEHRINGER INGELHEIM Germany).

Off-label uses

Certain types of viral infections.

Contraindications

•**Interferon alpha:** Autoimmune hepatitis, decompensated liver disease.

• **Interferon beta:** Known hypersensitivity to natural or recombinant interferon beta or any other component of the formulation; Severe depression and/or suicidal ideation

Cautions

• **Interferon alpha:** May cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Monitor closely with periodic clinical and laboratory evaluations.

• **Interferon beta:** Depression, suicidal ideation, or psychosis; seizures; cardiac disease (congestive heart failure, decreased cardiac function); hepatic or hematologic abnormalities.

Dose adjustment in renal failure: May require adjustment; monitor hematologic values more closely.

Dose adjustment in hepatic failure: May be required; use caution.

Pharmacokinetic parameters

Absorption, distribution, metabolism, and elimination can vary based on the specific formulation and individual patient characteristics.

Drug interaction

Interferon alpha:

• **Ribavirin:** use with Ribavirin can cause hemolytic anemia. Monitor hematologic values closely.

• **Theophylline:** use with Interferon alpha may increase theophylline levels, leading to potential toxicity.

Interferon Beta:

• **Zidovudine:** Interferon beta-1b may decrease the serum concentration of zidovudine.

• **Theophylline:** Interferon beta-1b may increase the serum concentration of theophylline.

Side effects

Common (more than 10%) Fatigue; flu-like symptoms; nausea; depression, Injection site reactions

Less common (1-10%) Weight loss; hair thinning; liver function abnormalities, Depression.

Rare but serious (less than 1%) serious infections; severe depression; suicidal ideation; cardiovascular complications.

Iohexol

ATC Code: V08AB02 Contrast Media (Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Iohexol is excreted in breast milk in small amounts, but no adverse effects on the infant are anticipated.

Dosage forms and trade names available in Iraq

Iohexol 300mg/ml vial

Iohexol 350mg/1ml -100ml vial

Hexoneer (Pioneer Iraq).

Indications and Dosage

Iohexol is used in adults and pediatric patients for intravascular administration in computed tomography and intra-arterial digital subtraction angiography. Dosage varies depending on the type and extent of the examination.

Off-label uses

None.

Contraindications

Known hypersensitivity to iohexol or any of its components.

Cautions

History of bronchial asthma or allergy; Dehydration; Renal impairment.

Dose adjustment in renal failure: In patients with severe renal impairment, the use of iohexol should be considered only if the potential benefit justifies the potential risk.

Dose adjustment in hepatic failure: Not typically required, but caution should be exercised.

Pharmacokinetic parameters

Absorption Not applicable, as it's used intravascularly.

Distribution Rapidly distributed in the extracellular fluid; not bound to plasma proteins.

Metabolism Iohexol is not metabolized.

Elimination Primarily renal, with a half-life of approximately 2 hours.

Drug interaction

Interactions have not been established; It's important to maintain hydration and assess kidney function when using with potentially nephrotoxic drugs.

Side effects

Common (more than 10%): Warm sensation; Taste perversion; Headache.

Less common (1-10%): Nausea; Vomiting; Dizziness.

Rare but serious (less than 1%): Hypersensitivity reactions; Anaphylaxis; Cardiac arrest.

Patient educations

- Inform the doctor of any allergies or asthma history.
- Hydrate before and after the procedure to help clear the contrast from your system.
- Contact healthcare professionals if experiencing delayed allergic reactions such as rash or difficulty breathing.

Ipratropium Bromide

ATC Code: R03BB01 Drugs for Obstructive Airway Diseases (Anticholinergics)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Bronchodilator for COPD: 2 inhalations qid, (max 12 inhalations daily).
• Asthma exacerbation: 8 inhalations every 20min as needed for up to 3 hr.

Off-label uses

None.

Contraindications

Hypersensitivity to ipratropium.

Cautions

Narrow angle glaucoma; Prostatic hypertrophy; Bladder neck obstruction; Myasthenia gravis.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Ipratropium as Bromide anhydrous 20mcg/puff oral inhalation
Atrovent (Boehringer Inglheim Germany).
Ipratropium bromide 250µg inhalation solution 2ml ampoule
Ipravent (Pioneer Iraq).
Ipratropium bromide 500µg inhalation solution 2ml ampoule
Atrovent (Boehringer Inglheim Germany),
Ipravent (PIONEER Iraq).

Pharmacokinetic parameters

Absorption F=20%.
Distribution Vd=4.6L/kg, 0-9%protein bound.
Metabolism Small amounts absorbed are metabolized by the liver.
Elimination Renal elimination is 80-100% with half-life of 2 hours.

Drug interactions

Tiotropium: Anticholinergic agents may enhance the anticholinergic effect of tiotropium, avoid combination.
Topiramate: Anticholinergic agents may enhance the adverse effect of topiramate.

Side effects

Common (more than 10%) Bronchitis; Chronic obstructive pulmonary disease (COPD) exacerbation; Sinusitis.
Less common (1-10%) Dizziness; Dry mouth; Dyspepsia; Back pain; Nausea; Cough; Flulike symptoms; Headache; Urinary tract infection; Dyspnea
Rare but serious (less than 1%) Hypotension; Palpitations; Tachycardia; Constipation; Stomatitis; Mouth edema; Dry throat; Throat irritation; Urinary retention; Bronchospasm; Narrow-angle glaucoma; Glaucoma; Conjunctival hyperemia; Corneal edema; Mydriasis; Acute eye pain; Blurry vision.

Patient educations

Avoid increase fluid intake (decreases lung secretion viscosity); Do not take more than 2 inhalations at any one time (excessive use may produce paradoxical bronchoconstriction, decreased bronchodilating effect); Rinsing mouth with water immediately after inhalation may prevent mouth and throat dryness; Avoid excessive use of caffeine derivatives (chocolate, coffee, tea, cola, cocoa).

Irbesartan

ATC Code: C09CA04 Agents Acting on The Renin-Angiotensin System (Angiotensin II Receptor Blockers (ARBs), Plain)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: No data available.

Indications and Dosage

• Diabetic nephropathy in patients with type 2 diabetes and hypertension: 75mg-300mg daily.
• Hypertension: 150mg-300mg daily.

Off-label uses

Reduce proteinuria in children with chronic kidney disease; Left ventricular hypertrophy.

Contraindications

Hypersensitivity to irbesartan.

Cautions

Heart failure; Unstented unilateral or bilateral renal artery stenosis; Dehydration; Heart failure; Idiopathic or hereditary angioedema.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Irbesartan 150 mg tablet
- Irbesartan 300 mg tab

Pharmacokinetic parameters

Absorption F=80%, food has no effect on absorption.

Distribution Vd=53-93L, 90% protein bound.

Metabolism Minor hepatic metabolism.

Elimination Renal elimination is 20% and fecal elimination is 80% with a half-life of 11-15 hours.

Drug interactions

Albuterol: Irbesartan increases and albuterol decreases serum potassium.

Aspirin: Irbesartan and aspirin both increase serum potassium.

Bisoprolol: Irbesartan and bisoprolol both increase serum potassium.

Perindopril: Dual blockade of renin-angiotensin system increases risks of hypotension, hyperkalemia, and renal impairment.

Side effects

Common (more than 10%) Hyperkalemia.

Less common (1-10%) Diarrhea; Dizziness; Dyspepsia; Fatigue; Orthostatic hypotension; Upper respiratory tract infection.

Rare (less than 1%) None.

Patient educations

May cause fetal or neonatal morbidity or mortality; Avoid tasks that require alertness, motor skills until response to drug is established (possible dizziness effect); Report any sign of infection (sore throat, fever); Avoid exercising during hot weather (risk of dehydration, hypotension).

Irinotecan

ATC Code: L01CE02 Antineoplastic Agents (Topoisomerase 1 (TOP1) Inhibitors)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Not recommended

Indications and Dosage

Indicated for metastatic colorectal cancer; typically administered intravenously at 125 mg/m^2 over 90 minutes every week for 4 weeks, followed by a 2-week rest period.

Off-label uses

Treatment of other cancers such as gastric cancer and lung cancer.

Contraindications

Hypersensitivity to irinotecan or any component of the formulation; severe bone marrow suppression.

Cautions

Patients should be monitored for bone marrow suppression, diarrhea, and signs of infection. It can cause severe myelosuppression.

Dose adjustment in renal failure: Dose adjustments may be necessary; monitoring is recommended.

Dose adjustment in hepatic failure: Dose reductions are required for patients with impaired hepatic function.

Dosage forms and trade names available in Iraq

Irinotecan Hcl 100mg/5ml vial
Campto (PFIZER Australia).

Irinotecan Hcl 40mg/2ml vial
Campto (PFIZER Australia).

Pharmacokinetic parameters

Irinotecan is metabolized to its active metabolite SN-38. This active metabolite is metabolized by UGT1A1 to an inactive form.

Drug interaction

CYP3A4 inhibitors (like ketoconazole): may increase concentrations of irinotecan‘s active metabolite, potentially increasing toxicity.

UGT1A1 inhibitors (like atazanavir): may also increase concentrations of the active metabolite, potentially increasing toxicity.

Side effects

Common (more than 10%): Diarrhea; nausea; vomiting; neutropenia.

Less common (1-10%): Alopecia; anemia; thrombocytopenia.

Rare but serious (less than 1%): Interstitial lung disease; severe allergic reactions.

Patient educations

1. Report severe or persistent diarrhea to your healthcare provider immediately.
2. Stay well-hydrated and maintain good nutrition during treatment.
3. Regular blood tests will be required to monitor your response to irinotecan.

Iron

ATC Code: B03 Antianemic Preparations

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Compatible with breastfeeding.

Indications and Dosage

• Iron deficiency anemia: Dextriferron 100mg bid, maintenance 100mg once daily; Ferrous gluconate 300mg tid, maintenance 300mg once daily. By i.v. or i.m. injection 25mg-100mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to iron salts; Hemochromatosis; Hemolytic anemias.

Cautions

Serious hepatic impairment; History of allergies; Bronchial asthma; Rheumatoid arthritis; Preexisting cardiac disease; Avoid use during acute kidney infection.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Ferric hydroxide polymaltose complex (100 mg Iron (III)/5ml) vial
- Ferric hydroxide sucrose complex 100mg/5ml vial
- Iron as iron (III) 10mg/ml syrup
- Iron succinylate 40 mg/15 ml vial of oral solution
- Ferrous gluconate BP 400mg/15ml (eq.to 47mg of iron) elixir
  Ferrodadoral (Wadi Alrafiden Iraq), kiron (Alkindi Iraq).
- Ferrous gluconate 300mg (eq.to 35mg of iron) tab
- Iron 15mg/1ml oral drop
- Ferric Hydroxide polymaltose complex (50 mg Iron III/1ml) oral drop

Pharmacokinetic parameters

Absorption F=10-35%.
Distribution Vd=3L, 90%protein bound.
Metabolism Undetermined.
Elimination Half-life is 6 hours.

Drug interactions

Captopril: may enhance the toxic effect of iron, specifically anaphylactic type reactions.
Doxycycline: Ferrous sulfate decreases levels of doxycycline by inhibition of gastrointestinal absorption.

Side effects

Common (more than 10%): None.
Less common (1-10%): Abdominal pain; Arthralgia; Arthritis; Brown discoloration of skin; Diarrhea; Nausea; Pruritus; Rash; Soreness; Urticaria; Vomiting.
Rare but serious (less than 1%): None.

Patient educations

Pain, brown staining may occur at injection site; Oral iron should not be taken when receiving iron injections; Stools often become black with iron therapy, but this is harmless unless accompanied by red streaking, sticky consistency of stool, abdominal pain and cramping; Immediately report fever, back pain, headache.

Isoflurane

ATC Code: N01AB06 Anesthetics (Halogenated Hydrocarbons)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Limited data available, but given the short half-life of isoflurane, breastfeeding can be considered approximately 24-12 hours after administration.

Dosage forms and trade names available in Iraq

Isoflurane 100% liquid for inhalation
Terrell (Piramal critical care USA).

Indications and Dosage

Induction and maintenance of general anesthesia. The dosage is highly individualized and should be administered by a trained healthcare professional.

Off-label uses

In veterinary medicine, it is commonly used as an anesthetic for animals.

Contraindications

Known hypersensitivity to isoflurane or other halogenated anesthetics, or severe hypotension.

Cautions

In patients with hepatic disease, renal disease, or malignant hyperthermia.
Dose adjustment in renal failure: No specific guidelines, but use with caution.
Dose adjustment in hepatic failure: No specific guidelines, but use with caution.

Pharmacokinetic parameters

Isoflurane is a volatile anesthetic, so **absorption** and **distribution** are highly dependent on the concentration inhaled, rate of pulmonary ventilation, and pulmonary blood flow. Minimal **metabolism** (<0.2%).

Drug interaction

• Other CNS depressants, including opioids and benzodiazepines, can have additive or synergistic sedative effects.
• Nondepolarizing muscle relaxants' effects may be enhanced.

Side effects

Common (more than 10%): Hypotension; respiratory depression.
Less common (1-10%): Nausea and vomiting; shivering.
Rare but serious (less than 1%): Malignant hyperthermia; severe hypotension; arrhythmias.

Patient educations

1. You may feel drowsy after the procedure. Arrange for transportation home.
2. Report any unusual side effects or symptoms to your healthcare provider.
3. Avoid eating or drinking for a specific period before the procedure, as instructed by your healthcare provider.

Isoniazid

ATC Code: J04AC01 Antimycobacterials (Hydrazides)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage
• Tuberculosis: 5mg/kg once daily, usual dose 300mg.

Off-label uses
None.

Contraindications
Hypersensitivity to isoniazid; Acute hepatic disease; Hepatic injury or severe adverse reactions with previous isoniazid therapy.

Cautions
Chronic hepatic disease; Alcoholism; Peripheral neuropathy; HIV infection.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use of isoniazid in acute hepatic disease with caution.

Dosage forms and trade names available in Iraq
Isoniazid 100mg tab
Isoniazid (IPI Iraq).

Pharmacokinetic parameters
Absorption Isoniazid absorption and bioavailability are reduced when administered with food, peak concentration 1-2 h.
Distribution Vd= 0.6L/kg, 10–15%protein bound.
Metabolism Metabolized by the liver by acetylation and dehydrogenation.
Elimination Renal elimination is 75%-90% with half-life of 1-4 hours.

Drug interactions
Clopidogrel: Isoniazid decreases effects of clopidogrel by decreasing metabolism, Cytochrome P450 2C19 inhibitors decrease the conversion of clopidogrel to its active form.
Erythromycin: Isoniazid will increase the level or effect of erythromycin by affecting hepatic enzyme CYP3A4 metabolism.

Side effects
Common (more than 10%) Loss of appetite; Peripheral neuropathy; Stomach pain; Vomiting; Weakness.
Less common (1-10%) Dizziness; Hyperreflexia; Lethargy; Progressive liver damage; Slurred speech.
Rare but serious (less than 1%) Agranulocytosis; Anemia; Megaloblastic anemia; Pancreatitis; Toxic epidermal necrolysis; Seizure; Systemic lupus erythematosus; Thrombocytopenia.

Patient educations
Do not skip doses, continue to take isoniazid for full length of therapy (6–24 months); Take preferably 1 hour before or 2hours following meals (with food if gastrointestinal upset); Avoid alcohol during treatment; Must take isoniazid at least 1 hour before antacid; Report any new symptom, immediately for vision difficulties, nausea, vomiting, dark urine, yellowing of skin or eyes (jaundice), fatigue, paresthesia of extremities.

Isosorbide

ATC Code: C01DA14 Cardiac Therapy (Organic Nitrates)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Prophylaxis angina: Initially, 30mg-60mg daily, may titrate to maintenance of 120mg-240mg daily, doses separated 7 hours apart to decrease tolerance development.

Off-label uses

Heart failure.

Contraindications

Hypersensitivity to nitrates.

Cautions

Inferior wall myocardial infarction; Head trauma; Increased intracranial pressure; Orthostatic hypotension; Blood volume depletion from diuretic therapy, systolic blood pressure less than 90mmHg; Hypertrophic cardiomyopathy; Alcohol consumption.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Isosorbide dinitrate 5 mg tab
  APO-ISDN (Apotex Canada).
- Isosorbide dinitrate 10 mg tab
  APO-ISDN (Apotex Canada).

Pharmacokinetic parameters

Absorption F=93%, food slows rate of absorption.
Distribution Vd=0.6L, less than 5% protein bound.
Metabolism Hepatic metabolism more than 95%.
Elimination Renal elimination is 96% with a half-life of 6 hours.

Drug interactions

Dapoxetine: Dapoxetine may enhance the orthostatic hypotensive effect of vasodilators (isosorbide).
Deferasirox: Deferasirox may decrease the serum concentration of CYP3A4 substrates.
Enzalutamide: Enzalutamide may decrease the serum concentration of CYP3A4 substrates, concurrent use of enzalutamide with isosorbide that have a narrow therapeutic index should be avoided. use of enzalutamide and any other CYP3A4 substrate should be performed with caution and close monitoring.

Side effects

Common (more than 10%) Dizziness; Headache.
Less common (1-10%) Bradycardia; Hypotension; Nausea; Orthostatic hypotension; Tachycardia; Vomiting.
Rare but serious (less than 1%) Severe hypotension; Syncope.

Patient educations

Teach patient to take oral drug 30 minutes before or 1 to 2 hours after a meal; Inform patient that drug may cause headache, advise him to treat headache as usual and not to alter drug schedule, if headache persists tell him to contact prescriber; Instruct patient to move slowly when sitting up or standing to avoid dizziness or light headedness from sudden blood pressure decrease.

Isotretinoin

ATC Code: D10BA01 Anti-Acne Preparations (Retinoids for Treatment of Acne)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

- Isotretinoin 10mg caps
- Isotretinoin 20 mg cap

Indications and Dosage

• Recalcitrant cystic acne that is unresponsive to conventional acne therapies this medication can diminish or clear severe acne and prevent new acne scars: Initially, 0.5mg-1mg/kg/day, may divided into 2 doses for 15-20 weeks, may repeat after at least 2 months of therapy. Severe acne spots may require 2 mg/kg/day.

Off-label uses

Treatment of gram negative folliculitis; Severe keratinization disorders; Certain cancers.

Contraindications

Hypersensitivity to isotretinoin.

Cautions

Women of childbearing potential; Anorexia nervosa; Depression; Hypertriglyceridemia; Osteoporosis; Osteomalacia.

Dose adjustment in renal failure: In severe renal failure reduce initial dose to 10mg daily then gradually increase to 1mg/kg/day as necessary.

Dose adjustment in hepatic failure: contraindicated in hepatic failure.

Pharmacokinetic parameters

Absorption F=23-25%, high fat meal increase absorption.

Distribution Vd=85L, 99.9%protein bound. mainly to serum albumin.

Metabolism Metabolized by the liver.

Elimination Renal elimination is 30-40% with half-life of 10-20 hours.

Drug interactions

Doxycycline: Isotretinoin and doxycycline. Increase risk of Pseudotumor cerebri.

Side effects

Common (more than 10%) Arthralgia; Bone or joint pain; Cheilitis; Conjunctivitis (including blepharoconjunctivitis); Decreased erythrocyte and leukocyte counts; Decreased HDLs; Decreased hemoglobin concentration and hematocrit; Dry nose; Epistaxis; Generalized muscle aches; Hypertriglyceridemia; Increased erythrocyte sedimentation rates; Increased platelet count; Irritation; Pruritus; Rash; Photosensitivity; Skin fragility; Skin infections; Thinning of hair; Xerosis; Xerostomia.

Less common (1-10%) Decreased bone mineral density; Premature epiphyseal closure.

Rare but serious (less than 1%) Anorexia; Fatigue; Headache; Increased appetite; Lethargy; Nausea; Thirst; Vomiting.

Patient educations

1- Take isotretinoin with meals; Transient flare-ups of acne may occur at beginning of therapy.

2- Use two forms of contraception 1 month before treatment, during treatment, and for 1 month after treatment is discontinued.

3- Do not donate blood while using this drug because of its potential effects on the fetus of a blood recipient; Avoid vitamin supplements containing vitamin A.

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Ispaghula Husk

ATC Code: A06AC01 Drugs for Constipation (Bulk-Forming Laxatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Generally considered safe to use during breastfeeding.

Indications and Dosage
Treatment of constipation. A common dosage for adults is one sachet (3.5g) mixed with water, taken once or twice daily.

Off-label uses
It may be used to help lower cholesterol levels.

Contraindications
Hypersensitivity to ispaghula husk, bowel obstruction, difficulty swallowing.

Cautions
It should be taken with plenty of water to prevent it from swelling and blocking the throat or esophagus.
Dose adjustment in renal failure: Not typically required.
Dose adjustment in hepatic failure: Not typically required.

Dosage forms and trade names available in Iraq
Ispaghula Husk 3.5g sachet
Fybogel Orange (Reckitt Benckiser Healthcare UK).

Pharmacokinetic parameters
Psyllium is not absorbed and acts locally in the bowel.

Drug interaction
- May decrease the absorption of other oral medications; separate administration by at least 2 hours.
- **Antidiabetic drugs:** Blood glucose levels should be monitored as psyllium may affect their absorption.

Side effects
Common (more than 10%): Bloating; gas.
Less common (1-10%): Stomach pain.
Rare but serious (less than 1%): Allergic reaction; bowel obstruction.

Patient educations
1. Mix the ispaghula husk with at least 8 ounces of fluid, such as water or fruit juice.
2. Swallow it immediately and do not save it for later use.
3. If you experience chest pain, vomiting, or difficulty swallowing after taking ispaghula husk, seek medical attention immediately.

Itraconazole

ATC Code: J02AC02 Antimycotics for Systemic Use (Triazole and Tetrazole Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Itraconazole 100 mg capsule
Versicazol (D & Fisher Cyprus).

Indications and Dosage

• Blastomycosis, aspergillosis: Initially, 200mg once daily, (max 200mg bid).
• Life threatening fungal infections: 200mg tid for 3-4 days, then 100mg-200mg bid.
• Onychomycosis of toenails: 200mg once daily for 12 weeks.
• Onychomycosis of fingernails: 200mg bid for 1 week, rest for 3 weeks, then 200mg bid for 1 week.

Off-label uses

Suppression of histoplasmosis; Treatment of disseminated sporotrichosis; Fungal pneumonia and septicemia; Ringworm of the hand.

Contraindications

Hypersensitivity to itraconazole; Treatment of onychomycosis in patients with evidence of ventricular dysfunction; Treatment of onychomycosis in women who are pregnant or are intending to become pregnant.

Cautions

Active hepatic disease; COPD; Myocardial ischemia.
Dose adjustment in renal failure: Use with caution.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=55%, absorption is enhanced by food.
Distribution Vd=796±185L, 99.8%protein bound.
Metabolism Mostly metabolized by the liver by the CYP3A4 isoenzyme.
Elimination Excreted in feces with half-life of 21 hours.

Drug interactions

Simvastatin: Itraconazole will increase the level or effect of simvastatin by affecting hepatic enzyme CYP3A4 metabolism, simvastatin contraindicated during and 2 weeks after itraconazole treatment, increased risk for rhabdomyolysis.

Side effects

Common (more than 10%) Arthralgia; Bone or joint pain; Cheilitis; Conjunctivitis; Dry nose; Epistaxis; Generalized muscle aches; Pruritus; Rash; Photosensitivity; Skin fragility; Xerosis; Xerostomia.
Less common (1-10%) Decreased bone mineral density; Premature epiphyseal closure.
Rare but serious (less than 1%) Anorexia; Fatigue; Headache; Increased appetite; Lethargy; Nausea; Thirst; Vomiting.

Patient educations

Take Itraconazol with food; Therapy will continue for at least 3 months, until lab tests, clinical presentation indicate infection is controlled.

Ivabradine

ATC Code: C01EB17 Cardiac Therapy (Other Cardiac Preparations)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Heart failure: Initially, 5mg bid for 14 days, then adjust dose to resting heart rate of 50–60 bpm, (max 7.5mg bid).

Off-label uses

None.

Contraindications

Hypersensitivity to ivabradine; Blood pressure less than 90/50mmHg; Sick sinus syndrome; Acute decompensated heart failure; Sinoatrial block or third degree AV block; Resting heart rate less than 60 beat per minute prior to initiation.

Cautions

Atrial fibrillation; Hypertension; Second degree heart block; Bradycardia.

Dose adjustment in renal failure: In severe renal failure, use with caution.

Dose adjustment in hepatic failure: In severe hepatic failure, use of ivabradine is Contraindicated.

Dosage forms and trade names available in Iraq

- Ivabradine 5mg tab
  Procoralan (Les Laboratoires Servier France).
- Ivabradine 7.5 mg tab
  Procoralan (Les Laboratoires Servier France).

Pharmacokinetic parameters

Absorption F=40%, it is recommended to take ivabradine with food to reduce variability in systemic exposure.
Distribution Vd=100L, 9-70%protein bound.
Metabolism Ivabradine is extensively metabolized by oxidation in the gut and liver by cytochrome P450 3A4 enzyme.
Elimination Renal elimination is 4% with half-life of 2 hours.

Drug interactions

Clarithromycin: Clarithromycin will increase the level or effect of ivabradine by affecting hepatic and intestinal enzyme CYP3A4 metabolism, coadministration of ivabradine with strong CYP3A4 inhibitors is contraindicated
Imatinib: Imatinib will increase the level or effect of ivabradine by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) None.
Less common (1-10%) Atrial fibrillation; Bradycardia; Hypertension; Luminous phenomena; Visual brightness.
Rare but serious (less than 1%) None.

Patient educations

Take medication with meals; Treatment may cause fetal harm. Female patients of reproductive potential should use effective contraception during treatment.

Ivermectin

ATC Code: P02CF01 Anthelmintics (Avermectines)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: No data available.

Indications and Dosage

• Rosacea (papulopustular): Apply small amount of 1% cream to affected area once daily, avoiding the eyes and lips.

Off-label uses

None.

Contraindications

Hypersensitivity to ivermectin.

Cautions

Immunocompromised patients; Severe hepatic impairment.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Plasma level following topical administration is very low.

Distribution Vd=3-3.5L/kg, 93%protein bound.

Metabolism Hepatic metabolism.

Elimination Renal elimination is 1% with half-life of 16-28 hours.

Dosage forms and trade names available in Iraq

Ivermectin 10mg/1g cream
Soolantra (Galderma France).

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%): Skin burning sensation.

Less common (1-10%): Dry skin; Pruritus; Skin irritation.

Rare but serious (less than 1%): Conjunctivitis; Dandruff; Dry skin; Eye irritation; Local adverse reactions: Contact dermatitis and allergic dermatitis; Ocular hyperemia; Skin burning sensation.

Patient educations

Avoid contact with eyes and lips; Apply cream to face, squeeze a pea-sized amount of cream from tube onto fingertip, apply to the affected areas of face once a day, use a pea-sized amount of cream for each area of face (forehead, chin, nose, each cheek) that is affected, spread cream smoothly and evenly in a thin layer.

Note

The anti-parasitic drug ivermectin is being investigated as a possible treatment for COVID-19 in adults.

Ivy Leaves Dry Extract

ATC Code: R05CA12 Cough and Cold Preparations (Expectorants).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not yet known

Dosage forms and trade names available in Iraq

Dried Ivy leaf powder extract 0.7gm /100ml syrup
PIOSPAN (Pioneer Iraq).

Indications and Dosage

Indicated for the relief of coughs and chesty congestion due to common colds. The typical dosage is 5 ml of syrup twice daily for adults and children over the age of 2.

Off-label uses

None recognized.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Cautions

This should not be used as a substitute for a balanced diet/healthy lifestyle. Discontinue use and consult a healthcare professional if symptoms persist.

Dose adjustment in renal failure: No specific information available

Dose adjustment in hepatic failure: No specific information available

Pharmacokinetic parameters

No specific pharmacokinetic information available for this herbal extract.

Drug interactions

No specific drug interactions known.

Side effects

Common (more than 10%) Not reported.
Less common (1-10%) Not reported.
Rare but serious (less than 1%) Allergic reactions such as difficulty in breathing, skin rash, redness, and itching.

Patient educations

1. Ivy leaf is usually well tolerated, but if you experience any side effects, stop taking it and consult a healthcare professional.
2. This product is for oral use only and should not be exceeded the recommended dosage.

Ketamine

ATC Code: N01AX03 Anesthetics (Other General Anesthetics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Anesthesia induction: By slow i.v. injection, 1mg-4.5mg/kg once, maintenance 0.1mg-0.5mg/min i.v. continuous infusion.

Off-label uses

Resistant depression
Infusion 0.5mg/kg IV twice weekly; not to exceed 6 weeks; therapy>6 week not studied.

Dosage forms and trade names available in Iraq

Ketamine 50mg/ml (10 ml vial)
CALYPSOL (Gedeon Richter Hungary).

Contraindications

Hypersensitivity to ketamine; Aneurysms; Angina; Congestive heart failure; Elevated intracranial pressure; Hypertension; Thyrotoxicosis.

Cautions

Cardiac decompensation; Chronic alcoholic or acutely alcohol intoxicated patients; Glaucoma; Schizophrenia; Acute psychosis; Seizures; Hyperthyroidism; Pulmonary infection; Intracranial mass lesions; Hypovolemia; Dehydration; CHF; Myocardial ischemia; Myocardial infarction.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=93%.
Distribution Vd=0.37-4L/kg, 53.5% protein bound.
Metabolism Ketamine presents a mainly hepatic metabolism and its major metabolite is norketamine.
Elimination Renal elimination is 85-95% with half-life of 186 minutes.

Drug interactions

Fentanyl: fentanyl, ketamine both increases effects of the other by pharmacodynamic synergism, coadministration with other CNS depressants, such as skeletal muscle relaxants, may cause respiratory depression, hypotension, profound sedation, coma, and/or death. Consider dose reduction of either or both agents to avoid serious adverse effects. Monitor for hypotension, respiratory depression, and profound sedation.

Side effects

Common (more than 10%) Hypertension; Increased cardiac output; Tonic clonic movements; Visual hallucinations; Vivid dreams.
Less common (1-10%) Bradycardia; Diplopia; Hypotension; Increased IOP; Injection site pain; Nystagmus.
Rare but serious (less than 1%) Cardiac arrhythmia; Depressed cough reflex; Fasciculations; Hypersalivation; Hypertonia; Laryngospasm; Respiratory depression or apnea with large doses or rapid infusions.

Ketoconazole

ATC Code: J02AB02 Antimycotics for Systemic Use (Imidazole Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Candidiasis of skin: Apply cream topically once daily for 2 weeks.
• Dandruff: Apply shampoo topically to wet hair, use twice weekly for 2-4 weeks, leave preparation on for 3-5 minutes before rinsing thoroughly.
• Pityriasis versicolor: Apply shampoo topically, leave on skin for 3- 5 min before rinsing , use once daily for maximum 5 days
• Seborrheic dermatitis: Apply cream topically to the affected area twice daily for 4 weeks or until clinical clearing.
• Tinea pedis, tinea corporis, tinea cruris: Apply cream topically twice daily for 2 weeks.

Dosage forms and trade names available in Iraq

Ketoconazole 2% cream
KENAZOL (Pharma International Jordan).
Ketoconazole 2% shampoo
KETONAZ (Pharmaline Lebanon).

Off-label uses

None.

Contraindications

Hypersensitivity to ketoconazole; Acute Porphyria.

Cautions

Avoid contact with eyes and mucous membrane
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Used with caution in patient with hepatic dysfunction.

Pharmacokinetic parameters

Absorption Minimal absorption.
Distribution Minimal absorption.
Metabolism Not metabolized.
Elimination Minimal absorption.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) Pruritis, stinging, and dryness at the application site. There are also reports of dry hair, dry scalp, and oily hair when using ketoconazole-containing shampoo.
Less common (1-10%) Alopecia, Angioedema, excessive tearing, folliculitis, hair changes, headache, impetigo and pyogenic granuloma.
Rare (less than 1%) Eye irritation, taste altered.

Patient educations

Instruct patient to apply cream to damp skin of affected area and wide surrounding area; Tell patient to wet hair before applying shampoo and to massage into scalp for 1 minute; then leave on for 5 minutes before rinsing off; Tell him to shampoo again, leaving it on for 3 minutes this time before rinsing; Caution patient not to apply shampoo to broken or inflamed skin; Instruct patient that the cream is only for external use, and hand washing is necessary after the application of the cream to prevent any adverse reactions from the medication.

Ketoprofen

ATC Code: M02AA10 Topical Products for Joint and Muscular Pain (Antiinflammatory Preparations, Non-Steroids for Topical Use).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Unknown whether excreted in breast milk, not recommended.

Dosage forms and trade names available in Iraq

Ketoprofen 2.5g/100g GEL

FASTUM GEL (Menarini Italy).

Indications and Dosage

• **Pain Management:** Immediate-release: 25-50 mg PO q6-8hr as necessary OR Extended-release: 200 mg PO qDay; not recommended for acute pain.

• **Rheumatoid Arthritis or Osteoarthritis:** Immediate-release: 75 mg PO q8hr or 50 mg PO q6hr OR Extended-release: 200 mg PO qDay

• **Dysmenorrhea:** Immediate-release: 25-50 mg q6-8hr PRN.

Off-label uses

Gout, vascular headache.

Contraindications

Hypersensitivity to ketoprofen or other NSAIDs, history of asthma, urticaria, active peptic ulcer disease or GI bleeding, severe renal impairment, and 3rd trimester of pregnancy, thrombotic events, MI & stroke(Black Box Warnings)

Cautions

history of GI disorders, HTN, heart failure, renal impairment, or hepatic impairment.

Dose adjustment in renal failure:

• GFR ≥25 to 60 mL/min/1.73 m2: Not recommended; if therapy must be initiated, may administer 150 mg/day maximum; monitor renal function closely.

• GGR <25 mL/min/1.74 m2: Not recommended if therapy must be administered may administer 100 mg/day maximum; monitor renal function closely.

Dose adjustment in hepatic failure: Serum albumin <3.5 g/dL: Not to exceed 100 mg/day; monitor closely; discontinue if hepatic function worsens

Pharmacokinetic parameters

Absorption Bioavailability: 90%, Peak Plasma Time: 0.5-2 hr (immediate release); 6-7 hr.

Distribution Protein Bound: 99%, Vd: 0.1 L/kg

Metabolism Ketoprofen undergoes hepatic metabolism primarily via cytochrome P450 enzymes.

Elimination Half-life:2-4 hr (immediate release); 3-7.5 hr (ER), Excretion: Urine 50-90% ; feces 1-8%.

Drug interactions

• Concurrent use with other NSAIDs or corticosteroids may increase the risk of GI bleeding or ulceration.

• Concurrent use with anticoagulants or antiplatelet agents may increase the risk of bleeding.

Side effects

Common (more than 10%): dyspepsia, abdominal pain, headache, dizziness, Increased liver function.

Less common (1-10%): Nausea, diarrhea, constipation, fluid retention, Rash, Bronchospasm.

Rare but serious (less than 1%): GI bleeding or ulceration, renal impairment, liver dysfunction, anaphylaxis, Scaling eczema, Stevens-Johnson syndrome

Ketorolac

ATC Code: M01AB15 Antiinflammatory and Antirheumatic Products (Acetic Acid Derivatives and Related Substances)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Contraindicated.

Indications and Dosage

• Pain, short-term (less than 5 days): 30mg i.v. as a single dose or 30mg i.v. every 6 hours; not to exceed 120mg per day, or 60mg i.m. as a single dose or 30 mg i.m. every 6 hours; not to exceed 120 mg per day.
• Corneal refractive surgery: Instill 1 drop in the operated eye(s) four times a day as needed for pain and burning/stinging for up to 4 days.
• Postoperative ocular inflammation: Instill 1 drop in the affected eye(s) four times a day beginning 24 hours after cataract surgery and continue through the first 2 weeks of the postoperative period.
• Seasonal allergic conjunctivitis: Instill 1 drop in the affected eye(s) four times a day.

Dosage forms and trade names available in Iraq

Ketorolac Tromethamin 30mg/1ml ampoule
Ketorolac Tromethamin 5mg/ml eye drop

Off-label uses

None.

Contraindications

Hypersensitivity to ketorolac; Patients with a history of peptic ulcer disease or GIT bleeding.

Cautions

Perioperative setting; Tonsillectomy in children; Gastric perforation, Hypertension.
Dose adjustment in renal failure: Severe: Contraindicated; Moderate: use 50% of recommended dosage; not to exceed 60mg/day.
Dose adjustment in hepatic failure: Use caution; discontinue if symptoms of liver toxicity develop.

Pharmacokinetic parameters:

Absorption F¬=80-100%
Distribution Vd=13 L, 99% protein bound.
Metabolism Metabolized in the liver.
Elimination Renal excretion (91%), feces (6%)with half-life of approximately 2-6 hours.

Drug interactions

NSAIDs: Concomitant use of Ketorolac with other NSAIDs, including aspirin, can increase the risk of GIT side effects and may potentiate the risk of bleeding.
Anticoagulants and Antiplatelet Drugs: Ketorolac can enhance the anticoagulant effects of medications such as warfarin, heparin, clopidogrel, and other antiplatelet drugs, increasing the risk of bleeding.
Diuretics: Ketorolac can reduce the effectiveness of certain diuretics (e.g., furosemide).
Methotrexate: Ketorolac can increase the toxicity of methotrexate.

Side effects

Common (more than 10%) Dizziness; Headache; Nausea.
Less common (1-10%) Constipation; Diarrhea; Dyspepsia; Edema; Pruritus; Vomiting.
Rare but serious (less than 1%) Acute renal failure; Anaphylaxis; Angioedema; GI bleeding; Hepatic failure; M.I; Stroke.

Ketotifen

ATC Code: R06AX17 Antihistamines for Systemic Use (Other Antihistamines for Systemic Use)

Pregnancy category:

FDA A B **C** D X N

TGA A **B1** B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

- Prevention of asthma: 1mg bid.
- Allergic rhinitis, allergic skin reaction: 1mg bid.
- Allergic conjunctivitis: 1 drop into affected eye bid.

Off-label uses

None.

Contraindications

Hypersensitivity to ketotifen.

Cautions

Patient with history of epilepsy.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Ketotifen 0.25mg/ml eye drop

Ketotifen 1mg tab

Ketotifen 1mg/5ml syrup

Samatifen(SDI Iraq), **KETOTIFEN** (AL-Kindi Iraq), **KETOTIFEN** (Wadi Al-Rafidain Iraq).

Pharmacokinetic parameters

Absorption F=50%, due to a significant first pass effect in the liver.

Distribution Vd=Undetermined, 75%protein bound.

Metabolism Ketotifen is extensively metabolized in liver.

Elimination Renal elimination is 60% with half-life of 22 hours.

Drug interactions

Betahistine: The therapeutic efficacy of betahistine can be decreased when used in combination with ketotifen.

Dapagliflozin: The risk or severity of thrombocytopenia can be increased when dapagliflozin is combined with ketotifen.

Metformin: The risk or severity of thrombocytopenia can be increased when metformin is combined with ketotifen.

Pseudoephedrine: Pseudoephedrine may decrease the sedative and stimulatory activities of ketotifen.

Side effects

Conjunctivitis; Eye pain; Eyelid disorder; Headache; Keratitis; Lacrimation disorder; Mydriasis; Photophobia; Rhinitis.

Patient educations

Ketotifen may cause drowsiness, somnolence and blurred vision, if affected, do not drive or operate machinery; Remove contact lenses prior to ophthalmic administration and reinsert after 10-15 minutes.

Lacosamide

ATC Code: N03AX18 Antiepileptics (Other Antiepileptics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Partial onset seizure: Initially, 100mg bid, may titrate by 50mg increments to max 200mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to lacosamide.

Cautions

Marked first degree AV block; Second degree or higher AV block; Sick sinus syndrome without pacemaker; Myocardial ischemia; Heart failure; patients at risk of suicide.

Dose adjustment in renal failure: CrCl less than 30ml/min: max. 300mg daily.

Dose adjustment in hepatic failure: Not recommended in severe impairment.

Dosage forms and trade names available in Iraq

- Lacosamide 10mg / 1ml oral solution
- Lacosamide 50mg tablet
- Lacosamide 100mg tablet
- Lacosamide 150mg Tablet

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=0.6L/kg.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 95% with a half-life of 13 hr.

Drug interactions

Lidocaine (systemic): Lidocaine may enhance the adverse effect of lacosamide, the risk for bradycardia, ventricular tachyarrhythmias, or a prolonged PR interval may be increased.

Mexiletine: Mexiletine may enhance the adverse effect of lacosamide, the risk for bradycardia, ventricular tachyarrhythmias, or a prolonged PR interval may be increased.

Orlistat: Orlistat may decrease the serum concentration of anticonvulsants.

Side effects

Common (more than 10%) Ataxia; Blurred vision; Chest pain; Diplopia; Dizziness; Dry mouth; Fatigue; Headache; Nausea; Nystagmus; Somnolence; Vomiting.

Less common (1-10%) Abnormal coordination; Asthenia; Balance disorder; Depression; Diarrhea; Gait disturbance; Hyperhidrosis; Memory impairment; Nystagmus; Oral hypoesthesia; Oral paresthesia; Paresthesia; Pruritus; Tremor; Vertigo.

Rare (less than 1%) None.

Patient educations

Strict maintenance of drug therapy is essential for seizure control; Avoid tasks that require alertness, motor skills until response to drug is established; Avoid alcohol; Report depression, suicidal ideation, unusual behavioral changes.

Lactulose

ATC Code: A06AD11 Drugs for Constipation (Osmotically Acting Laxatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

Lactulose 10mg/15ml syrup
Lactulakin (Al-Kindi Iraq), **Piolac** (PIONEER IRAQ).

Indications and Dosage

• Constipation: 15–30 ml (10g–20g) daily, up to 60 ml (40 g) daily.
• Prevention of portal-systemic encephalopathy: 30–45 ml (20g–30g) 3–4 times/day, adjust dose every 1–2 days to produce 2–3 soft stools per day.
• Treatment of portal-systemic encephalopathy: Initially, 30–45 ml (20g–30g) every hour to induce rapid laxation, then, 30–45 ml 3–4 times/day, adjust dose every1–2 days to produce 2–3 soft stools per day.

Off-label uses

None.

Contraindications

Hypersensitivity to lactulose; Patients requiring a low-galactose diet.

Cautions

Diabetes; Dehydration.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=3%.
Distribution Undetermined.
Metabolism lactulose is metabolized by colonic bacteria to lactic, acetic, and formic acids.
Elimination lactulose is largely excreted with stool.

Drug interactions

Warfarin: Lactulose may enhance the anticoagulant effect of warfarin.

Side effects

Common (more than 10%) Diarrhea-Gas (flatulence)-Nausea-Abdominal cramping or discomfort
Less common (1-10%) Vomiting-Electrolyte imbalance (including hypokalemia and hypernatremia)-Dehydration (due to diarrhea or excessive bowel movements)
Rare but serious (less than 1%) Hypervolemia (excess fluid in the blood, can be a risk in patients with heart or kidney disease)-Allergic reactions, including rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing

Patient educations

Evacuation occurs in 24–48 hours of initial dose; Institute measures to promote defecation (increase fluid intake, exercise, high fiber diet); Drink plenty of fluids; If therapy was started to treat high ammonia levels, notify physician if worsening of confusion, lethargy, weakness occurs.

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Lamotrigine

ATC Code: N03AX09 Antiepileptics (Other Antiepileptics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

• Bipolar I disorder: 100mg-400mg daily.
• Partial seizure, tonic-clonic seizure: 50mg-200mg bid, (max 400mg daily).

Off-label uses

Drug-resistant seizures; Mood stabilization in rapid cycling bipolar II disorder.

Contraindications

Hypersensitivity to lamotrigine.

Cautions

Patients at high risk of suicide; Patients taking estrogen containing oral contraceptives.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Moderate to severe impairment
without ascites: reduce dose by 25%; Severe impairment with ascites:
reduce dose by 50%.

Dosage forms and trade names available in Iraq

- Lamotrigine 25 mg tablet
- Lamotrigine 50 mg tablet

Pharmacokinetic parameters

Absorption F=98%, food has no effect on absorption.
Distribution Vd=0.9-1.3L, 55% protein bound.
Metabolism hepatic metabolism 90%.
Elimination Renal elimination is 94% with a half-life of 25-70 hr.

Drug interactions

Acetaminophen: Acetaminophen may decrease the serum concentration of lamotrigine.
Olanzapine: Lamotrigine may enhance the sedative effect of olanzapine.

Side effects

Common (more than 10%) Ataxia; Blurred vision; Diplopia; Dizziness; Headache; Rhinitis; Somnolence.
Less common (1-10%) Abnormal thoughts; Agitation; Chest pain; Dermatitis; Dry skin; Dysarthria; Edema; Fatigue; Fever; Increased libido; Insomnia; Migraine; Peripheral edema; Rectal hemorrhage; Suicidal ideation; Tremor; Urinary frequency; Weakness.
Rare (less than 1%) None.

Patient educations

Tell patient that lamotrigine may be taken with or without food; Inform patient not to stop drug abruptly and that dosage is adjusted slowly, as indicated; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness.

Lanreotide

ATC Code: H01CB03 Hypothalamic Hormones (Somatostatin and Analogues).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: There is no information available, Caution is advised.

Dosage forms and trade names available in Iraq

- Lanreotide 90mg Prefilled Syringe **Somatuline** (IPSEN PHARMA France).
- Lanreotide 120mg Prefilled Syringe **Somatuline** (IPSEN PHARMA France).

Indications and Dosage

• **Acromegaly:** patients with failed or contraindicated radiation/surgery, 90mg SC q4Week for 3 months; THEN adjust based on GH and/or IGF-1 levels.

• **Carcinoid Syndrome & Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs):** Indicated for unresectable, well-or moderately-differentiated, locally advanced or metastatic (GEP-NETs) to improve progression-free survival, 120 mg SC q4Week.

Off-label uses

None.

Contraindications

Hypersensitivity to lanreotide or any component of the formulation, and severe uncontrolled D.M.

Cautions

Gallbladder or biliary tract disorders, renal impairment, or hepatic impairment, thyroid dysfunction, Bradycardia, hypertension.

Dose adjustment in renal failure: Acromegaly: Acromegaly: Moderate-severe: 60 mg deep SC q4 Week for 3 months initially; adjust based on GH and/or IGF-I levels thereafter AND in case of (GEP-NETs): only Moderate-severe: Safety and efficacy not established.

Dose adjustment in hepatic failure: (GEP-NETs): (GEP-NETs): Safety and efficacy not established.

Acromegaly: (Child Pugh B or C): 60 mg deep SC q4Week for 3 months initially; adjust based on GH and/or IGF-I levels thereafter.

Pharmacokinetic parameters

Absorption Lanreotide is slowly absorbed after subcutaneous injection, Bioavailability: ~69-83%

Distribution Protein binding: 79-83%, Vd: 0.2 L/kg.

Metabolism Lanreotide undergoes hepatic metabolism via peptidases and cytochrome P450 enzymes.

Elimination Primarily via the hepatobiliary route; Half-Life: 23-36 days, Excretion: Urine (<5%); feces (<0.5%)

Drug interactions

• Concurrent use with cyclosporine may increase lanreotide levels, requiring dosage adjustments and monitoring for adverse effects.

• Concurrent use with insulin or oral hypoglycemic agents may result in altered blood glucose levels.

Side effects

Common (more than 10%): GIT symptoms (diarrhea, abdominal pain, nausea), injection site reactions Cholelithiasis, Anemia.

Less common (1-10%): Headache, dizziness, gallstone formation, Arthralgia, Sinus bradycardia.

Rare but serious (less than 1%): Aortic valve regurgitation, Steatorrhea, Pancreatitis, liver dysfunction.

Patient educations

Report any new or worsening symptoms, especially gastrointestinal symptoms, or changes in blood glucose levels, to your healthcare provider & Lanreotide can cause dizziness. If you have dizziness, do not drive a car, or operate machinery.

Lansoprazole

ATC Code: A02BC03 Drugs for Acid Related Disorders (Proton Pump Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Lansoprazole 15 mg capsule
  Takepron (APM Jordan).
- Lansoprazole 30 mg capsule
  Takepron (APM Jordan).

Indications and Dosage

• Duodenal ulcer disease: 15mg daily for up to 4 weeks.
• Gastric ulcer disease: 30mg daily for up to 8 weeks.
• H. pylori GI tract infection, triple therapy: 30mg bid for 10-14 days in combination with amoxicillin 1000mg and clarithromycin 500mg bid.
• Erosive esophagitis, GERD: 30mg daily for 8-16 weeks.
• Zollinger-Ellison syndrome: 60mg bid up to 180mg daily.

Off-label uses

Stress ulcer prophylaxis in critically ill.

Contraindications

Hypersensitivity to lansoprazole.

Cautions

Lansoprazole may increase risk of hip, wrist, spine fractures; GI infections.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Reduce dose in severe impairment.

Pharmacokinetic parameters

Absorption F=80%.
Distribution Vd=14-18L, 97% protein bound.
Metabolism Hepatic metabolism 70-75%.
Elimination Renal elimination is 15-25% with a half-life of 90 min.

Drug interactions

Enzalutamide: Enzalutamide will decrease the level or effect of lansoprazole by affecting hepatic or intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Constipation; Diarrhea; Headache; Nausea.
Rare (less than 1%) Allergic reaction; Angina; Anorexia; Anxiety; Dry mouth; Edema; Flatulence; Melena; Myalgia; Palpitations; Syncope; Tenesmus; Tinnitus.

Patient educations

Do not chew, crush delayed release capsules; For patients who have difficulty swallowing capsules, open capsules, sprinkle granules on 1 tablespoonful of soft food, swallow immediately.

Laronidase

ATC Code: A16AB05 Other Alimentary Tract and Metabolism Products (Enzymes)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Mucopolysaccharidosis I: By i.v. infusion, 100IU/kg every week (3-4 hr infusion).

Off-label uses

None.

Contraindications

Hypersensitivity to laronidase.

Cautions

Acute respiratory complications associated with administration and risk of acute cardio-respiratory failure, patients should receive antipyretics and antihistamines prior to infusion, appropriate medical support should be readily available.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Laronidase 100 U/ml, 5ml vial

Aldurazyme (Vetter Pharma UK).

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=0.24-0.6L/kg.

Metabolism Laronidase is a protein and is expected to be metabolically degraded through peptide hydrolysis.

Elimination Renal elimination of laronidase is considered to be a minor pathway for clearance with half-life of 1.5-3.6 hours.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) Abdominal pain or discomfort; Arthralgia; Chills; Diarrhea; Flushing; Headache; Hyperreflexia; Injection site reaction; Nausea; Otitis media; Paresthesia; Pruritus; Pyrexia; Rash; Upper respiratory tract infection; Urticaria; Vomiting.

Less common (1-10%) Chest pain; Corneal opacity; Face edema; Gravitational edema; Hyperbilirubinemia; Hypotension; Injection site pain; Thrombocytopenia.

Rare but serious (less than 1%) Angioedema; Cyanosis; Erythema; Fatigue; Laryngeal edema; Peripheral edema.

Patient educations

A Patient education is not currently available for this monograph.

Note

Laronidase does not contain any preservatives, therefore, after dilution with saline, the infusion bags should be used immediately. If immediate use is not possible, the diluted solution should be stored refrigerated at 2°-8°C for up to 36 hours, room temperature storage of diluted solution is not recommended.

Latanoprost

ATC Code: S01EE01 Ophthalmologicals (Prostaglandin Analogues)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Open angle glaucoma: 1 drop in affected eye once daily in the evening.

Off-label uses

None.

Contraindications

Hypersensitivity to latanoprost.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Systemic absorption following ocular instillation is very low.

Distribution Vd=0.16L/kg.

Metabolism Latanoprost metabolized within the cornea; any entering systemic circulation is metabolized in the liver, extent unknown.

Elimination Renal elimination is 88-98% with a half-life of 17 min.

Dosage forms and trade names available in Iraq

Latanoprost 50mcg/ml (0.005%) Eye drop
Xalatan (PFIZER Belgium).

Drug interactions

Pilocarpine: Coadministration of latanoprost with pilocarpine decreases access of latanoprost to the receptor and increases resistance to flow through the uveosclera pathway, bedtime dose of pilocarpine should be given at least 10 minutes (preferably 1 hour) after latanoprost.

Side effects

Common (more than 10%) Blurred vision; Burning and stinging; Conjunctival hyperemia; Foreign body sensation; Increase in brown pigmentation of the iris; Itching; Punctate epithelial keratopathy.

Less common (1-10%) Chest pain; Dry eye; Excessive tearing; Eye pain; Lid crusting; Lid pain; Lid edema; Lid erythema; Photophobia; Flu.

Rare (less than 1%) Conjunctivitis; Diplopia; Discharge from the eye.

Patient educations

Remove contact lenses before using latanoprost; Separate administration from other ophthalmic products by at least 5 minutes; Advise patients that there is a risk of permanent increased iris pigmentation associated with instillation of latanoprost; Do not administer more than once daily to avoid loss of therapeutic effect; Store intact bottles under refrigeration; Opened dropper may be stored at room temperature or 6 weeks.

Lauromacrogol 400

ATC Code: C05BB02 Vasoprotectives (Sclerosing Agents for Local Injection)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

Sclerotherapy of varicose veins of the lower extremities: 2mg/kg should not be exceeded, depending on the type and size of the varicose veins to be treated.

Off-label uses

None.

Contraindications

Hypersensitivity to lauromacrogol 400; Diabetes mellitus; Toxic hyperthyroidism; Tuberculosis; Asthma; Neoplasm; Systemic infections; Blood dyscrasias; Acute respiratory or skin diseases; Patient is immobile; Severe arterial occlusive disease; Thromboembolic diseases; Hereditary thrombophilia.

Cautions

Fever; Bronchial asthma; Leg edema; Inflammatory skin disease; Neuropathy; Patients with reduced mobility.

Dose adjustment in renal failure: Not specified.

Dose adjustment in hepatic failure: Not specified.

Dosage forms and trade names available in Iraq

Lauromacrogol 400 (Polidocanol)
10 mg (0.5%) amp
Aethoxysklerol (Siegfried Hameln Germany).

Lauromacrogol 400 (Polidocanol)
20 mg (1%) amp
Aethoxysklerol (Siegfried Hameln Germany).

Pharmacokinetic parameters

They are not well defined for lauronacrogol 400.

Drug interaction

Specific interactions with lauronacrogol 400 have not been defined.

Side effects

Common (more than 10%) Injection site reactions (pain, itching, discoloration, tenderness).
Less common (1-10%) Headache, vasovagal reactions.
Rare but serious (less than 1%) Thrombosis, necrosis of the skin, allergic reactions.

Patient educations

1. This medication is usually administered in a healthcare setting, and you should follow all post-procedure care instructions provided by your healthcare professional.
2. After receiving treatment, you may experience some discomfort or changes at the injection site.
3. If you notice any severe side effects or symptoms, such as difficulty breathing, severe pain, or changes in skin color around the injection site, contact your healthcare provider immediately.

Lenalidomide

ATC Code: L04AX04 Immunosuppressants (Other Immunosuppressants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Myelodysplastic syndrome: 10mg once daily.
• Mantle cell lymphoma: 25mg once daily on days 1–21 of repeated 28-day cycle.
• Multiple myeloma: 25mg daily on days 1–21 of repeated 28-day cycle.

Dosage forms and trade names available in Iraq

Lenalidomide 10mg capsule
Revlimid (celgene Switzerland).
Lenalidomide 25mg capsule
Revlimid (Celgene Switzerland).

Off-label uses

Systemic amyloidosis; Non-Hodgkin's lymphoma; Relapsed or refractory chronic lymphocytic leukemia.

Contraindications

Hypersensitivity to lenalidomide.

Cautions

Arterial thromboembolic events; Glucose intolerance; Hypertension; Hyperlipidemia; Lactase deficiency.
Dose adjustment in renal failure: CrCl 30-59ml per minute, in myelodysplastic syndrome 5mg once daily, in multiple myeloma 10mg; CrCl less than 30ml per minute, in myelodysplastic syndrome 2.5mg once daily, in multiple myeloma 15mg every 48 hours.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=50-75%.
Distribution Vd=75.8±7.3L, 30%protein bound.
Metabolism Undergoes limited metabolism to form 5-hydroxy-lenalidomide and N-acetyl-lenalidomide.
Elimination Renal elimination is 82% with half-life of 3 hours.

Drug interactions

Covid-19 vaccine: immunosuppressant may diminish the therapeutic effect of covid-19 vaccine.

Side effects

Common (more than 10%): Anemia; Arthralgia; Back pain; Constipation; Cough; Diarrhea; Dizziness; Dyspnea; Fatigue; Headache; Muscle cramp; Nausea; Neutropenia; Peripheral edema; Pneumonia; Pruritus; Pyrexia; Rash; Thrombocytopenia.
Less common (1-10%): Abdominal pain; Bronchitis; Febrile neutropenia; Leukopenia; Myalgia; Pain; Peripheral neuropathy; Rhinitis.
Rare but serious (less than 1%): Hypothyroidism; Angioedema; Tumor lysis syndrome; Stevens-Johnson Syndrome.

Patient educations

Avoid crowds; avoid those with active infection; Treatment may cause blood clots in the arms, legs, or lungs; report arm or leg pain and swelling, difficulty breathing, chest pain.

Lercanidipine

ATC Code: C08CA13 Calcium Channel Blockers (Dihydropyridine Derivatives).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not recommended during lactation.

Indications and Dosage

• **Hypertension:** Initially 10 mg orally once daily; 15 minutes before eating. The dose may be increased to 20 mg depending on the patient's response.

Off-label uses

No data available.

Contraindications

Hypersensitivity to lercanidipine or any component of the formulation, severe hypotension, shock (including cardiogenic shock), unstable angina, and history of heart failure after acute myocardial infarction.

Cautions

Caution is advised in patients with hepatic impairment, as lercanidipine is extensively metabolized in the liver.

Dose adjustment in renal failure: No specific dose adjustment is typically required in renal failure. However, caution is advised, and monitoring may be necessary.

Dose adjustment in hepatic failure: Lercanidipine should be used with caution in patients with hepatic impairment. Lower doses may be necessary, and close monitoring of blood pressure and liver function is recommended.

Dosage forms and trade names available in Iraq

- Lecranidipine hydrochloride 10mg tab
  Zanidip (Recordati Italy).
- Lecranidipine hydrochloride 20mg tab
  Zanidip (Recordati Italy).

Pharmacokinetic parameters

Absorption Lercanidipine is well absorbed after oral administration.
Distribution Volume of distribution information is not readily available; approximately 98% protein bound.
Metabolism Lercanidipine undergoes extensive hepatic metabolism via cytochrome P450 enzymes, primarily CYP3A4.
Elimination Lercanidipine is primarily excreted in bile and feces; elimination half-life is approximately 8-10 hours.

Drug interactions

• Concurrent use with strong inhibitors of CYP3A4 (such as ketoconazole, itraconazole) may increase lercanidipine levels, leading to potential adverse effects such as hypotension and bradycardia.
• Concurrent use with strong inducers of CYP3A4 (such as rifampicin, carbamazepine) may decrease lercanidipine levels, reducing its effectiveness.

Side effects

Common (more than 10%): Peripheral edema, headache, flushing, dizziness.
Less common (1-10%): Palpitations, tachycardia, abdominal pain, dyspepsia.
Rare but serious (less than 1%): Hypotension, bradycardia, allergic reactions (including angioedema).

Patient educations

• Be aware of the signs of low blood pressure (hypotension), such as dizziness, lightheadedness, or fainting, and seek medical attention if they occur.
• Avoid consuming grapefruit or grapefruit juice while taking lercanidipine, as it may increase the risk of side effects.

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Letrozole

ATC Code: L02BG04 Endocrine Therapy (Aromatase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Breast cancer: 2.5mg once daily.

Off-label uses

Treatment of ovarian cancer; Treatment endometrial cancer.

Contraindications

Hypersensitivity to letrozole.

Cautions

Hyperlipidemia.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In severe hepatic failure, 2.5mg every other day.

Pharmacokinetic parameters

Absorption F=99.9%.

Distribution Vd=1.87L/kg, 55-60% protein bound.

Metabolism Mostly metabolized by the liver.

Elimination Renal elimination is 90% with half-life of 2 days.

Dosage forms and trade names available in Iraq

Letrozole 45mg tab

Drug interactions

Tamoxifen: Tamoxifen decreases levels of letrozole by unspecified interaction mechanism, letrozole should not be given concurrently with tamoxifen, letrozole therapy after the completion of standard tamoxifen treatment is not associated with impaired effects of letrozole.

Side effects

Common (more than 10%) Back pain; Bone pain; Cough; Diaphoresis; Dyspnea; Fatigue; Hot flashes; Nausea; Night sweats.

Less common (1-10%) Bone fractures; Breast pain; Chest pain; Constipation; Diarrhea; Edema; Headache; Hypercalcemia; Hypertension; Osteoporosis; UTI; Vomiting; Weakness.

Rare but serious (less than 1%) Angioedema; Blurred vision; Carpal tunnel syndrome; Erythema multiforme; Hepatitis; Increased hepatic enzyme levels; Toxic epidermal necrolysis; Trigger finger.

Patient educations

Report if nausea, asthenia, hot flashes become unmanageable; Discuss importance of negative pregnancy test prior to beginning therapy; Explain possible risk to fetus if patient is or becomes pregnant before or during therapy.

Levamisole

ATC Code: P02CE01 Anthelmintics (Imidazothiazole Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Ascariasis: 120mg as single dose.

Off-label uses

used as an immuneomodulator agent in treatment of various autoimmune disease such as rheumatoid arthritis and systemic lupus erythematosus.

Contraindications

Hypersensitivity to levamisole; Preexisting blood disorders; Rheumatoid arthritis.

Cautions

Sjogren's syndrome.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use with caution.

Dosage forms and trade names available in Iraq

Levamisole 40mg/5ml Syrup

Pharmacokinetic parameters

Absorption Levamisole is rapidly absorbed 2 hours from the gastrointestinal tract.
Distribution Vd=Undetermined, 20-25%protein bound.
Metabolism Primarily hepatic (extensive) with both active and inactive metabolites.
Elimination Renal elimination is 75% with half-life of 4.4-5.6 hours.

Drug interactions

Adalimumab: together with levamisole may increase the risk of serious and potentially life-threatening infections.
Clozapine: together with levamisole is not recommended. Clozapine can lower white blood cell count, and combining it with other medications that can also affect bone marrow function such as levamisole may increase the risk.
Many types of vaccines (zoster, yellow fever, typhoid vaccine, BCG…) increase risk for developing an infection from the vaccine or have a reduced response to the vaccine.

Side effects

Common (more than 10%) Nausea and vomiting; Abdominal pain; Diarrhea; Dizziness; Fatigue or malaise
Less common (1-10%) Rash or skin changes; Headache; Insomnia or other sleep disturbances; Loss of appetite; Fever
Rare but serious (less than 1%) Agranulocytosis (severe decrease in white blood cells leading to increased susceptibility to infections); Severe skin conditions like Stevens-Johnson syndrome and toxic epidermal necrolysis; Neurological effects like peripheral neuropathy or encephalopathy; Liver damage; Pulmonary inflammation or fibrosis

Patient educations

A Patient education is not currently available for this monograph.

Levetiracetam

ATC Code: N03AX14 Antiepileptics (Other Antiepileptics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding; Monitor breastfed infant for drowsiness, adequate weight gain.

Indications and Dosage

• Myoclonic seizure, tonic-clonic seizure: 500mg bid, maintenance 3000mg daily.
• Partial seizure: 500mg bid, (max 3000mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to levetiracetam.

Cautions

Patients with depression at high risk for suicide.
Dose adjustment in renal failure: CrCl 30-50ml/min: reduce dose by 50%.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Levetiracetam 500mg /5ml ampule
- Levetiracetam 100 mg/1ml syrup
  Levemax (PIONEER Iraq), **Kepprdain** (Wadi Al-Rafidain Iraq).
- Levetiracetam 250 mg tab
  Levemax (PIONEER Iraq).
- Levetiracetam 500 mg tab
  Levemax (PIONEER Iraq),
  Levetiracetam 1000 mg tab

Pharmacokinetic parameters

Absorption F=100%, food has minor effect on absorption.
Distribution Protein bound less than 10%.
Metabolism Minimal and via hydrolysis.
Elimination Renal elimination is 66% and 20-25% in feces, with half-life of 6-8 hr.

Drug interactions

Carbamazepine: Levetiracetam may enhance the adverse effect of carbamazepine, carbamazepine may decrease the serum concentration of levetiracetam.

Side effects

Common (more than 10%) Anorexia; Asthenia; Cough; Drowsiness; Fatigue; Headache; Increased blood pressure; Infection; Nasopharyngitis; Somnolence; Weakness.
Less common (1-10%) Albuminuria; Amblyopia; Amnesia; Anxiety; Asthma; Ataxia; Conjunctivitis; Depression; Diplopia; Dizziness; Hostility; Nervousness; Paresthesia; Sinusitis; Viral infection.
Rare (less than 1%) Abnormal hepatic function tests; Bone marrow suppression; Decreased hematocrit; Dyskinesia; Eczema; Epidermal necrolysis; Hepatitis; Leukopenia; Neutropenia; Pancreatitis; Suicidal tendencies.

Patient educations

Tell patient to take with or without food; Advise family to contact prescriber if patient poses a danger to himself or others; Caution patient not to stop taking drug abruptly, because doing so may increase seizure activity; Instruct patient to avoid activities that require mental alertness until CNS reactions are known.

Levocetirizine Dihydrochloride

ATC Code: R06AE09 Antihistamines for Systemic Use (Piperazine Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

Levocetirizine is an antihistamine that may be used to reduce allergy symptoms such as red, itchy, or watery eyes; a runny nose; sneezing; rashes; or reactions to insect bites or stings; uncomplicated skin manifestations of chronic idiopathic urticaria, and perennial or seasonal allergic rhinitis. 5mg once daily, doses should be given in the evening.

Dosage forms and trade names available in Iraq

Levocetirizine 5mg tablet
Lacozin (Inpharmasci France).

Off-label uses

None.

Contraindications

Hypersensitivity to levocetirizine; End stage renal disease; Hemodialysis.

Cautions

Elderly patients.
Dose adjustment in renal failure: CrCl 30-50ml/min: 2.5mg every other day; CrCl 10-29ml/min: 2.5mg twice weekly; CrCl less than 10ml/min: avoid.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=85%, food has limited effect on absorption.
Distribution Vd=0.4L/kg, 95% protein bound.
Metabolism Hepatic metabolism less than 14%.
Elimination Renal elimination is 85% with a half-life of 7-8 hr.

Drug interactions

Betahistine: Levocetirizine may diminish the therapeutic effect of betahistine.
Metoclopramide: Metoclopramide may enhance the CNS depressant effect of levocetirizine.
Tiotropium: Levocetirizine may enhance the anticholinergic effect of tiotropium.
Topiramate: Levocetirizine may enhance the adverse effect of topiramate.
Levocetirizine and olopatadine intranasal: both increase sedation. Coadministration increases the risk of CNS depression.

Side effects

Common (more than 10%) Drowsiness; Dry mouth; Fatigue
Less common (1-10%) Headache; Abdominal pain; Cough
Rare but serious (less than 1%) Allergic reactions including rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing; Hallucinations; Difficulty urinating; Seizures

Patient educations

Tell patient drug can be taken with or without food; Instruct patient to avoid alcohol and other depressants, such as sleeping pills, unless prescriber approves; Caution patient to avoid hazardous activities until drug's effects on concentration and alertness are known; Advise female patient to notify prescriber if she is pregnant or intends to become pregnant; Tell breastfeeding patient to discontinue breastfeeding during therapy.

Levofloxacin

ATC Code: J01MA12 Antibacterials for Systemic Use (Fluoroquinolones)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

- Chronic bacterial prostatitis: 500mg once daily for 28 days.
- Acute bacterial sinusitis: 750mg once daily for 5 days.
- Chronic bronchitis: 500mg once daily for 7 days.
- Community acquired pneumonia: 500mg-750mg once daily for 7-14 days.
- Infection of skin and subcutaneous tissue: 500mg daily for 7-14 days.
- Acute pyelonephritis: 250mg daily for 10 days.
- Bacterial conjunctivitis: 1-2 drops in affected eye every 2 hr on days 1 and 2, while awake, up to 8 times daily, then 1-2 drops every 4 hr, not to exceed qid on days 3 to 7.

Off-label uses

Urethritis; Traveler's diarrhea; Diverticulitis; Enterocolitis; Legionnaire's disease; Peritonitis; Treatment of prosthetic joint infection.

Dosage forms and trade names available in Iraq

- Levofloxacin 250 mg tablet
- Levofloxacin 500 mg tablet

LEVOSAM (SDI IRAQ), **LEVONEER** (Pioneer Iraq), ETC.

- Levofloxacin 5mg/ml (500mg/100ml) IV Infusion
- Levofloxacin 5mgl1ml 0.5 % eye drop

LEVONEER (Pioneer Iraq).

Contraindications

Hypersensitivity to levofloxacin.

Cautions

Bradycardia; Acute myocardial ischemia; Prolonged QT interval; Cirrhosis; Hypocalcemia; Elderly patients; Children.

Dose adjustment in renal failure: CrCl 20-50ml/min: reduce dose by 50%; CrCl 5-19ml/min: extend dosing interval to 48 hr.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=99%, food has no effect on absorption.

Distribution Vd= 74-112 L.

Metabolism Not metabolized.

Elimination Renal elimination is 87% with a half-life of 6-8 hr.

Drug interactions

Zinc: May decrease the serum concentration of levofloxacin.

Side effects

Common (more than 10%) None.

Less common (1-10%) Chest pain; Constipation; Diarrhea; Dizziness; Dyspepsia; Dyspnea; Edema; Fatigue; Headache; Injection-site reaction; Insomnia; Moniliasis; Nausea; Pain; Pruritus; Rash; Vaginitis; Vomiting.

Rare (less than 1%) None.

Patient educations

Instruct patient not to take with milk, yogurt, multivitamins containing zinc or iron.

Levothyroxine

ATC Code: H03AA01 Thyroid Therapy (Thyroid Hormones)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Hypothyroidism: 1.6mcg/kg/day as single daily dose, maintenance dose 100mcg–125mcg daily.
• Pituitary thyroid stimulating hormone (TSH) suppression: Doses greater than 2mcg/kg/day usually required to suppress TSH below 0.1 milliunits/L.

Off-label uses

Management of hemodynamically unstable potential organ donors; Toxicity due to radiotherapy.

Contraindications

Hypersensitivity to levothyroxine; Acute myocardial infarction; Thyrotoxicosis; Adrenal insufficiency.

Cautions

Elderly patients; Angina pectoris; Hypertension; Cardiovascular disease; Myxedema; Diabetes mellitus; Diabetes insipidus; Swallowing disorders.
Levothyroxine in daily dose is ineffective for weight reduction should not be used for the treatment of obesity, Higher doses produce serious or even life-threatening manifestations of toxicity.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Levothyroxine sodium 25mcg tab
  Euthyrox (Merck Germany).
- Levothyroxine sodium 50mcg tab
  Euthyrox (Merck Germany).
- Levothyroxine sodium 100mcg tab
  Euthyrox (Merck Germany).

Pharmacokinetic parameters

Absorption F=40-80%, increase with fasting.
Distribution Vd=8.7-9.7L, 99% protein bound.
Metabolism Approximately 80% of levothyroxine is deiodinated into T3 in the liver, kidney, and other tissues.
Elimination Renal elimination is 50% with a half-life of 7 days.

Drug interactions

Furosemide: may decrease the protein binding of levothyroxine. This may lead to a transient increase in free thyroid hormone concentrations and to a later decrease in total thyroid hormone concentrations.

Side effects

Common (more than 10%) Weight loss; Increased appetite; Insomnia; Excessive sweating; Choking sensation; Diarrhea; Fever; Arthralgia; Cramps
Less common (1-10%) Nervousness, anxiety; Heat sensitivity; Headache; Increased heart rate, palpitations; Hair loss (usually temporary); Decreased bone mineral density; Infertility
Rare but serious (less than 1%) Difficulty breathing, shortness of breath; Swelling of the face, throat, or tongue (allergic reactions); Severe dizziness, fainting; Myasthenia; Myocardial infarction; Angina pectoris Congestive heart failure; Arrhythmias.

Patient educations

Levothyroxine should be taken on an empty stomach 1-1.5 before breakfast. Alternatively, may administer at night 3 to 4 hours after the last meal. It should not be given with soy protein or within 4 hours of calcium- or iron-containing products or bile acid sequestrants.

Lidocaine

ATC Code: N01BB02 Anesthetics (Amides)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X N
Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

lidocaine 100mg/ml spray
Xylocaine (Aspen Ireland).
Lidocaine 5% cream
EMLA (Aspen Ireland).
Lidocaine 5% ointment
LIDOCAIN (SDI Iraq), **Licodain** (Wadi Al-Rafidain Iraq), **LIDOCAINE** (PIONEER IRAQ), **Lidocan –K** (AL-Kindi Iraq).
Lidocaine hydrochloride 2% gel
Lidocan –K (AL-Kindi Iraq).
lidocaine hydrochloride 20mg/1ml 2% inj / Vial
LIDOCAINE (PIONEER IRAQ).

Indications and Dosage

• Rapid control of acute ventricular arrhythmias, cardiac catheterization, cardiac surgery, or digitalis induced ventricular arrhythmias: By i.v. injection, 50mg-100mg (1 mg/kg) may repeat in 5 min, give no more than 200mg-300mg in 1 hr.
• Dental or surgical procedures, childbirth: (max dose 4.5mg/kg do not repeat within 2 hr).
• Local skin disorders (minor burns, insect bites, chickenpox, abrasions) and local anesthesia of nasal and laryngeal mucous membranes, relief of discomfort of pruritus ani, hemorrhoids: Apply to affected areas as needed.

Off-label uses

None.

Contraindications

Hypersensitivity to lidocaine or other anesthetics of the amide type; Supraventricular arrhythmias; Wolff-Parkinson-White syndrome.

Cautions

Hepatic disease; Severe respiratory depression; Malignant hyperthermia; Shock; Elderly patients; Heart failure.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: In sever hepatic failure dosage reduction may be needed.

Pharmacokinetic parameters

Absorption F=35%, food has no effect on absorption.
Distribution Vd=1.7L/kg, 60-80%protein bound.
Metabolism Metabolized by liver by de-ethylation to form active metabolites.
Elimination Renal elimination is 90% with half-life of 2.5-8 hours.

Drug interactions

Ivabradine: lidocaine will increase the level or effect of ivabradine by affecting hepatic and intestinal enzyme CYP3A4 metabolism; Avoid or use alternate drug.

Side effects

Common (more than 10%) redness, itching, or rash , Mild discomfort or slight burning sensation immediately after application (topical use); Nausea or vomiting , Drowsiness or light-headedness (systemic use); Hypotension.
Less common (1-10%) Numbness in the mouth or throat (if used orally or in the throat); Changes in vision; Confusion.
Rare but serious (less than 1%) Seizures; Slow or irregular heartbeats, cardiac arrest; dyspnea; anaphylaxis; Methemoglobinemia.

Patient educations

Due to loss of feeling and sensation, protective measures may be needed until anesthetic wears off.

Linagliptin

ATC Code: A10BH05 Drugs Used in Diabetes (Dipeptidyl Peptidase 4 (DPP4-) Inhibitors)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid—present in milk in animal studies.

Indications and Dosage

Adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control. The recommended dose is 5 mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to linagliptin.

Cautions

Pancreatitis, heart failure, Hypoglycemia, hypersensitivity reactions, Arthralgia, Bullous pemphigoid.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required

Dosage forms and trade names available in Iraq

- Linagliptin 5mg tablet

Pharmacokinetic parameters

Absorption Linagliptin is rapidly absorbed, with peak plasma concentration occurring about 1.5 hours after administration. The absolute bioavailability is approximately 30%.

Distribution Vd= ~1110 L, Plasma protein binding of linagliptin is concentration-dependent, decreasing from about 99% at 1 nmol/l to 75-89% at ≥30 nmol/l

Metabolism Minimally metabolized.

Elimination eliminated in feces (80%) or urine (5%) within 4 days of dosing, The effective half-life for accumulation of linagliptin, as determined from oral administration of multiple doses of 5 mg linagliptin, is approximately 12 hours.

Drug interaction

Insulin or insulin secretagogues: May increase the risk of hypoglycemia.

Strong P-glycoprotein/CYP3A4 inducer: The efficacy may be reduced when administered in combination (e.g., with rifampin).

Side effects

Common (more than 10%) hypoglycemia (observed in combination with metformin plus sulphonylurea); increased lipase.

Less common (1-10%) nasopharyngitis, hypersensitivity (e.g., bronchial hyperreactivity), cough, constipation (observed in combination with insulin), rash, increased amylase.

Rare but serious (less than 1%) pancreatitis, angioedema, urticaria, bullous pemphigoid.

Patient educations

1. Take linagliptin as directed by your healthcare provider, with or without food.
2. Contact your healthcare provider immediately if you experience severe stomach pain, which may be pancreatitis.
3. Regularly monitor blood glucose as directed by your healthcare provider.

Linezolid

ATC Code: J01XX08 Antiinfectives for Systemic Use (Other Antibacterials)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Linezolid is excreted in breast milk; discontinue nursing or discontinue the drug.

Dosage forms and trade names available in Iraq

- Linezolide 600mg tab

Indications and Dosage

For treatment of infections like MRSA and VRE, dosage is typically 600mg every 12 hours, orally or intravenously, for 10 to 14 days or longer depending on the infection and clinical judgment.

Off-label uses

Treatment of drug-resistant tuberculosis (as part of a multi-drug regimen).

Contraindications

Concurrent use or use within two weeks of MAO inhibitors.

Cautions

Monitor for myelosuppression; peripheral and optic neuropathy (especially with prolonged use); serotonin syndrome (with concurrent serotonergic drugs); pseudomembranous colitis.

Dose adjustment in renal failure: Not needed

Dose adjustment in hepatic failure: No needed.

Pharmacokinetic parameters

Absorption Bioavailability is approximately 100%.

Distribution Vd= 40-50 L, 31% protein bound.

Metabolism Undergoes minimal metabolism.

Elimination About 30-35% is excreted in urine and 40% in feces; half-life is 4-5 hours.

Drug interaction

Selective serotonin reuptake inhibitors (SSRIs): Increased risk of serotonin syndrome.

MAO inhibitors: Increased risk of hypertensive crisis.

Side effects

Common (more than 10%): Diarrhea; headache; nausea.

Less common (1-10%): Vomiting; rash; taste disturbance.

Rare but serious (less than 1%): Myelosuppression; lactic acidosis; neuropathy; serotonin syndrome; Clostridioides difficile colitis.

Patient educations

1. Report signs of prolonged nausea, vomiting, diarrhea, or unexpected bleeding/bruising.
2. Avoid large quantities of food or drink high in tyramine content (e.g., matured cheeses, fermented or air-dried meats).

Liraglutide

ATC Code: A10BJ02 Drugs Used in Diabetes (Glucagon-like Peptide1- (GLP1-) Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Liraglutide 6mg/ml (3ml) pre-filled pen **VICTOZA** (Novo Nordisk Denmark), **Saxenda** (Novo Nordisk Denmark).

Indications and Dosage

• Diabetes (type 2): By subcutaneous injection, 0.6mg once daily for 1 week then increase to 1.2mg once daily, if 1.2mg dose does not result in acceptable glycemic control, dosage can be increased to 1.8mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to liraglutide; Personal or family history of medullary thyroid carcinoma; patients with multiple endocrine neoplasia syndrome type 2 or gastroparesis.

Cautions

Pancreatitis; Cholelithiasis; Alcohol abuse; Diabetes type 1; Diabetic ketoacidosis.
Dose adjustment in renal failure: Use cautiously.
Dose adjustment in hepatic failure: Use cautiously.

Pharmacokinetic parameters

Absorption F=55%.
Distribution Vd=13L, 98% protein bound.
Metabolism Endogenously metabolized to large proteins.
Elimination Renal elimination is 6% and fecal elimination 5% with a half-life of 13 hr.

Drug interactions

Insulins: Liraglutide may enhance the hypoglycemic effect of insulins, consider reducing the liraglutide dose if coadministered with insulin. prescribing information for liraglutide recommends a dose decrease of 50% and monitor blood glucose for hypoglycemia.
Oral medication: duo to liraglutide cause delay of gastric emptying

Side effects

Common (more than 10%) Diarrhea; Nausea; Vomiting.
Less common (1-10%) Constipation; Headache; Injection site reactions.
Rare (less than 1%) Back pain; Dizziness; Hypertension; Hypoglycemia; Nasopharyngitis; Pancreatitis; Papillary thyroid carcinoma; Sinusitis; Thyroid C-cell hyperplasia; Upper respiratory tract infection; Urinary tract infection; Urticaria.

Patient educations

Instruct patient to take drug without regard to meals; Instruct patient to discontinue drug and immediately notify prescriber if persistent severe abdominal pain occurs that may radiate to the back and may or may not be accompanied by vomiting; Instruct patient to immediately notify prescriber if signs and symptoms of thyroid tumor occur (such as persistent hoarseness, mass in the neck, difficulty swallowing, or difficulty breathing). Advise patient about not sharing the pen with another person duo to risk of blood born pathogen transmission.

Lisinopril

ATC Code: C09AA03 Agents Acting On The Renin-Angiotensin System (Ace Inhibitors, Plain)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid; A decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Indications and Dosage

- Acute myocardial infarction: 5mg-10mg daily for 6 weeks.
- Heart failure: 2.5mg-5mg daily, may titrate to 40mg daily.
- Hypertension: 10mg daily, may titrate to 80mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to lisinopril; Angioedema.

Cautions

Unstented unilateral or bilateral renal artery stenosis; Volume depletion; Ischemic heart disease; Cerebrovascular disease; Severe aortic stenosis; Hypertrophic cardiomyopathy; Heart failure; systolic blood pressure less than 100mmHg; dialysis; Hyponatremia; Major surgery.

Dose adjustment in renal failure: CrCl 10-30ml/min: 5mg daily; CrCl less than 10ml/min: 2.5mg daily.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Lisinopril 5mg tab
  Zestril (AstraZeneca UK).
- Lisinopril 10mg tablet
  LINOPRIL (Pharma International Jordan).
- Lisinopril 20mg tab
  LINOPRIL (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=25% (F=16% in heart failure), food has no effect on absorption.
Distribution Protein bound 25%.
Metabolism Not metabolized.
Elimination Renal elimination is 50-70% with a half-life of 12 hr.

Drug interactions

Allopurinol: Angiotensin converting enzyme inhibitors may enhance the potential for allergic or hypersensitivity reactions to allopurinol.
Duloxetine: Angiotensin converting enzyme inhibitors may enhance the hypotensive effect of duloxetine.

Side effects

Abdominal pain; Alopecia; Angina pectoris; Chest pain; Cough; Diarrhea; Dry mouth; Dyspnea; Fatigue; Flatulence; Gout; Heart failure; Hyperkalemia; Hypotension; Infection; Nausea; Pancreatitis; Photosensitivity; Rash; Syncope; Urticaria.

Patient educations

Advise patient to take once a day in morning, with or without food; Tell patient that drug may cause temporary blood pressure decrease if he stands up suddenly. Advise him to rise slowly and carefully; Instruct patient to avoid potassium based salt substitutes or potassium supplements.

Loperamide

ATC Code: A07DA03 Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents (Antipropulsives)
Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N
Lactation: Compatible with breastfeeding.

Indications and Dosage

• Acute and chronic diarrhea: Initially, 4mg, then 2mg after each unformed stool, (max 16mg daily).
• Traveler diarrhea: Initially, 4mg, then 2mg after each loose bowel movement, (max 8mg daily).

Off-label uses

Chemotherapy induced diarrhea.

Contraindications

Hypersensitivity to loperamide; Abdominal pain without diarrhea; Children younger than 2 years; Acute dysentery; Acute ulcerative colitis; Bacterial enterocolitis caused by invasive organisms including salmonella, shigella, campylobacter.

Cautions

Hepatic impairment; Use in young children; Megacolon; QT prolongation.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Loperamide Hcl 2mg tab
VACOSAM (SDI Iraq), **DIARRHEA – STOP** (Al-Kindi Iraq).

Pharmacokinetic parameters

Absorption F=0.3%, not well absorbed following oral administration.
Distribution Vd=Undetermined, 97%protein bound.
Metabolism Metabolized partially by the liver, undergoes enterohepatic recirculation.
Elimination Fecal elimination is 30% with half-life of 10.8 hours.

Drug interactions

Atorvastatin: Atorvastatin will increase the level or effect of loperamide by P-glycoprotein efflux transporter.
Itraconazole: Itraconazole will increase the level or effect of loperamide, monitor ECG when itraconazole is coadministered with loperamide (dose more than16mg per day).
Gemfibrozil: Gemfibrozil will increase the level or effect of loperamide by decreasing metabolism.
Verapamil: Verapamil will increase the level or effect of loperamide by P-glycoprotein efflux transporter.

Side effects

Abdominal pain; Diarrhea; Dizziness; Dry mouth; Fatigue; Headache; Nausea; Pancreatitis; Vomiting.

Patient educations

Do not exceed prescribed dose; May cause dry mouth; Avoid alcohol; Avoid tasks that require alertness, motor skills until response to drug is established; Report diarrhea lasting more than 3 days, abdominal pain with distention, new onset fever.

Large & Small Volume Iv Fluids

Piodol
Paracetamol,Intravenous infusion solution
10mg / ml

Levoneer
Levofloxacin Solution for IV infusion
500mg 100ml

Dextrose
IV Infusion
5 %

Sodium Chorlde
IV Infusion 0.9 %

PIONEER PIONEER CO. FOR PHARMACEUTICAL INDUSTRIES

Loratidine

ATC code: R06AX13 Antihistamines for Systemic Use (Other Antihistamines for Systemic Use)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Avoid.

Indications and Dosage

• Allergic rhinitis, urticaria: 10mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to loratidine; Children less than 2 years.

Cautions

Narrow angle glaucoma; Prostatic hypertrophy; Stenosing peptic ulcer; Pyloroduodenal obstruction; Bladder neck obstruction.

Dose adjustment in renal failure: CrCl less than 30ml per minute 10mg every other day.

Dose adjustment in hepatic failure: 10mg every other day.

Dosage forms and trade names available in Iraq

Loratidine 10mg tab

Lorasam (SDI Iraq), **Laritin** (PIONEER Iraq), **TIDILOR** (Pharma International Jordan).

Loratidine 5mg/5ml syrup

Laritin (PIONEER Iraq), **TIDILOR** (Pharma International Jordan).

Pharmacokinetic parameters

Absorption Food delays time to peak plasma concentration and increases bioavailability.

Distribution Vd=120L/Kg, 97-99%protein bound.

Metabolism Loratidine undergoes extensive first pass metabolism in the liver and is primarily metabolized by CYP3A4, CYP2D6, CYP1A1 and CYP2C19.

Elimination Renal elimination is 40% with half-life of 10 hours.

Drug interactions

Erythromycin: Erythromycin increases levels of loratidine by decreasing metabolism.

Gabapentin: Gabapentin and loratadine both increases effects of the other by pharmacodynamic synergism, coadministration of CNS depressants can result in serious, life-threatening, and fatal respiratory depression. Use lowest dose possible and monitor for respiratory depression and sedation.

Side effects

Common (more than 10%) Cough; Diarrhea; Fever; Headache; Irritability; Upper respiratory infection; dry mouth; abdominal pain.

Less common (1-10%) Bronchitis; Dizziness; Dysmenorrhea; Epistaxis; Erythema; Fatigue; Macupopular rash; Somnolence; Urinary tract infection.

Rare but serious (less than 1%) Increased appetite; Psychomotor hyperactivity; Tachycardia, palpitation.

Patient educations

Avoid the use of alcohol; serious sedation could occur.

Lorazepam

ATC Code: N05BA06 Psycholeptics (Benzodiazepine Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Sedation and inability to suckle have occurred in neonates.

Dosage forms and trade names available in Iraq

- Lorazepam tab 1mg tab
  Lorazesam (SDI Iraq).
- Lorazepam tab 2mg tab
  Lorazesam (SDI Iraq).

Indications and Dosage

• Anxiety disorders, insomnia: 1mg-6mg bid or tid, (max 10mg daily).

Off-label uses

Treatment of alcohol withdrawal; Psychogenic catatonia; Partial complex seizures; Antiemetic for chemotherapy; Rapid tranquilization of agitated patient; Status epilepticus in children.

Contraindications

Hypersensitivity to lorazepam or other benzodiazepines; Acute narrow angle glaucoma; Severe respiratory depression.

Cautions

Compromised pulmonary function; Depression; History of drug dependence Alcohol abuse; Personality disorder; Patients at risk for suicide.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90-93%, food has no effect on absorption.

Distribution Vd=1.3L/kg, 85% protein bound.

Metabolism Extensive hepatic metabolism.

Elimination Renal elimination is 88% with a half-life of 12 hr.

Drug interactions

Metoclopramide: Metoclopramide may enhance the CNS depressant effect of lorazepam.

Metronidazole: Metronidazole may enhance the adverse effect of lorazepam, a disulfiram-like reaction may occur, avoid combination.

Side effects

Amnesia; Asthenia; Ataxia; Blood dyscrasias; Change in appetite; Change in libido; Confusion; Constipation; Convulsions; Depression; Disorientation; Dizziness; Drowsiness; Dysarthria; Extrapyramidal symptoms; Fatigue; Hypersensitivity reactions; Hypotension; Impotence; Jaundice; Nausea; Paradoxical reactions (anxiety, excitation, agitation, hostility, aggression, rage); Respiratory depression; Sedation; Sleep apnea; Tremor; Unsteadiness; Vertigo; Visual disturbances; Weakness.

Patient educations

Explain that with long-term use, lorazepam must be discontinued slowly (typically over 8 to 12 weeks); Instruct patient to avoid alcohol, because it increases drowsiness and other CNS effects; Caution patient to avoid smoking.

Losartan

ATC Code: C09CA01 Agents Acting on The Renin-Angiotensin System (Angiotensin II receptor blockers (ARBs), plain)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid; A decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Indications and Dosage

• Hypertension: 50mg daily, maintenance 25mg-100mg daily or bid

• Reduce risk of cerebrovascular accident in hypertensive patients with left ventricular hypertrophy, diabetic nephropathy: Initially, 50mg daily, maintenance 100mg daily.

Off-label uses

Slow rate of progression of aortic root dilation in children with Marfan's syndrome; Heart failure in patient intolerant of ACE inhibitors.

Contraindications

Hypersensitivity to losartan.

Cautions

Unstented renal arterial stenosis; Significant aortic or mitral stenosis; Patients with history of angioedema.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: 25mg daily.

Dosage forms and trade names available in Iraq

- Losartan potassium 50mg tablet
  LOSART (Pioneer Iraq).
- Losartan potassium 100mg tablet
  L-SARTAN (Al-Kindi Iraq), **LOSART** (Pioneer Iraq).

Pharmacokinetic parameters

Absorption F=33%, food slows absorption and decreases Cmax by 10%.

Distribution Vd=34L/kg, 99% protein bound.

Metabolism Hepatic metabolism 14%.

Elimination Renal elimination is 35% with a half-life of 2 hr.

Drug interactions

Heparin: Heparin may enhance the hyperkalemic effect of losartan.

Rifampicin: Rifampicin may decrease the serum concentration of losartan.

Side effects

Common (more than 10%) Upper respiratory infections; dizziness; back pain.

Less common (1-10%) Back pain; Dizziness; Nasal congestion; Upper respiratory tract infection.

Rare (less than 1%) None.

Patient educations

Instruct patient to avoid potassium supplements and salt substitutes containing potassium; Instruct patient to immediately report hypersensitivity reactions, especially lip or eyelid swelling, throat tightness, and difficulty breathing.

Loteprednol Etabonate

ATC Code: S01BA14 Ophthalmologicals (Corticosteroids, Plain)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: It is not known

Dosage forms and trade names available in Iraq

Loteprednol etabonate 0.5% gel
Lotemax (Busch & Lomb USA).

Indications and Dosage

Loteprednol etabonate is used to treat eye inflammation and pain following ocular surgery, or conditions like allergic conjunctivitis. Dosage will vary by indication, but often starts with applying 1-2 drops into the conjunctival sac of the affected eye(s) 4 times daily.

Off-label uses

None recognized.

Contraindications

Known hypersensitivity to loteprednol etabonate or any ingredients in the formulation.

Cautions

Prolonged use may result in glaucoma, cataract formation, or fungal or viral eye infections. Do not use contact lenses during treatment.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Being a topical application, traditional pharmacokinetic parameters are not readily available or applicable.

Drug interaction

No major known interactions, as the systemic absorption is minimal.

Side effects

Common (more than 10%): Burning upon instillation; blurry vision.
Less common (1-10%): Dry eyes; itching sensation; increased intraocular pressure.
Rare but serious (less than 1%): Perforation of the eyeball; cataract formation; glaucoma; fungal or viral eye infections.

Patient Education

1. Avoid touching the tip of the medication bottle to the eye, fingertips, or other surfaces to prevent contamination.
2. Temporary blurred vision may occur after applying; do not drive or operate machinery until vision is clear.
3. If you wear contact lenses, remove them before using this medication and wait at least 15 minutes before reinserting.

Macrogol

ATC Code: A06AD15 Drugs for Constipation (Osmotically Acting Laxatives)

Pregnancy category:
FDA A B C D X **N**
TGA A **B1** B2 B3 C D X N

Lactation: There is no known risk for use while breastfeeding.

Dosage forms and trade names available in Iraq

Macrogol 3350 (13.125mg) oral solution sachet
Movicol (NORGINE UK).

Indications and Dosage

Macrogol is used to treat constipation. Typical dosage for adults and children over 12 years old is one sachet (13.125g) dissolved in 125 mL of water, once to three times a day.

Off-label uses

None.

Contraindications

• Hypersensitivity to macrogol or any other ingredient in the product.
• In people with bowel perforation, obstruction, or fecal impaction.

Cautions

In patients with renal impairment or heart disease due to increased sodium levels.
Dose adjustment in renal failure: No specific guidelines available.
Dose adjustment in hepatic failure: No specific guidelines available.

Pharmacokinetic parameters

Macrogol is minimally absorbed from the gastrointestinal tract and thus pharmacokinetic parameters such as absorption, distribution, metabolism, and elimination are not applicable in the traditional sense.

Drug interactions

1. Macrogol can decrease the absorption of other oral medications if taken concurrently. Medications should be taken at least one hour before or two hours after macrogol.
2. Concurrent use with diuretics or other medications that may impact electrolyte levels should be monitored due to the potential for electrolyte imbalance.

Side effects

Common (more than 10%): Bloating, abdominal pain, gas, diarrhea.
Less common (1-10%): Nausea, upset stomach.
Rare but serious (less than 1%): Allergic reactions, severe diarrhea, electrolyte imbalance.

Patient education

1. Dissolve the sachet content in 125 mL of water before taking.
2. Medications should be taken at least one hour before or two hours after taking macrogol.
3. Seek immediate medical attention for severe diarrhea or allergic reactions.

Magnesium Carbonate

ATC Code: A02AA01 Antacids (Magnesium Compounds).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is generally considered safe to use magnesium carbonate during lactation.

Indications and Dosage

• **Dyspepsia:** 10 mL (250 mg/5 mL suspension) orally every 3 to 4 hours as needed, Maximum dose: 40 mL/day, Duration of therapy: Up to 2 weeks.

Off-label uses

None.

Contraindications

Hypersensitivity to magnesium carbonate or any component of the formulation, severe renal impairment, and hypermagnesemia.

Cautions

Caution is advised in patients with renal impairment, as magnesium carbonate can accumulate and lead to hypermagnesemia. Use with caution in patients with heart block or myasthenia gravis.

Dose adjustment in renal failure: Dosage adjustment may be necessary in patients with renal failure to avoid magnesium accumulation and hypermagnesemia, Hypermagnesemia is common with creatinine clearance under 10 mL/min.

Dose adjustment in hepatic failure: No specific dose adjustment is typically required in hepatic failure.

Dosage forms and trade names available in Iraq

- Magnesium carbonate 200mg tablet

Pharmacokinetic parameters

Absorption 40-60% of magnesium is absorbed following oral administration.

Distribution Vd for magnesium is 0.2-0.4L/kg 5. About 50% is distributed to bone; 30% of magnesium is bound to proteins.

Metabolism Magnesium carbonate does not undergo significant metabolism.

Elimination Magnesium carbonate is primarily excreted in urine; elimination half-life is variable.

Drug interactions

• Concurrent use with certain antibiotics (such as tetracyclines or fluoroquinolones) may reduce the absorption of both medications when taken simultaneously. Administer these medications at least 2 hours apart.

• Concurrent use with medications that lower stomach acid (such as proton pump inhibitors or H2 blockers) may affect the dissolution and absorption of magnesium carbonate, potentially reducing its efficacy.

Side effects

Common (more than 10%): Diarrhea (with high doses), abdominal discomfort, flatulence.

Less common (1-10%): Nausea, vomiting, headache.

Rare but serious (less than 1%): Hypermagnesemia (with excessive intake or renal impairment), allergic reactions (such as rash or itching).

Patient education

• Be cautious not to exceed the recommended dosage, as excessive intake can lead to side effects such as diarrhea or hypermagnesemia.

• Inform your healthcare provider about any existing medical conditions or medications you are taking before using magnesium carbonate, especially if you have kidney problems or are taking other medications that may interact with it.

Magnesium Sulfate

ATC Code: A12CC02 Mineral Supplements (Magnesium)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Acute hypomagnesemia: By i.m. injection, 1g every 6 hr for up to 4 doses. By i.v. injection 1g-2g for one dose.
• Preeclampsia, eclampsia: Initially, 4g-5g bolus diluted, then 1g-2g/hr by i.v. continuous infusion.

Off-label uses

Asthma exacerbation unresponsive to conventional treatment.

Contraindications

Hypersensitivity to magnesium sulfate; Heart block; Myocardial damage; During the 2 hr prior to delivery; Appendicitis; Ileostomy; Intestinal obstruction.

Cautions

Myasthenia gravis or other neuromuscular diseases.
Dose adjustment in renal failure: Use with caution.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Magnesium Sulphate 50% Ampoule
Magnesium sulphate (Pioneer Iraq).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=Undetermined, 25-30%protein bound.
Metabolism Not metabolized.
Elimination Excreted primarily by the kidneys with half-life of 43.2 hours.

Drug interactions

Verapamil: Magnesium Sulfate may enhance the adverse effect of verapamil, the risk of hypotension or muscle weakness may be increased.

Side effects

Circulatory collapse; Depressed cardiac function; Depressed reflexes; Diaphoresis; Drowsiness; Flushing; Hyperkalemia; Hypocalcemia; Hypophosphatemia; Hypotension; Hypothermia; Pulmonary edema; Respiratory paralysis; Visual changes.

Patient educations

Teach patient about adverse reactions, instruct him to report symptoms that occur during i.v. administration.

Mannitol

ATC Code: B05BC01 Blood Substitutes and Perfusion Solutions (Solutions Producing Osmotic Diuresis)
Pregnancy category:
FDA A B **C** D X N
TGA A B1 **B2** B3 C D X N
Lactation: It's not yet known

Dosage forms and trade names available in Iraq

Manitol 20% (20 gm/100ml) 500ml I.V. infusion
MANNITOL (Pioneer Iraq).

Indications and Dosage

Mannitol is used to reduce high pressure in the eyes (in situations like glaucoma) and to help your body produce more urine (in situations like oliguric renal failure). Dosage varies based on the specific indication and patient condition, and should be determined by a healthcare professional.

Off-label uses

Reduce intracranial pressure in situations like traumatic brain injury.

Contraindications

• Mannitol is contraindicated in people with anuria.
• Severe dehydration, active intracranial bleeding except during craniotomy, severe renal disease, and in patients with known hypersensitivity to it.

Cautions

In patients with heart failure or renal impairment.
Dose adjustment in renal failure: may be necessary.
Dose adjustment in hepatic failure: No specific guidelines available. Caution is advised.

Pharmacokinetic parameters

Absorption Not relevant for IV administration.
Distribution Vd= 0.2-0.7 L/kg, not protein bound.
Metabolism Minimal, if any.
Elimination Renal excretion with a half-life of 100 minutes (1.66 hours).

Drug interactions

Lithium: Mannitol can reduce the renal elimination of lithium, leading to increased lithium levels.
Other diuretics: Additive effects may occur, increasing the risk of dehydration and electrolyte abnormalities.

Side effects

Common (more than 10%): Electrolyte imbalances; fluid and electrolyte loss; dehydration; headache.
Less common (1-10%): Nausea; vomiting; rhinitis; chest discomfort.
Rare but serious (less than 1%): Kidney failure; heart failure; blurred vision; seizures.

Patient education

Report any unusual side effects to your doctor, such as persistent nausea/vomiting, dizziness, or changes in the amount of urine.

Mebendazole

ATC Code: P02CA01 Anthelmintics (Benzimidazole Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Trichuriasis, ascariasis, hookworm: 100mg bid for 3 days, a second course is recommended after 2 weeks.
• Enterobiasis (pinworm): 100mg as a single dose.

Off-label uses

Trichinosis; Visceral larva migrans.

Contraindications

Hypersensitivity to mebendazole.

Cautions

Neutropenia; Granulocytosis; Not effective for hydatid disease.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=5-10%, fatty food increases absorption.
Distribution Vd=1-2L/kg, 90-95%protein bound.
Metabolism Primarily hepatic metabolism.
Elimination Renal elimination is 2% with half-life of 2.5-5.5 hours.

Dosage forms and trade names available in Iraq

- Mebendazole 100mg tab
- Mebendazole 20mg/ml oral suspension

Drug interactions

Deferiprone: deferiprone and mebendazole both increases toxicity of the other by pharmacodynamic synergism, avoid use of deferiprone with other drugs known to be associated with neutropenia or agranulocytosis; if an alternative is not possible, monitor absolute neutrophil count more frequently.
Metronidazole: Mebendazole increases toxicity of metronidazole, may increase the risk for toxic epidermal necrolysis or Stevens-Johnson syndrome.
Phenytoin: Phenytoin decreases levels of mebendazole by increasing metabolism, use of phenytoin with mebendazole is contraindicated.

Side effects

Abdominal pain; Agranulocytosis; Alopecia (with high doses); Angioedema; Decreased hemoglobin; Diarrhea; Dizziness; Drowsiness; Fever; Glomerulonephritis; Headache; Hematuria; Itching; Leukopenia; Nausea; Neutropenia (sore throat, unusual fatigue); Rash; Seizures; Stevens Johnson syndrome; Toxic epidermal necrolysis; Toxic epidermal necrolysis; Unusual weakness; Vomiting.

Patient educations

Mebendazole may be taken with or without food; Avoid in children under 2 years.

Mebeverine

ATC Code: A03AA04 Drugs for Functional Gastrointestinal Disorders (Synthetic Anticholinergics, Esters with Tertiary Amino Group)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

Mebeverine is used to relieve symptoms of IBS. The usual adult dose is 135mg taken three times daily, 20 minutes before meals.

Off-label uses

None.

Contraindications

Hypersensitivity to Mebeverine; Paralytic ileus.

Cautions

Heart block; liver or kidney disorders

Dose adjustment in renal failure: Use with caution.

Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption Rapidly absorbed from the gastrointestinal tract, time to peak plasma concentration 1-3 hours.

Distribution Vd= Undetermined, 75%protein bound.

Metabolism Metabolized primarily in the liver.

Elimination Primarily renal excretion, the half-life is about 2.5 to 5 hours.

Dosage forms and trade names available in Iraq

- Mebeverine HCl 135 mg tablet
  Samapatalin (SDI Iraq), **PiOVERIN** (Pioneer Iraq), **Duspaline** (Al-Kindi Iraq), **Duspatadain** (Wadi Al-Rafidain Iraq).
- Mebeverine HCl 200 mg tablet
  DUSPATALIN® RETARD (Abbott Netherland).

Drug interactions

No major interactions have been reported with mebeverine.

Side effects

Common (more than 10%) Not reported, generally well tolerated.

Less common (1-10%) Hypersensitivity reactions, heartburn, indigestion, constipation, loss of appetite, and general malaise.

Rare but serious (less than 1%) Isolated cases of angioedema; agranulocytosis or aplastic anaemia.

Patient educations

1. Take Mebeverine 20 minutes before a meal.
2. Contact your doctor if your symptoms do not improve after two weeks of treatment.

Mecobalamin

ATC Code: B03BA05 Antianemic Preparations (Vitamin B12 (Cyanocobalamin and Analogues))

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

Megaloblastic anemia caused by vitamin B12 deficiency, peripheral neuropathy: Dosage can vary, but a common dose is 1,500 micrograms/day orally in divided doses.

Off-label uses

For sleep-wake rhythm disorders, diabetic neuropathy, and adjunctive treatment for major depressive disorder.

Contraindications

Known hypersensitivity to cobalamin or any component of the formulation.

Cautions

in patients with Leber's disease (hereditary optic nerve atrophy).

Dose adjustment in renal failure: Not typically required.

Dose adjustment in hepatic failure: Not typically required.

Dosage forms and trade names available in Iraq

Mecobalamin 500 µg ampoule

Methycobal (Nipro Japan).

Pharmacokinetic parameters

Absorption Actively absorbed from the gastrointestinal tract, time to peak plasma concentration 3 hours (oral), 3 minutes (i.v.), 0.9 hour (i.m.).

Distribution Stored in the liver.

Metabolism Converted to active coenzyme forms, methylcobalamin and adenosylcobalamin.

Elimination Primarily renal excretion. Half-life is about 6 days (but can range from 3-10 days).

Drug interactions

Chloramphenicol: can delay or interrupt the response to mecobalamin in the treatment of pernicious anemia.

Colchicine, Metformin, Extended-release Potassium products: These can decrease the absorption of vitamin B12 in the gastrointestinal tract.

Side effects

Common (more than 10%) Generally, it's well tolerated

Less common (1-10%) Rash, itching, headache

Rare but serious (less than 1%) Anaphylactic shock and pulmonary edema

Patient educations

- Inform your doctor if you experience any severe or persistent side effects.
- Do not self-medicate; take the medication as directed by a healthcare provider.

Medroxyprogesterone Acetate

ATC Code: G03AC06 Hormonal Contraceptives for Systemic Use (Progestogens).

Pregnancy category:

FDA A B C D **X** N

TGA A B1 B2 B3 C **D** X N

Lactation: Medroxyprogesterone acetate is not recommended during lactation due to potential adverse effects on the infant.

Indications and Dosage

Contraception: Intramuscular injection: 150 mg once every 3 months (13 weeks) in the gluteal or deltoid muscle.

Off-label uses

No data available.

Contraindications

Hypersensitivity to medroxyprogesterone acetate or any component of the formulation, known or suspected pregnancy, history of thromboembolic disorders, liver dysfunction, undiagnosed vaginal bleeding, and breast cancer (current or past).

Cautions

History of depression, migraine, epilepsy, asthma, cardiovascular disease, D.M, or renal impairment.

Dose adjustment in renal failure: Not studied, caution is advised, and monitoring may be necessary.

Dose adjustment in hepatic failure: Contraindicated in liver impairment or disease.

Dosage forms and trade names available in Iraq

Medroxyprogesterone acetate 150 mg/1 ml vial **Depo-Provera** (Pfizer Belgium).

Pharmacokinetic parameters

Absorption Medroxyprogesterone acetate is well absorbed after intramuscular injection.

Distribution Protein bound: ~90%, Vd: Oral (single dose): 78,024 L (2 x 10-mg doses); 62,748 L (8 x 2.5-mg doses), AND Oral (multiple doses): 40,654 ng/mL (10-mg dose).

Metabolism MPA (oral) is extensively metabolized in the liver via hydroxylation, with subsequent conjugation and elimination in the urine.

Elimination it is primarily excreted in urine and feces; elimination half-life is about 12-50 hours.

Drug interactions

• Concurrent use with antibiotics (such as rifampicin) may decrease the effectiveness of medroxyprogesterone acetate, potentially leading to breakthrough bleeding or contraceptive failure.

• Concurrent use with antiepileptic drugs (such as phenytoin or carbamazepine) may decrease medroxyprogesterone acetate levels, reducing its efficacy.

Side effects

Common (more than 10%): metrorrhagia, amenorrhea, headache, breast tenderness, weight changes.

Less common (1-10%): Mood changes, abdominal discomfort, nausea, acne, Urinary tract infections

Rare but serious (less than 1%): Thromboembolic disorders (DVT or pulmonary embolism), breast cancer, ovarian cysts.

Patient educations

Report any unusual or persistent side effects to your healthcare provider, especially changes in menstrual bleeding patterns or mood disturbances.

Mefenamic Acid

ATC Code: M01AG01 Antiinflammatory and Antirheumatic Products (Fenamates)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Acute pain: 500mg once daily, then 250mg qid or prn usually not to exceed 7 days.
• Primary dysmenorrhea: 500mg once daily, then 250mg qid or prn usually not to exceed 3 days.

Off-label uses

None.

Contraindications

Hypersensitivity to mefenamic acid; Patients with active or history of recurrent peptic ulcer or hemorrhage; History of asthma.

Cautions

Hypertension; Hyperlipidemia; Diabetes mellitus; Smoking; Dehydration; Debilitated patient; Elderly.
Dose adjustment in renal failure: Use of mefenamic acid in severe renal failure is contraindicated.
Dose adjustment in hepatic failure: Use of mefenamic acid in severe hepatic failure is contraindicated.

Dosage forms and trade names available in Iraq

- Mefenamic Acid 50mg/5ml susp
  MONSTAN (ALKINDI Iraq), **PoniPain** (Al-Mansour Iraq), **MEFEDAD** (WRC Iraq),
- Mefenamic Acid BP 250mg cap
  PIOSTAN (Pioneer Iraq), **Fenamic** (Pharma International Jordan).
- Mefenamic Acid BP 250mg tab
  Mefenadin (WRC Iraq).
- Mefenamic Acid 500 mg tab
  PONSTIDIN (SDI Iraq), **PIOSTAN** (Pioneer Iraq), **Mefenadin** (WRC Iraq).

Pharmacokinetic parameters

Absorption Mefenamic acid is rapidly absorbed after oral administration.
Distribution Vd=1.06L/kg, 90%protein bound.
Metabolism Mefenamic acid undergoes metabolism by CYP2C9 to 3-hydroxymethyl mefenamic acid.
Elimination Renal elimination is 66% with half-life of 2 hours.

Drug interactions

Captopril: Coadministration mefenamic acid and captopril may result in a significant decrease in renal function.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Anorexia; Constipation; Diarrhea; Flatulence; Gastritis; Gross bleeding/perforation; Nausea; Pyrosis; Steatorrhea; Upper GI ulcers.
Rare but serious (less than 1%) Acute interstitial nephritis has been associated with hematuria, proteinuria and nephrotic syndrome; Agranulocytosis; Bone marrow hypoplasia; Eosinophilia; Leukopenia; Pancytopenia; Renal failure (including papillary necrosis and acute interstitial nephritis); Thrombocytopenic purpura.

Patient educations

Take drug with food, do not take the drug longer than 1 week.

Meloxicam

ATC Code: M01AC06 Antiinflammatory and Antirheumatic Products (Oxicams)

Pregnancy category:
FDA A B **C** **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: No data available.

Indications and Dosage

Osteoarthritis: Mobic or Qmiiz: 7.5-15 mg PO qDay; not to exceed 15 mg/day. OR Vivlodex: Start with 5 mg PO qDay; if needed, may increase to 10 mg/day. Use the lowest effective dose for shortest duration consistent with individual patient treatment goals.

Rheumatoid Arthritis: Mobic or Qmiiz: 7.5-15 mg PO qDay; not to exceed 15 mg/day.

Moderate-to-Severe Pain: alone or in combination with non-NSAID analgesics: Anjeso: 30 mg IV qDay

Dosage forms and trade names available in Iraq

- Meloxicam 15 mg/1.5ml amp
- Meloxicam 15mg suppository
- Meloxicam 15mg tab
  MOVINEER (Pioneer Iraq).
- Meloxicam 7.5mg tab
  MOVINEER (Pioneer Iraq).

Off-label uses

None.

Contraindications

Hypersensitivity to meloxicam;History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs;Perioperative pain management in the setting of (CABG) surgery;renal insufficiency in patients at risk for renal failure.

M

Cautions

Bleeding disorders; GI or cardiac disorders; Peptic ulcer; Elderly patients. Renal toxicity and hyperkalemia

Dose adjustment in renal failure: CrCl less than 15ml/min: Avoid.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=89%, food has minimal effect on absorption.

Distribution Vd: ~10 L , 99.4% protein bound.

Metabolism Hepatic metabolism.

Elimination 15-20 hr (PO); 24 hr (IV). Plasma clearance: 7-9 mL/min

Drug interactions

Metformin: Meloxicam may enhance the adverse effect of metformin.

Warfarin/Clopidogrel: it may increase the effect of Anticoagulants and antiplatelets and leads to severe bleeding.

Cyclosporine: Concomitant use of MOBIC and cyclosporine may increase cyclosporine's nephrotoxicity.

Side effects

Common (more than 10%) Nausea;Indigestion or heartburn;Abdominal pain or discomfort;Diarrhea; Dizziness; Headache; edema.

Less common (1-10%) Anemia; Angina; Constipation;Dizziness; GIT perforation,bleeding or ulcers; Hepatitis;Nausea; Upper respiratory infection; Vomiting.

Rare (less than 1%) Angioedema;Bronchospasm;Cerebrovascular accident;Hearing loss; Liver failure; Renal failure;Stevens-Johnson syndrome;Toxic epidermal necrolysis.

Melphalan

ATC Code: L01AA03 Antineoplastic Agents (Nitrogen Mustard Analogues)

Pregnancy category:
FDA A B C D X **N**
TGA A B1 B2 B3 C **D** X N

Lactation: Not recommended for use while breastfeeding

Dosage forms and trade names available in Iraq

- Melphalan 2mg tablets
  Alkeran (Aspen Germany).

Indications and Dosage

• Multiple Myeloma: 6 mg every day for 2-3 weeks, after adequate recovery from toxicity (monitor WBCs and platelets) give 1-3 mg or 0.05 mg/kg every day.
• Ovarian Cancer :0.2 mg/kg/day for 5 days; repeat every 4-5weeks depending on hematologic tolerance.

Off-label uses

Other types of cancers.

Contraindications

Hypersensitivity to melphalan or any component of the formulation.

Cautions

In patients with bone marrow suppression and renal impairment.
Dose adjustment in renal failure: Dose adjustments may be necessary
Dose adjustment in hepatic failure: Specific guidelines are not available.

Pharmacokinetic parameters

Absorption Oral bioavailability varies widely (25-89%)
Distribution Vd= ~0.5 L/kg, ~30-60% protein bound.
Metabolism Hepatic; converted to active metabolites
Elimination Kidney; t1/2: ~90 minutes

Drug interaction

Live vaccines: Enhanced toxicity of live vaccines.
CYP2B6 Substrates: Melphalan may increase the serum concentration of CYP2B6 Substrates.

Side effects

Common (more than 10%): Nausea; vomiting; diarrhea; mouth sores.
Less common (1-10%): Allergic reactions; skin rash; hair loss.
Rare but serious (less than 1%): Secondary malignancies; severe bone marrow suppression.

Patient education

• This medication can lower your body's ability to fight infections. Stay away from people who are sick and wash your hands regularly.
• Notify your healthcare provider if you experience unusual bleeding or bruising, mouth sores, persistent diarrhea, or signs of infection.
• It's important not to become pregnant or father a child while on this medication due to potential harm to the baby. Use effective contraception.

Memantine

ATC Code: N06DX01 Psychoanaleptics (Anti-Dementia Drugs)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Alzheimer disease: Initially, 5mg daily, (max 10mg bid).

Off-label uses

Treatment of mild to moderate vascular dementia.

Contraindications

Hypersensitivity to memantine or components of the formulation.

Cautions

Cardiovascular disease; Seizure disorder; Genitourinary conditions that increase pH.

Dose adjustment in renal failure: CrCl less than 30ml/min: 5mg bid.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Memantine Hcl 10mg tab

Pharmacokinetic parameters

Absorption F=100%, food has no effect on absorption.

Distribution Vd=9-11L, 45% protein bound.

Metabolism Hepatic metabolism which minimally active metabolites.

Elimination Renal elimination is 50% with a half-life of 60-80 hr.

Drug interactions

Alkalinizing agents: Alkalinizing agents may increase the serum concentration of memantine.

Carbonic anhydrase inhibitors: Carbonic anhydrase inhibitors may increase the serum concentration of memantine.

Trimethoprim: Trimethoprim may enhance the adverse effect of memantine, the risk of myoclonus and delirium may be increased. trimethoprim may increase the serum concentration of memantine.

Side effects

Common (more than 10%) None.

Less common (1-10%) Backache; Confusion; Constipation; Cough; Dizziness; Dyspnea; Fatigue; Headache; Hypertension; Pain; Somnolence; Syncope; Vomiting.

Rare (less than 1%) Acute renal failure; Cerebral infarction; Cerebrovascular accident; Deep venous thrombosis; Hepatitis, liver failure; Intracranial hemorrhage; Neuroleptic malignant syndrome; Seizure; Stevens-Johnson syndrome; Transient ischemic attack.

Patient educations

Tell patient may take with or without food; Instruct patient or caregiver not to mix solution with other liquids and to take or give oral solution only with included dosing device; Make sure patient or caregiver understands dose escalation.

PHARMALYS LABORATORIES

Nutrimilk

نوتريميلك

3

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SWISS ORIGIN

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Menotrophin

ATC Code: G03GA02 Sex Hormones and Modulators of The Genital System (Gonadotropins)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Information is not available.

Indications and Dosage

• Ovulation Induction: 150 IU i.m./s.c. for 5 days.
• Spermatogenesis: 75 IU s.c./i.m. 3 times/week for at least 4 months.

Off-label uses

None.

Contraindications

Hypersensitivity to menotrophin or other components, high levels of prolactin in the blood, uncontrolled thyroid or adrenal dysfunction, organic intracranial lesion, Sex hormone dependent tumors of the reproductive tract and accessory organ, Tumors of pituitary gland or hypothalamus, Abnormal uterine bleeding of undetermined origin, Ovarian cysts or enlargement of undetermined origin, not due to polycystic ovary syndrome

Dosage forms and trade names available in Iraq

Menotrophin (HMG) 75IU Vial

Cautions

In women with a history of blood clots, stroke, or certain heart diseases.
Dose adjustment in renal failure: Specific guidelines not available.
Dose adjustment in hepatic failure: Specific guidelines not available.

Pharmacokinetic parameters

Absorption Variable (after IM or SC injection)
Distribution, metabolism, and elimination: Information is not well established.

Drug interaction

Gonadotropin-releasing hormone (GnRH) agonists: Co-administration can stimulate follicular development.
Clomiphene: Concurrent use may enhance the effectiveness of each drug.

Side effects

Common (more than 10%) Headache; abdominal pain; Nausea; OHSS (dose related); injection site reactions.
Less common (1-10%) Flushing, Dizziness, Malaise, Migraine, Breast tenderness Hot flashes, Menstrual irregularities, Abdominal cramping/fullness, Constipation, Diarrhea, Ovarian disease
Rare but serious (less than 1%) Ovarian hyperstimulation syndrome; multiple pregnancies; thromboembolic events.

Patient education

• Monitor your health and report any adverse effects to your healthcare provider immediately.
• Follow your healthcare provider‘s instructions on how to administer this medication.

Mercaptopurine

ATC Code: L01BB02 Antineoplastic Agents (Purine Analogues).

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: It's not recommended to breastfeeding while taking mercaptopurine

Dosage forms and trade names available in Iraq

- Mercaptopurine 50mg tablets
  Puri-Nethol (Aspen Pharma Ireland).

Indications and Dosage

Acute Lymphatic Leukemia: 2.5 mg/kg orally every day; usually 100-200 mg every day in average adult, may increase by 5 mg/kg/day after 4 weeks, maintenance 1.5-2.5 mg/kg every day.

Off-label uses

Crohn disease; Ulcerative colitis; Histiocytosis X.

Contraindications

In patients with a hypersensitivity to mercaptopurine or any component of the formulation.

Cautions

Patients should be monitored for bone marrow suppression; liver toxicity, and infections due to immunosuppression and do not have any immunizations (vaccines) without your doctor's approval

Dose adjustment in renal failure: Reduce dose in renal impairment.

Dose adjustment in hepatic failure: Adjustments may be necessary.

Pharmacokinetic parameters

Absorption Bioavailability is about 50% due to first-pass metabolism.
Distribution Vd= ~0.9 L/kg, 19% protein bound.
Metabolism Hepatic; via TPMT, XO and HPRT enzymes.
Elimination Urine (46%, < 9% as unchanged drug); feces (~44%); half-life of 1.9 hours.

Drug interactions

Allopurinol: Allopurinol can increase mercaptopurine levels by inhibiting its metabolism, increasing toxicity risk. Dose adjustment of mercaptopurine is usually needed.
Warfarin: Mercaptopurine may increase the anticoagulant effect of warfarin and increasing the risk of bleeding.

Side effects

Common (more than 10%): Myelosuppression (leukopenia; anemia; thrombocytopenia); nausea; vomiting.
Less common (1-10%): Rash; liver enzyme elevations; oral ulcers.
Rare but serious (less than 1%): Hepatotoxicity; severe skin reactions; pancreatitis; secondary malignancies.

Patient education

1.This medication can lower your body's ability to fight infections. Avoid contact with people who are sick, and report any signs of infection to your healthcare provider.
2.Do not become pregnant or father a child while on this medication due to potential harm to the baby. Use effective contraception.
3.Report any unusual bleeding, bruising, tiredness, or symptoms of liver problems (such as yellowing of the skin or eyes, dark urine) to your healthcare provider. Take medication at around the same time every day

Meropenem

ATC Code: J01DH02 Antibacterials for Systemic Use (Carbapenems)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Skin infection, intraabdominal infections: By i.v. injection, 500mg-1g tid.
• Meningitis and concurrent bacteremia: By i.v. injection, 2g tid.

Off-label uses

Febrile neutropenia; Liver abscess; Otitis externa; Prosthetic joint infection.

Contraindications

Hypersensitivity to meropenem, patients who experienced anaphylactic reactions to other beta lactams.

Cautions

Seizures.
Dose adjustment in renal failure: CrCl 26-50ml per minute increase interval to every 12 hours; CrCl 10-25ml per minute decrease dosage to 50% of normal dose every 12 hours; CrCl less than 10ml per minute decrease dosage to 50% of normal dose every 24 hours.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Meropenem 1g vial
Meronem (Pfizer UK).
meropenem 500mg vial
Meronem (Pfizer UK).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=21L, 2%protein bound.
Metabolism Metabolized in the liver via hydrolysis into inactive form.
Elimination Renal elimination is 50-75% with half-life of 1 hours.

Drug interactions

Sodium valproate: Meropenem may decrease the serum concentration of valproate, concurrent use of meropenem with valproic acid is generally not recommended, alternative antimicrobial agents should be considered, but if a concurrent meropenem is necessary, consider additional anti-seizure medication.

Side effects

Common (more than 10%) None.
Less common (1-10%) Apnea; Bleeding; Constipation; Constipation; Diarrhea; Glossitis; Headache; Inflammation at injection site; Injection site reaction; Nausea; Phlebitis or thrombophlebitis; Pruritus; Rash; Sepsis; Oral moniliasis; Septic shock; Vomiting.
Rare but serious (less than 1%) Agranulocytosis; Angioedema; Drug reaction with eosinophilia and systemic symptoms (DRESS); Erythema multiforme; Hypokalemia; Leukopenia; Neutropenia; Pleural effusion; Stevens-Johnson syndrome; Toxic epidermal necrolysis.

Patient educations

Report persistent diarrhea, abdominal cramps, fever.

Mesalazine

ATC Code: A07EC02 Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents (Aminosalicylic Acid and Similar Agents)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding; Diarrhea reported in breast-fed infants.

Dosage forms and trade names available in Iraq

- Mesalazine 1gm/5g rectal Enema
- Mesalazine 500mg slow release tab
- Mesalazine 400mg tab
- Mesalazine 1g prolonged release Suppository

PENTASA (Ferring Switzerland).

Indications and Dosage

• Ulcerative colitis: 800mg-1000mg tid for 3-8 weeks.

• Remission maintenance of ulcerative colitis: 1g qid.

• Active ulcerative proctitis: Insert 500mg-1000mg suppository in rectum daily at bedtime.

• Distal ulcerative colitis, proctosigmoiditis, proctitis: Retention enema 100ml (1g) at bedtime.

• Children 6 years of age and older, depends on the child's weight. It is generally recommended that half the adult dose is given to children up to 40kg of body weight and the normal adult dose to children above 40kg of body weight.

Off-label uses

None.

Contraindications

Hypersensitivity to mesalazine, Patient allergic to other salicylates e.g. acetyl salicylic acid, patients have severe liver and/or kidney problems.

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Cautions

Myocarditis;Pericarditis;Active peptic ulceration;Do not give the tablets to children under 2 years of age.

Dose adjustment in renal failure: CrCl less than 20ml per minute, use of mesalazine is contraindicated.

Dose adjustment in hepatic failure: Use of mesalazine in severe hepatic failure is contraindicated.

Pharmacokinetic parameters

Absorption F=20-30%.

Distribution Vd=0.2L/kg, 43%protein bound.

Metabolism The primary metabolite of mesalazine (5-aminosalicylic acid) is predominantly N-acetyl-5-aminosalicylic acid.

Elimination Renal elimination is 8% with half-life of 7-12 hours.

Drug interactions

Heparin: Mesalazine may enhance the adverse effect of heparin, specifically, the risk for bleeding.

Side effects

Common (more than 10%) Headache;Abdominal pain;Diarrhea;Nausea;Indigestion;Acne;Fatigue.

Less common (1-10%) Vomiting; Flatulence; Rash; Itching; Fever

Rare but serious (less than 1%) Pancreatitis;agranulocytosis;aplastic anemia;Acute intolerance syndrome ;Hepatitis and other liver disorders;Myocarditis and pericarditis.

Patient educations

Tell patient to contact prescriber if partially intact tablets repeatedly appear in stools; Advise patient using suppository to avoid excessive handling and to retain suppository for 1 to 3 hours or longer for maximum benefit; Teach patient about proper enema administration; Tell him to stay in position for at least 30 minutes and, if possible, retain medication overnight. if the patient forget to take drug at time, If there is difficulty in swallowing, the patient can disperse the tablet in a small quantity of cold water (approximately 50 mL) then stir and drink immediately.

Mesna

ATC Code: V03AF01 All Other Therapeutic Products (Detoxifying Agents for Antineoplastic Treatment)

Pregnancy category:

FDA A B C D X **N**

TGA A **B1** B2 B3 C D X N

Lactation: Avoid; Taking into account the importance of the drug to the mother.

Indications and Dosage

• Prevention of hemorrhagic cystitis in patients receiving ifosfamide: By i.v. injection, 20% of ifosfamide dose at time of ifosfamide administration and 4 and 8 hours after each dose of ifosfamide, total dose 60% of ifosfamide dosage.

Off-label uses

Reduce incidence of cyclophosphamide induced hemorrhagic cystitis with high dose cyclophosphamide.

Contraindications

Hypersensitivity to mesna.

Cautions

Preexisting autoimmune disorders. as well as any history of hypersensitivity to thiol-containing compounds.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Mesna 100mg/ml (400mg/4ml) amp

MESNEER (Pioneer Iraq).

Pharmacokinetic parameters

Absorption F=58-89%.

Distribution Vd=0.652±0.242L/Kg, (69-75%) protein bound.

Metabolism Rapidly converted to mesna disulfide, then back to mesna in the kidneys where it binds to toxic metabolites of ifosfamide. Peak plasma time: 4 hr

Elimination Renal elimination is 18-26% with half-life of 0.36 hours.

Drug interactions

None.

Side effects

Common (more than 10%) Abdominal pain; Alopecia; Anemia; Anorexia; Asthenia; Constipation; Fatigue; Fever; Granulocytopenia; Leukopenia; Nausea; Thrombocytopenia; Vomiting.

Less common (1-10%) Anxiety; Back pain; Chest pain; Confusion; Cough; Dehydration; Diarrhea; Dizziness; Dyspnea; Edema; Flushing; Headache; Hematuria; Hypokalemia; Injection site reaction; Insomnia; Pain; Pallor; Pneumonia; Somnolence; Tachycardia.

Rare but serious (less than 1%) None.

Nursing considerations

Assess morning urine specimen for hematuria, if such occurs, dosage reduction or discontinuation may be necessary; Monitor daily pattern of bowel activity, stool consistency and record time of evacuation; Monitor blood pressure for hypotension; Report headache, myalgia, nausea.

Metformin

ATC Code: A10BA02 Drugs Used in Diabetes (Biguanides)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 **C** D X N

Lactation: No data available.

Indications and Dosage

• Diabetes mellitus (type 2): 500mg-1000mg bid, (max 2250mg daily).

Off-label uses

Polycystic ovarian syndrome; Gestational diabetes mellitus; Prevention of type 2 diabetes.

Contraindications

Hypersensitivity to metformin;Acute or chronic metabolic acidosis; DKA;Renal dysfunction;Heart failure requiring drug therapy;Septicemia;Shock.

Cautions

Alcohol intake ; Elderly.

Dose adjustment in renal failure: Contraindicated in patients with serum creatinine greater than 1.5mg/dL (males) or greater than 1.4mg/dL (females). Alternative Recommendation; CrCl 30-44ml/min: use cautiously; CrCl less than 30ml/min: Discontinue use.

Dose adjustment in hepatic failure: Avoid use (risk factor for lactic acidosis).

Dosage forms and trade names available in Iraq

- Metformin HCl 500mg tab
  Piophage (PIONEER IRAQ), **Metphage** (Al-Kindi Iraq).
- Metformin 500mg prolonged release tablets
  Glucophage® XR (Merck France).
- Metformin 750mg prolonged release tablets
  Glucophage® XR (Merck France).
- Metformin HCl 850 mg tab
  Metphage (Al-Kindi Iraq), **Piophage** (PIONEER IRAQ).
- Metformin HCl 1000 mg tab
  Piophage (PIONEER IRAQ).

Pharmacokinetic parameters

Absorption F=40-60%, food reduce absorption.
Distribution Vd=654L, not protein bound.
Metabolism Not metabolized.
Elimination Renal elimination is 90% with a half-life of 7-12 hr.

Drug interactions

Selegiline: Selegiline will increase the level or effect of metformin by unspecified interaction mechanism, avoid or use alternate drug.

Side effects

Common (more than 10%) GIT symptomes(diarrhea,nausea,abdominal pain);Metallic taste in mouth.
Less common (1-10%) Vomiting; Loss of appetite;Heartburn;Bloating/gas;Constipation;Weight loss; Headache; Myalgia.
Rare but serious (less than 1%) Hypoglycemia;Lactic acidosis;Severe allergic reactions; Vitamin B12 deficiency.

Patient educations

Report immediately if evidence of lactic acidosis appears (unexplained hyperventilation, muscle aches, extreme fatigue, unusual drowsiness); Prescribed diet is principal part of treatment, do not skip or delay meals; Diabetes requires lifelong control; Avoid alcohol; Do not take dose for at least 48 hours after receiving i.v. contrast dye with radiologic testing. Patients should be informed of the potential risks and benefits of Metformin hydrochloride extended-release tablets and of alternative modes of therapy. regular testing of blood glucose, glycosylated hemoglobin, renal function, and hematologic parameters. Are important.

Methotrexate

ATC Code: L01BA01 Antineoplastic Agents (Folic Acid Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Rheumatoid arthritis: Initially, 7.5mg once weekly or 2.5 mg every12 hours for 3 doses once weekly.
• Psoriasis: Initially, 10mg–25mg once weekly or 2.5mg–5mg every 12 hours for 3 doses once weekly.

Off-label uses

Treatment of acute myelocytic leukemia; Bladder carcinoma; Ectopic pregnancy; Abortion; Systemic lupus erythematosus; Treatment of and maintenance of remission in Crohn's disease.

Contraindications

Hypersensitivity to methotrexate; Alcoholism; Immunodeficiency syndrome; Preexisting blood dyscrasias.

Dosage forms and trade names available in Iraq

Methotrexate 5000mg/50ml vial
Ebetrexat (Ebewe Austria).
Methotrexate 50mg (10mg/ml) 5ml vial
Methotrexate" Ebewe„ (Ebewe AUSTERIA).
Methotrexate 500 mg/5ml vial
METHOTREXAT EBEWE (Ebewe Austria).
methotrexate 50mg\ml PFS
Metoject (Medac Germany).
Methotrexate 2.5mg tablet
METHOTREXAT EBEWE (Ebewe Austria).

Cautions

Peptic ulcer; Ulcerative colitis; Preexisting myelosuppression; History of chronic hepatic disease; Alcohol consumption; Obesity; Diabetes; Hyperlipidemia; Significant pleural effusion.

Dose adjustment in renal failure: CrCl 50-60ml per minute reduce dose to 70% of normal dose; CrCl 10-50ml per minute reduce dose to 50% of normal dose; CrCl less than 10ml per minute avoid use.

Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=64-90%.

Distribution Vd=1L/kg, 46.5-54%protein bound.

Metabolism Methotrexate is metabolized by folylpolyglutamate synthase to methotrexate polyglutamate in the liver as well as in tissues.

Elimination Excreted unchanged by kidney with half-life of 3-15 hours.

Drug interactions

Aspirin, Diclofenac, Ibuprofen, Naproxen: increase risk of methotrexate toxicity.

Side effects

Common (more than 10%) Anorexia; Azotemia; Diarrhea; Gingivitis; Glossitis; Hyperuricemia; Intestinal perforation; Leukopenia; Nephropathy; Pharyngitis; Thrombocytopenia; Ulcerative stomatitis.

Less common (1-10%) Abdominal distress; Alopecia; Chills; Fatigue; Fever; Gastrointestinal hemorrhage; Malaise; Photosensitivity.

Rare but serious (less than 1%) None.

Patient educations

Maintain strict oral hygiene; Avoid alcohol; Avoid ultraviolet sunlight exposure.

Note

Folinic acid following methotrexate administration helps to prevent methotrexate induced myelosuppression.

Methyldopa

ATC Code: C02AB01 Antihypertensives (Antiadrenergic Agents, Centrally Acting)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• **Moderate to severe hypertension:** Initially, 250mg bid or tid for 2 days, adjust dosage at intervals of 2 days, (max 3g daily).

Off-label uses

None.

Contraindications

Hypersensitivity to methyldopa; Hepatic disease; Pheochromocytoma.

Cautions

Hemolytic anemia; Liver disease; Depression; Parkinsonism; Hepatic porphyria. Not intended for the treatment of pheochromocytoma.

Dose adjustment in renal failure: CrCl 10-50ml per minute increase interval to every 12 hours; CrCl less than 10ml per minute increase interval to every 24 hours.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Methyldopa 250mg tab
ALDOSAM (SDI Iraq), **Dumet** (Dubai Iraq).

Pharmacokinetic parameters

Absorption F=50%.
Distribution Vd=0.6 L/kg, 15%protein bound.
Metabolism Partially metabolized by the liver.
Elimination Renal elimination is 70% with half-life of 1.7 hours.

Drug interactions

Fluphenazine: Fluphenazine decreases effects of methyldopa by pharmacodynamic antagonism.
Prochlorperazine: Prochlorperazine decreases effects of methyldopa by pharmacodynamic antagonism.
Risperidone: Risperidone decreases effects of methyldopa by pharmacodynamic antagonism.

Side effects

Angina; Arthralgia; Autoimmune disease; Bradycardia; Depression; Dizziness; Dry mouth; Gynecomastia; Hemolytic anemia; Impotence; Lethargy; Liver toxicity; Lupus-like syndrome; Nausea; Orthostatic hypotension; Rash; Sedation; Thrombocytopenia; Vomiting.

Patient educations

Tell patient not to stop taking drug abruptly; Inform patient that urine may darken after exposure to air; Advise patient to move slowly when changing position, to avoid dizziness from sudden blood pressure decrease; Caution patient to avoid driving and other hazardous activities until effects of drug are known or dosage titration is completed.

Methylergometrine

ATC Code: G02AB01 Genito Urinary System and Sex Hormones (Ergot Alkaloids)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Avoid; breastfeeding discontinue 12 hours after the last dose.

Indications and Dosage

• Prophylaxis and treatment of postpartum hemorrhage: By i.v. or i.m. injection, 200mcg every 2-4 hours or prn, not to exceed 5 doses.

Off-label uses

Treatment of incomplete abortion.

Contraindications

Hypersensitivity to methylergometrine; Toxemia; Hypertension.

Cautions

Sepsis; Coronary artery disease; Obliterative vascular disease; Use during the second stage of labour.
Dose adjustment in renal failure: Use with caution.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=78%.
Distribution Vd=39-73L.
Metabolism Probably metabolized by the liver.
Elimination Half-life is 3.39 hours.

Dosage forms and trade names available in Iraq

Methylergometrine maleate 200mcg/1ml Amp
Gynogene (pioneer Iraq).

Drug interactions

Itraconazole: Itraconazole may increase the serum concentration of methylergometrine, avoid combination.
Macrolide antibiotics: Macrolide antibiotics (such as erythromycin and clarithromycin) may increase the serum concentration of ergot derivatives, avoid combination.
Isosorbide: Isosorbide increases effects of methylergometrine by decreasing metabolism, risk of increased blood pressure, angina pectoris.

Side effects

Common (more than 10%) Hypertension -Abdominal pain or cramps; Diarrhea; Dizziness; Foul taste-Hallucinations; Leg cramps; Nasal congestion; Tinnitus
Less common (1-10%) Headache; Nausea or vomiting; Diarrhea; Diaphoresis; Dyspnea; Hematuria Thrombophlebitis
Rare but serious (less than 1%) Severe allergic reactions, including skin rash, itching or hives, swelling of the face, lips, or tongue; Myocardial ischemia or infarction (blockage of blood flow to the heart muscle)-Seizures-Pulmonary edema

Patient educations

Avoid smoking, causes increased vasoconstriction; Report increased cramping, bleeding, foul-smelling lochia; Report pale, cold hands and feet (possibility of diminished circulation); Methylergometrine should not be needed for longer than 1 week.

Methylphenidate

ATC Code: N06BA04 Psychoanaleptics (Centrally Acting Sympathomimetics).

Pregnancy category:
FDA A B C D X **N**
TGA A B1 B2 B3 C **D** X N

Lactation: There is no data.

Dosage forms and trade names available in Iraq

- Methylphenidate Hydrochloride 10mg tablet
  Rubifen (Rubio Spain).

Indications and Dosage

Methylphenidate is indicated for the treatment of ADHD in pediatric patients aged 6 and older and adults, and for the treatment of narcolepsy. The typical dose for ADHD in children is 5 mg twice daily before breakfast and lunch, then increase by 5 to 10 mg a week until optimal response is achieved. Maximum dose is usually 60 mg per day.

Off-label uses

Treatment of depression, treatment-resistant cases of bipolar disorder, and to reduce opioid withdrawal symptoms.

Contraindications

Hypersensitivity to methylphenidate or other components of the product, glaucoma, motor tics or family history or diagnosis of Tourette's syndrome, and during or within 14 days following the administration of monoamine oxidase inhibitors (MAOIs).

Cautions

Include risk of dependence, potential for exacerbating psychiatric conditions, possible cardiovascular events, and circulation problems in fingers and toes.

Dose adjustment in renal failure: There is no specific guidance, but given its metabolism, dose adjustments may not be necessary.

Dose adjustment in hepatic failure: There is no specific guidance, but given its metabolism, dose adjustments may not be necessary.

Pharmacokinetic parameters

Absorption Bioavailability is approximately 30% for the immediate release tablet.

Distribution Vd= 20L/kg, 15-33% protein bound.

Metabolism Primarily hepatic, by de-esterification.

Elimination Renal excretion with a half-life of 2-3 hours.

Drug interactions

MAOIs: Can lead to hypertensive crisis if taken together with methylphenidate.

Antihypertensives: Methylphenidate may decrease the effectiveness of medications taken for high blood pressure.

Side effects

Common (more than 10%): Nervousness, insomnia; decreased appetite; weight loss; stomach pain.

Less common (1-10%): Dizziness; palpitations; headache.

Rare but serious (less than 1%): Severe hypertension; heart attack; stroke; drug dependence; serious psychiatric symptoms.

Patient education

1. This medication can be habit-forming, so use it exactly as directed by your doctor.
2. Inform your doctor of any heart conditions or high blood pressure before starting this medication.
3. Report any new or worsening mental symptoms or problems to your healthcare provider.

Methylprednisolone

ATC Code: H02AB04 Corticosteroids for Systemic Use (Glucocorticoids)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Breastfeeding discontinue 8 hours after the last dose.

Indications and Dosage

● Anti-Inflammatory, immunosuppressive: By i.m. injection methylprednisolone acetate, 40mg-80mg as a single dose. By i.m. injection methylprednisolone succinate, 125mg-500mg once daily.

Off-label uses

Acute spinal cord injury.

Contraindications

Hypersensitivity to methylprednisolone; Systemic fungal infection; Administration of live or attenuated virus vaccines; Idiopathic thrombocytopenia purpura.

Cautions

Respiratory tuberculosis; Untreated systemic infections; Hypertension; Heart failure; Diabetes; Peptic ulcer; Seizures; Cataracts; Glaucoma; Psychiatric conditions; Osteoporosis.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Methylprednisolone 40mg/ml vial
DEPO-MEDROL (PFIZER Belgium).

Methylprednisolone 125mg/2ml vial
SOLU-MEDROL (PFIZER Belgium).

Pharmacokinetic parameters

Absorption Slowly absorbed following deep i.m. injection.

Distribution Vd=1.38L/kg, 76.8% protein bound.

Metabolism The metabolism of methylprednisolone is thought to be mostly mediated by 11beta-hydroxysteroid dehydrogenases and 20-ketosteroid reductases.

Elimination Renal elimination is 25-31% with half-life of 3.5 hours.

Drug interactions

Clarithromycin: clarithromycin will increase the level or effect of methylprednisolone by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Acne; Adrenal suppression; Amenorrhea; Delayed wound healing; Erythema; Fluid retention; Glucose intolerance; Hallucinations; Headache; Hepatitis; Hepatomegaly; Peptic ulcer; Perianal pruritus; Pituitary adrenal axis suppression; Psychosis; Seizure; Sodium and water retention; Tachycardia; Urticaria; Vasculitis; Vertigo; Weight gain.

Patient educations

Do not change dose/schedule or stop taking drug, must taper off gradually under medical supervision; Maintain strict personal hygiene, avoid exposure to disease, trauma; Severe stress (serious infection, surgery, trauma) may require increased dosage; Children must be assessed for growth retardation.

Metoclopramide

ATC Code: A03FA01 Drugs for Functional Gastrointestinal Disorders (Propulsives)

Pregnancy category:
FDA A **B** C D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Treat nausea and vomiting in patients with Diabetic gastroparesis: 10mg 30 min before meals and at bed time for 2-8 weeks.
• Treat nausea and vomiting in patients with gastroesophageal reflux disease: 10mg-15mg qid 30 min before meals and at bed time.
• Control nausea and vomiting associated with chemotherapy: By i.v. infusion over at least 30 min before chemotherapy, 2mg/kg then repeated every 2 hr after initial dose.

Off-label uses

Decrease lactation; Hiccups; Postoperative nausea and vomiting.

Contraindications

Hypersensitivity to metoclopramide; Situations in which GI motility may be dangerous (such as GI hemorrhage, GI perforation or obstruction); History of seizure disorder; Pheochromocytoma.

Dosage forms and trade names available in Iraq

- Metoclopramide 5mg/ml (2ml amp)
  Metocol (Pioneer Iraq), **Elitan** (Medochemie Cyprus), **Metamid** (Ibn Hayan Syria), Etc.
- Metoclopramide Hcl 4mg/ml oral drop
  Meclodin (SDI Iraq).
- Metoclopramide Hcl 5mg/5ml Syrup
  Meclokindin (Alkindi Iraq).
- Metoclopramide 5 mg tablet
  Mecloden–H (Hukamaa Iraq).
- Metoclopramide 10mg tab
  Meclodin (SDI Iraq), **Clopram** (A.P.M Jordan), **Premosan** (Julphar UAE), Etc.

Cautions

Heart failure; Cirrhosis; Hypertension; Depression; Parkinson's disease; Elderly.
Dose adjustment in renal failure: CrCl 10-50ml/min: reduce dose by 25%; CrCl less than 10ml/min: reduce dose by 50%.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=80%, food has minimal effect on absorption.
Distribution Vd=3.5L/kg, 30% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 75-80% with half-life of 5-6 hr.

Drug interactions

Citalopram: Metoclopramide and citalopram both increase serotonin levels, increased risk for serotonin syndrome, neuroleptic malignant syndrome, dystonia, or other extrapyramidal reactions.

Side effects

Common (more than 10%) Extrapyramidal symptoms.
Less common (1-10%) Dizziness; Fatigue; Headache; Restlessness; Sedation; Somnolence.
Rare (less than 1%) None.

Patient educations

Tell patient to take 30 minutes before meals; Instruct patient to report involuntary movements of face, eyes, or limbs, muscle rigidity; Caution patient to avoid driving and other hazardous activities until drug's effects are known.

Cephalosporine Line By Pioneer

Forpime

Cefepime

IV	2 g
IV	1 g
IM / IV	500 mg

Pioxone

Ceftriaxone

IM	1 g
IV	1 g
IM / IV	500 mg

Piocefix

Cefixime (as Trihydrate)

100 mg
200 mg
400 mg

PIONEER CO.
FOR PHARMACEUTICAL INDUSTRIES

Metoprolol

ATC Code: C07AB02 Beta Blocking Agents (Beta Blocking Agents, Selective)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Angina: 50mg bid, maintenance 100mg-400mg daily.
• Heart failure: 25mg daily, (max 200mg daily).
• Hypertension: 50mg bid, maintenance 450mg daily in 2-3 divided doses.
• Acute myocardial infarction: By i.v. injection, 5mg every 2 min up to 3 doses then 50mg 15 min after last i.v. and 50mg every 6 hours for 48 hours then 50mg-100mg every 12 hours.

Off-label uses

Treatment of ventricular arrhythmias; Migraine prophylaxis; Essential tremor; Aggressive behavior; Prevent reinfarction post myocardial infarction; Prevent and treat atrial fibrillation and atrial flutter; Hypertrophic cardiomyopathy; Thyrotoxicosis.

Dosage forms and trade names available in Iraq

- Metoprolol succinate 25mg Tablet
  Betaloc zok (Astra Zenca Sweden).
- Metoprolol succinate 50 mg Tablet
- Metoprolol succinate 100 mg Tablet
- Metoprolol tartarate 50 mg Tablet
- Metoprolol tartarate 100mg Tablet
- Metoprolol tartrate 5mg/5ml injection
  Betaloc (Astra Zenca Sweden).

Contraindications

Hypersensitivity to metoprolol; Second and third degree heart block; Cardiogenic shock; Bradycardia; Systolic blood pressure below 100mmHg; Sick sinus syndrome.

Cautions

Pulmonary disease; Diabetes mellitus; Thyrotoxicosis.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=65-70%, food increase Cmax and AUC.
Distribution Vd=3-5L, 12% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 95% with half-life of 3-7 hours.

Drug interactions

Duloxetine: Metoprolol may enhance the hypotensive effect of duloxetine.

Side effects

Common (more than 10%) None.
Less common (1-10%) Bradycardia; Bronchospasm; Cold extremities; Constipation; Depression; Diarrhea; Dizziness; Dyspepsia; Dyspnea; Flatulence; Headache; Heart failure; Heartburn; Hypotension; Nausea; Pruritus; Rash; Tiredness; Wheezing; Xerostomia.
Rare (less than 1%) None.

Patient educations

Advise patient to take with or immediately after meals; Tell patient that extended-release tablets are scored and can be divided, but that he should swallow tablets or half-tablets whole and not crush or chew them; Instruct patient to notify health care providers (including dentists) that he is taking drug before having surgery.

Metronidazole

ATC Code: J01XD01 Antibacterials For Systemic Use (Imidazole Derivatives)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation: Avoid.

Indications and Dosage

- Anaerobic abscess: 7.5mg/kg qid, (max 4g daily).
- Acute amebic dysentery: 750mg tid for 5-10 day.
- Bacterial vaginosis: 250mg tid for 7 days.
- Trichomoniasis: 2g single dose.

Off-label uses

Crohn's disease; Urethritis; Antibiotic associated pseudomembranous colitis caused by C. difficile.

Contraindications

Hypersensitivity to metronidazole; Pregnancy (first trimester with trichomoniasis); Use of alcohol during therapy or within 3 days of discontinuing.

Cautions

Blood dyscrasias; Seizure disorder; Heart failure; Sodium retaining states; Elderly.

Dose adjustment in renal failure: CrCl less than 10ml/min: reduce dose by 50%.

Dose adjustment in hepatic failure: Reduce dose by 50%.

Dosage forms and trade names available in Iraq

- Metronidazole 0.75% gel
- Metronidazole 200mg tab
- Metronidazole 200mg/5ml Susp.
- Metronidazole 250mg tab
- Metronidazole 500mg suppository
- Metronidazole 500mg tab
- Metronidazole 500mg vaginal ovules
- Metronidazole 500mg/100ml infusion

Pharmacokinetic parameters

Absorption F=80%.

Distribution Widely distributed in the body.

Metabolism Hepatic metabolism.

Elimination Renal elimination is 60-80% with half-life of 8 hr.

Drug interactions

Cimetidine: Metronidazole metabolism inhibited by cimetidine.

Warfarin: Metronidazole enhances anticoagulant effect of warfarin.

Side effects

Appetite loss; Aseptic meningitis; Ataxia; Candidiasis; Dark urine; Decreased libido; Diarrhea; Disulfiram-type reaction with ethanol; Dizziness; Encephalopathy; Furry tongue; Headache; Hypersensitivity; Metallic taste; Nausea; Neuropathy; Neutropenia; Optic neuropathy; Pancreatitis; Seizures; Stevens-Johnson syndrome; Thrombocytopenia; Thrombophlebitis; Toxic epidermal necrolysis; Vomiting; Xerostomia.

Patient educations

Advise patient to take drug with food if it causes gastrointestinal upset; Tell patient with trichomoniasis to refrain from sexual intercourse or to have male partner wear a condom to prevent reinfection. Inform patients that the drug may cause metallic taste and may discolor urine deep brownish red.

Micafungin

ATC Code: J02AX05 Antimycotics for Systemic Use (Other Antimycotics for Systemic Use)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: It is unknown

Dosage forms and trade names available in Iraq

Micafungin as sodium 50mg vial
Mycamine (Astellas pharm Japan).

Indications and Dosage

For treatment of esophageal candidiasis, the recommended dosage is 150 mg/day. For prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantation, the recommended dosage is 50 mg/day. Dosages may vary based on the specific patient and the condition being treated.

Off-label uses

Treatment of invasive aspergillosis and candida infections in pediatric patients.

Contraindications

In patients with known hypersensitivity to micafungin, any component of micafungin, or other echinocandins.

Cautions

Hypersensitivity reactions. Hepatic reactions, including abnormalities in liver function tests, hepatitis and hepatic failure, have been reported.
Dose adjustment in renal failure: Not required
Dose adjustment in hepatic failure: No specific adjustment is recommended for patients with mild, moderate, or severe hepatic insufficiency. However, increased monitoring should be considered.

Pharmacokinetic parameters

Absorption Micafungin is given intravenously; bioavailability is presumed to be 100%.
Distribution Vd= ~0.3 L/kg, 99.8% protein bound.
Metabolism Metabolized in the liver, primarily via arylsulfatase and catechol-O-methyltransferase.
Elimination Predominantly fecal excretion, with a half-life of ~14 hours.

Drug interactions

Sirolimus: Micafungin may increase the blood concentration of sirolimus. Monitor therapy.
Nifedipine: Micafungin may enhance the anti-hypertensive effect of nifedipine. Monitor therapy.

Side effects

Common (more than 10%) Diarrhea, nausea, vomiting, thrombocytopenia, and anemia.
Less common (1-10%) Headache, rash, pruritus.
Rare but serious (less than 1%) Hepatic dysfunction, severe hypersensitivity reactions.

Patient education

• Report any signs of allergic reaction, like rash or difficulty breathing, immediately to your healthcare provider.
• Regular blood tests may be needed to monitor your body‘s response to micafungin.

Miconazole

ATC Code: J02AB01 Antimycotics for Systemic Use (Imidazole Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Miconazole 20mg/1g oral gel
  Miconadain (Wadi Al-Rafidain Iraq).
- Miconazole nitrate 20mg/1g 2% Vag. Cream
- Miconazole nitrate 200mg vag. Ovules
- Miconazole nitrate 400mg Vag. Supp
  MICOZOL (SDI Iraq).

Indications and Dosage

• Vulvovaginal candidiasis: One 400mg vaginal suppository at bedtime for 3 days, or one 200mg vaginal suppository or one applicatorful at bedtime for 7 days.
• Topical fungal infections, cutaneous candidiasis: Apply cream to the affected area bid for 2-4 weeks.
• Oral thrush: Apply oral gel once daily or bid for 14 days.

Off-label uses

None.

Contraindications

Hypersensitivity to miconazole; Children younger than 2 years old.

Cautions

Do not use with tampons, douches and spermicide; Used with caution in hepatic failure.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption Miconazole absorption through intact skin is minimal.
Distribution Vd=10-911L.
Metabolism Miconazole is metabolized in the liver.
Elimination Renal elimination is 1% with half-life of 24 hours.

Drug interactions

Progesterone intravaginal gel: Miconazole vaginal alter progesterone release.
Ergotamine: Miconazole vaginal will increase the level and effect of ergotamine by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Abdominal cramps; skin allergic reaction; vulvovaginal burning; itching and pain; serious allergic systemic reaction is rare (dizziness; dyspnea; swelling of face; tongue and throat).

Patient educations

Take the full course of drug therapy even if symptoms improve; Continue during menstrual period even if vaginal route is being used; Beneficial effects may not be seen for several weeks; Insert vaginal suppositories high into the vagina; Use hygiene measures to prevent reinfection or spread of infection; Refrain from sexual intercourse, or advise partner to use a condom to avoid reinfection, with vaginal form of drug, use a sanitary napkin to prevent staining of clothing.

Midazolam

ATC Code: N05CD08 Psycholeptics (Benzodiazepine Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; breastfeeding discontinue 24 hours after the last dose.

Dosage forms and trade names available in Iraq

Midazolam 15mg / 3ml Amp
ZONAM (Pioneer Iraq).

Indications and Dosage

• Preoperative sedation: By i.v. injection, 0.02mg–0.04mg/kg.
• Continuous sedation during mechanical ventilation: By i.v. injection, 0.01mg–0.05mg/kg (1mg–5mg in 70 kg adult), may repeat at 5-15 min intervals until adequate sedation achieved or continuous infusion rate of 0.02mg–0.1mg/kg/hr and titrated to desired effect.

Off-label uses

Anxiety; Status epilepticus.

Contraindications

Hypersensitivity to midazolam; Acute narrow angle glaucoma.

Cautions

Pulmonary impairment; Impaired gag reflex; Heart failure; Open angle glaucoma; Obese patients; Alcohol dependency; Elderly patients; Debilitated patients.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=90%, due to first pass metabolism.
Distribution Vd=1-3.1L/kg, 97%protein bound.
Metabolism Extensively metabolized in the liver by CYP3A isoenzyme to form 1-hyrdoxy-midazolam or α-hydroxymidazolam (active metabolite).
Elimination Renal elimination is 90% with half-life of 3 hours.

Drug interactions

Carbamazepine: Carbamazepine will decrease the level or effect of midazolam by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abnormal taste; Dysarthria; Headache; Lacrimation increased; Nasal discomfort; Rhinorrhea; Somnolence; Throat irritation.
Rare but serious (less than 1%) None.

Patient educations

Midazolam will help you to relax and will make you go to sleep; Avoid using alcohol.

Miglustat

ATC Code: A16AX06 Other Alimentary Tract and Metabolism Products (Various Alimentary Tract and Metabolism Products)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C **D** X N

Lactation: It is unknown

Indications and Dosage

• Gaucher disease type 1: 100 mg orally 3 times a day.

• Niemann-Pick disease type C: 200 mg orally 3 times a day.

Off-label uses

may include other lysosomal storage disorders.

Contraindications

In patients with known hypersensitivity to miglustat or any of its components.

Cautions

peripheral neuropathy, tremor, diarrhea, and weight loss.

Dose adjustment in renal failure: In patients with moderate and severe renal impairment, the dose should be reduced.

Dose adjustment in hepatic failure: No guidelines have been suggested, use with caution.

Dosage forms and trade names available in Iraq

Miglustat 100mg cap

Zavesca (Janssen Cilag Switzerland).

Pharmacokinetic parameters

Absorption Rapidly absorbed, peak plasma concentration within 2-3 hours.

Distribution Vd= 83-117 L, not significantly protein bound.

Metabolism Miglustat does not undergo significant metabolism.

Elimination Primarily renal excretion with a half-life of 6-7 hours.

Drug interaction

Imiglucerase: Concurrent use of miglustat and imiglucerase may reduce the efficacy of imiglucerase.

Zavesca: Use of Zavesca with food reduces the absorption of the drug.

Side effects

Common (more than 10%) Diarrhea, flatulence, abdominal pain, weight loss.

Less common (1-10%) Numbness, tingling, or pain in the hands or feet (peripheral neuropathy), tremors, fatigue.

Rare but serious (less than 1%) Serious skin reactions.

Patient educations

• Patients should take miglustat capsules whole and not split, chewed, or crushed.

• Patients should inform their healthcare provider of all current medications, as some may interact with miglustat.

• Report any unusual symptoms, particularly those related to the nervous system, such as tremors or numbness, to your healthcare provider.

Minocycline

ATC Code: J01AA08 Antibacterials for Systemic Use (Tetracyclines)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Breastfeeding while using this drug is not recommended.

Dosage forms and trade names available in Iraq

- minocycline 55 mg extended release tablet
- minocycline 80 mg extended release tablet
- minocycline 105 mg extended release tablet

Indications and Dosage

It's often used for the treatment of moderate to severe acne. The typical dose for this indication is 100-200 mg daily in two divided doses, depending on the severity of the condition. Doses for other bacterial infections may vary.

Off-label uses

Treatment of certain skin and soft tissue infections, and as a part of a multi-drug regimen for the treatment of Mycobacterium avium complex (MAC) disease.

Contraindications

In individuals with a history of hypersensitivity to any of the Tetracyclines.

Cautions

In individuals with impaired kidney function and in those with a history of idiopathic intracranial hypertension.

Dose adjustment in renal failure: Dosage adjustment is needed in patients with severe renal impairment.

Dose adjustment in hepatic failure: Minocycline should be used with caution in patients with hepatic dysfunction.

Pharmacokinetic parameters

Absorption Minocycline is well absorbed after oral administration. Food does not significantly affect the absorption.

Distribution It's widely distributed in the body, and it's about 76% bound to plasma proteins.

Metabolism Minocycline is metabolized in the liver but the degree of metabolism is not extensive.

Elimination It is eliminated primarily unchanged in the urine and feces, with a half-life of 11-22 hours.

Drug interaction

Antacids and Iron Salts: They can reduce the absorption of minocycline. These medications should be taken at least 2 hours before or after minocycline.

Warfarin: Minocycline may enhance the anticoagulant effect of warfarin. Monitor therapy.

Side effects

Common (more than 10%) Nausea, vomiting, diarrhea, discoloration of teeth if used in patients below 8 years old.

Less common (1-10%) Dizziness, discoloration of body fluids, photosensitivity, urticaria.

Rare but serious (less than 1%) Hepatotoxicity, Pseudotumor cerebri, hypersensitivity reactions.

Patient educations

• Minocycline should be taken on an empty stomach with a full glass of water.

• Avoid excessive sunlight and UV light exposure as minocycline can make the skin more sensitive leading to sunburns.

• Immediately report symptoms like a headache, blurred vision, or rash to your healthcare provider.

Minoxidil

ATC Code: D11AX01 Dermatological preparations

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Hair regrowth: 1 ml to affected areas of scalp bid, total daily dose not to exceed 2 ml.

Off-label uses

None.

Contraindications

Hypersensitivity to minoxidil; Pheochromocytoma; Hypertension; Psoriasis; Sunburn; Shaved scalp.

Cautions

Pulmonary hypertension; Angina pectoris; Chronic heart failure; Recent myocardial infarction.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Minoxidil 20mg/ml 2% Topical solution
- Minoxidil 50mg/ml 5% Topical solution

Pharmacokinetic parameters

Absorption Minoxidil absorption from intact skin is minimal.
Distribution Vd= Undetermined, Minoxidil does not bind to plasma proteins.
Metabolism 90% of absorbed minoxidil metabolized by the liver.
Elimination Half-life is 4.2 hours.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) Abnormal ECG; Hypertrichosis.
Less common (1-10%) Pericardial effusion.
Rare but serious (less than 1%) Angina; Cardiac tamponade; Fluid and sodium retention; Hirsutism; Hypotension; Leukopenia; Pericarditis; Stevens-Johnson syndrome; Tachyarrhythmia; Thrombocytopenia; Toxic epidermal necrolysis.

Patient educations

Teach patient how to use topical form; Urge him to read package insert carefully; Caution patient not to use topical form on other body parts and not to let it contact mucous membranes; Tell patient using topical form that new scalp hair will be soft and barely visible; Caution him to use only 1 ml twice daily, regardless of amount of balding; Clinical alert drug suddenly, because new hair growth will be lost.

Mirabegron

ATC Code: G04BD12 Urologicals (Drugs for Urinary Frequency and Incontinence)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: It is not known Due to the lack of conclusive data, use caution when administering to nursing women.

Indications and Dosage

For overactive bladder: 25 mg once daily initially, may increase to 50 mg once daily based on individual response and tolerance.

Off-label uses

None.

Contraindications

End-stage renal disease (ESRD) or severe uncontrolled hypertension (i.e., systolic blood pressure >180mm Hg or diastolic blood pressure >110 mm Hg).

Cautions

Increased blood pressure may occur, monitor blood pressure regularly. Use caution in patients with bladder outlet obstruction and patients taking ant muscarinic medications for overactive bladder.

Dose adjustment in renal failure: Recommended dose in patients with severe renal impairment is 25 mg once daily.

Dose adjustment in hepatic failure: In patients with severe hepatic impairment, the recommended dose is 25 mg once daily.

Dosage forms and trade names available in Iraq

Mirabegron 50mg tablet

Betmiga (Astellas Pharma Netherlands).

Pharmacokinetic parameters

Absorption High (F=29-35%).
Distribution Vd=1670 L, 71% protein bound.
Metabolism Predominantly by CYP3A4 and, to a lesser extent, by CYP2D6.
Elimination Urine (55%), feces (34%), half-life of approximately 50 hours.

Drug interaction

CYP2D6 substrates (e.g., Thioridazine, Tetrabenazine): Mirabegron may increase the serum concentration of CYP2D6 substrates.
Digoxin: Mirabegron may increase the serum concentration of Digoxin. Monitor therapy.

Side effects

Common (more than 10%) Hypertension, urinary tract infection, headache.
Less common (1-10%) Nasopharyngitis, tachycardia, constipation, nausea, diarrhea.
Rare but serious (less than 1%) Angioedema, interstitial lung disease.

Patient educations

- Take this medication with or without food. Do not crush or chew extended-release tablets.
- Notify your healthcare provider if you experience a fast or irregular heartbeat.
- Regular monitoring of blood pressure may be required while taking this medication.

Mirtazapine

ATC Code: N06AX11 Psychoanaleptics (Other Antidepressants)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: It is excreted in low amounts in breast milk. Caution should be exercised when used in nursing mothers.

Dosage forms and trade names available in Iraq

Mirtazapine 30 mg tab
Demissal (D & Fisher Portugal).

Indications and Dosage

For the treatment of depression: Start with 15 mg orally once daily at bedtime, which can be increased in increments of 15 mg/day at intervals of 1-2 weeks up to a maximum of 45 mg/day.

Off-label uses

occasionally for conditions such as insomnia, anxiety disorders, and certain eating disorders.

Contraindications

contraindicated within 14 days of administering a monoamine oxidase inhibitor (MAOI).

Cautions

It may increase suicidal thoughts especially in children, adolescents, and young adults. Use caution in patients with a history of mania/hypomania or seizures.

Dose adjustment in renal failure: Not typically required; however, caution is advised as there is a lack of data in this population.

Dose adjustment in hepatic failure: Use with caution, starting with a lower dose and slow titration may be necessary due to increased plasma concentrations in these patients.

Pharmacokinetic parameters

Absorption F¬= about 50%
Distribution Vd= not available, about 85% protein bound.
Metabolism Extensive metabolism in the liver via demethylation and oxidation followed by conjugation.
Elimination Mostly (75%) excreted in urine with a half-life of 20-40 hours.

Drug interaction

MAO inhibitors: Can result in serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability, and mental status changes.
Alcohol and other CNS depressants: Can enhance the sedative and impairment effects of mirtazapine.

Side effects

Common (more than 10%) Increased appetite, weight gain, sedation, dizziness, dry mouth.
Less common (1-10%) Constipation, fatigue, tremor.
Rare but serious (less than 1%) Neutropenia, agranulocytosis, suicidal ideation.

Patient educations

• Mirtazapine is usually taken once daily at bedtime. It can be taken with or without food.
• It may cause drowsiness and impair your ability to drive or operate machinery.
• Regular follow-ups with your healthcare provider are necessary to monitor progress and adjust the dosage if needed.

Misoprostol

ATC Code: A02BB01 Drugs for Acid Related Disorders (Prostaglandins)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid; Breastfeeding discontinue 5 hours after the last dose.

Dosage forms and trade names available in Iraq

Misoprostol 200 mcg tab
Cytotec (Pfizer UK).

Indications and Dosage

• Prevention of NSAID induced gastric ulcer 100mcg-200mcg qid with food (last dose at bedtime).
• Termination of early pregnancy: there are many regimens but according to ministry of health protocol 800 mg vaginally followed by 800 mg vaginally after 12 hours.

Off-label uses

Treatment of gastric ulcer; Used in low dose intravaginal protocols for cervical ripening.

Contraindications

Hypersensitivity to misoprostol.

Cautions

Cardiovascular disease; Elderly.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Well absorbed following oral administration and rapidly converted to its active form (misoprostol acid).
Distribution Vd=13.6±8.0L/kg, 85%protein bound.
Metabolism Rapidly metabolized to misoprostol acid (active form) and further metabolized via oxidation in several body organs.
Elimination Renal elimination is 80% with half-life of 20-40 minutes.

Drug interactions

Oxytocin: Misoprostol increases effects of oxytocin by pharmacodynamic synergism, misoprostol may augment the effects oxytocic agents, especially when given less than 4 hours before initiating oxytocin.

Side effects

Common (more than 10%) Abdominal pain; Diarrhea.
Less common (1-10%) Headache.
Rare but serious (less than 1%) Anaphylaxis; Anemia; Cardiac dysrhythmia; Chest pain; Flatulence; Gastrointestinal hemorrhage; Hearing loss; Myocardial infarction; Nausea; Rupture of uterus; Thromboembolic disorder.

Patient educations

Avoid magnesium-containing antacids (minimizes potential for diarrhea); Women of childbearing potential must not be pregnant before or during medication therapy (may result in hospitalization, surgery, infertility, fetal death). Incidence of diarrhea may be lessened by taking immediately following meals.

Mitoxantrone

ATC Code: L01DB07 Antineoplastic Agents (Anthracyclines and Related Substances)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Breastfeeding is not recommended during treatment and for six months after the last dose.

Dosage forms and trade names available in Iraq

Mitoxantron 20mg/10ml IV injection
Onkotrone (Baxter Oncology Germany).

Indications and Dosage

• For treatment of acute nonlymphocytic leukemia (ANLL): 12 mg/m^2/dose IV on days 1 to 3 of the induction therapy cycle.
• For treatment of multiple sclerosis: 12 mg/m^2 IV every 3 months.

Off-label uses

Treatment of metastatic breast cancer, non-Hodgkin's lymphoma, and prostate cancer.

Contraindications

Hypersensitivity to mitoxantrone, baseline neutrophil count less than 1,500 cells/mm^3, severe hepatic dysfunction.

Cautions

Mitoxantrone can cause severe myelosuppression leading to infection and bleeding. It also may cause cardiac toxicity and can turn the urine blue-green in color.
Dose adjustment in renal failure: Not required
Dose adjustment in hepatic failure: Mitoxantrone dose should be reduced by 50% in patients with bilirubin levels 1.2-3.0 mg/dL.

Pharmacokinetic parameters

Absorption Not applicable for IV administration.
Distribution Vd= not available, 78% protein bound.
Metabolism Hepatic metabolism.
Elimination Primarily fecal excretion with a half-life of 23 to 215 hours.

Drug interaction

Live vaccines: Avoid concurrent use due to the risk of developing a potentially fatal infection.
Other myelosuppressive agents or radiation therapy: May increase the risk of myelosuppression.

Side effects

Common (more than 10%) Nausea, hair loss, urinary tract infections, leukopenia, anemia, thrombocytopenia.
Less common (1-10%) Diarrhea, constipation, stomatitis, fever, cough, shortness of breath.
Rare but serious (less than 1%) Congestive heart failure, secondary acute myeloid leukemia, severe neutropenia and thrombocytopenia.

Patient educations

• Mitoxantrone can lower your body's ability to fight infections, avoid contact with people who have infections.
• It may cause bluish-green color of the urine or whites of the eyes; this is not harmful.
• Regular cardiac monitoring and blood tests are required during treatment to monitor for side effects.

Mometasone

ATC Code: D07AC13 Corticosteroids, Dermatological Preparations (Corticosteroids, Potent (Group III)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Inflammatory hyperkeratotic dermatosis: Apply cream or ointment or lotion to affected area once daily.

• Nasal polyp: 2 sprays in each nostril bid.

Off-label uses

None.

Contraindications

Hypersensitivity to mometasone or milk proteins; Status asthmaticus or acute bronchospasm.

Cautions

Thyroid impairment; Elderly; Diabetes; Cardiovascular disease; Glaucoma; Cataracts; Myasthenia gravis; Patients at risk for osteoporosis; Seizures; GI ulcer; colitis; Myocardial infarction; Untreated systemic infection.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Mometasone 0.1% lotion
- Mometasone furoate 0.05% nasal spray
- Mometasone furoate 1mg/1g 0.1% ointment
  Elika- Derm (SDI IRAQ).
- Mometasone furoate 1mg/1g 0.1% cream
  Elna (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=2%.

Distribution Undetermined.

Metabolism Not absorbed.

Elimination Not absorbed.

Drug interactions

Clarithromycin: Clarithromycin is strong CYP3A4 inhibitor decrease metabolism and increase level of budesonide, concurrent use of clarithromycin with mometasone not recommended.

Side effects

Common (more than 10%) Cough; Epistaxis; Headache; Pharyngitis; Viral infection.

Less common (1-10%) Conjunctivitis; Diarrhea; Dysmenorrhea; Dyspnea; Flu-like syndrome; Musculoskeletal pain; Myalgia; Otitis media; Vomiting.

Rare (less than 1%) Anaphylaxis; Angioedema; Growth suppression; Nasal burning and irritation; Nasal candidiasis; Nasal septal perforation; Taste disturbance.

Patient educations

Do not change dose schedule or stop taking drug, must taper off gradually under medical supervision; Report if symptoms do not improve, report if sneezing, nasal irritation occur; Clear nasal passages prior to use; Do not cover affected skin with bandage, dressing.

Montelukast

ATC Code: R03DC03 Drugs for Obstructive Airway Diseases (Leukotriene Receptor Antagonists)

Pregnancy category:

FDA A **B** C D X N

TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Asthma: 12 months-5 years :4 mg/day; 6-14 years: 5 mg/day; 15 years and older:10 mg/day.

• Exercise-induced bronchoconstriction: 6-14 years: 5 mg/day; 15 years and older:10 mg/day.

• Allergic rhinitis: 2-5 years:4 mg/day; 6-14 years:5 mg/day; 15years and older:10 mg/day.

Off-label uses

Atopic dermatitis; Urticaria.

Contraindications

Hypersensitivity to montelukast.

Cautions

Phenylketonuria; Not for use in acute asthma attacks.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Montelukast 4mg/Sachet
- Montelukast 4 mg chewable tab
  MONTIX (Pioneer Iraq), **LUKAST** (Pharma International Jordan).
- Montelukast 5 mg chewable tab
  LUKAST (Pharma International Jordan), **MONTIX** (Pioneer Iraq).
- montelukast 10 mg tab
  MONTIX (Pioneer Iraq), **LUKAST** (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=63-73%, food decrease absorption.

Distribution Vd=8-11L, 99% protein bound.

Metabolism hepatic metabolism.

Elimination Montelukast and its metabolites are excreted almost singly via bile, with half-life of 3-6 hr.

Drug interactions

Carbamazepine: it will decrease the level or effect of montelukast by affecting hepatic and intestinal enzyme CYP3A4 metabolism. .

Gemfibrozil: will increase the plasma concentration of montelukast oral by slowing drug metabolism.

Concurrent use of prednisone and montelukast may result in severe peripheral edema.

Side effects

Common (more than 10%) Headache.

Less common (1-10%) Abdominal pain;Bronchitis;Cough;Dental pain;Dizziness;Dyspepsia;Eczema; Elevated liver enzymes;Fever;Gastroenteritis;Nasal congestion;Otitis;Upper respiratory tract infection;Wheezing.

Rare (less than 1%) Aggressive behavior;Allergic granulomatous angiitis;Cholestatic hepatitis;Suicidal thoughts.

Patient educations

Increase fluid intake (decreases lung secretion viscosity); Take as prescribed, even during symptom-free periods as well as during exacerbations of asthma; Do not stop other asthma medications;Report increased use or frequency of short-acting bronchodilators, changes in behavior, suicidal ideation.

Morphine

ATC Code: N02AA01 Analgesics (Natural Opium Alkaloids)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding in single dose.

Indications and Dosage

• Acute pain: 10mg-30mg every 4 hr. or prn.
• Chronic pain, moderate to severe: 30mg-60mg every 12 hr.

Off-label uses

Atopic dermatitis; Urticaria.

Contraindications

Hypersensitivity to morphine; Acute bronchial asthma; Respiratory depression; GI obstruction; Paralytic ileus.

Cautions

Head trauma; Increased intracranial pressure; Pulmonary disease; Hypothyroidism; Adrenal insufficiency; Prostatic hypertrophy Elderly patients.

Dose adjustment in renal failure: CrCl 10-50ml/min: reduce dose by 25%; CrCl less than 10ml/min: reduce dose by 25%.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Morphine sulphate 10mg/ml ampule
Morphine-Hameln (Macarthys Laboratories United Kingdom).

Morphine sulphate 15mg/ml ampule
Morphine-Hameln (Siegfried Hameln Germany).

Pharmacokinetic parameters

Absorption F=40%, food slows rate but not extent of absorption.
Distribution Vd=1-4.7L/kg, 20-36% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 90% with a half-life of 15 hr.

Drug interactions

Alfuzosin: Alfuzosin may enhance the hypotensive effect of morphine.

Side effects

Common (more than 10%) Constipation; Headache; Pruritus; Somnolence; Urinary retention; Vomiting.
Less common (1-10%) Abdominal pain; Abnormal liver function test results; Amblyopia; Anxiety; Asthenia; Backache; Depression; Diarrhea; Dizziness; Dyspnea; Fever; Hiccups; Insomnia; Loss of appetite; Nausea; Orthostatic hypotension; Paresthesia; Peripheral edema; Rash; Respiratory depression Sweating; Syncope; Urinary retention; Xerostomia.
Rare (less than 1%) Respiratory depression.

Patient educations

Discomfort may occur with injection; Change positions slowly to avoid orthostatic hypotension; Avoid tasks that require alertness, motor skills until response to drug is established; Avoid alcohol, CNS depressants; Tolerance, dependence may occur with prolonged use of high doses; Report ineffective pain control, constipation, urinary retention.

Moxifloxacin

ATC Code: J01MA14 Antibacterials for Systemic Use (Fluoroquinolones)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Moxifloxacin 5mg/1ml 0.5% eye drop
  VIMOXI (Pioneer Iraq).
- Moxifloxacin 400mg/250ml infusion
- Moxifloxacin 400 mg tablet

Indications and Dosage

• Acute infective exacerbation of chronic obstructive pulmonary disease: 400mg daily for 5 days.
• Acute bacterial sinusitis: 400mg daily for 10 days.
• Community acquire pneumonia: 400mg daily for 7-14 days.
• Infection of skin or subcutaneous tissue: 400mg daily for 7-21days.
• Bacterial conjunctivitis: 1 drop instilled into affected eye bid or tid.

Off-label uses

Tuberculosis.

Contraindications

Hypersensitivity to moxifloxacin.

Cautions

Bradycardia, Acute myocardial ischemia; Myasthenia gravis; Diabetes; Rheumatoid arthritis; Seizures; Patients with prolonged QT interval; Hypokalemia; Hypomagnesemia; Elderly; Patients with suspected CNS disorder; Tendonitis.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.

Distribution Vd=1.7-2.7L/kg, 50% protein bound.

Metabolism Hepatic metabolism 52%.

Elimination Renal elimination is 20% with a half-life of 12 hr.

Drug interactions

Chlorpromazine: Chlorpromazine and moxifloxacin both increase QTc interval.

Side effects

Common (more than 10%) None.

Less common (1-10%) Diarrhea; Dizziness; Prolonged QT interval.

Rare (less than 1%) Agranulocytosis; Aplastic anemia; Hemolytic anemia; Hepatic necrosis; Pancytopenia; Seizure; Stevens-Johnson syndrome; Tendinitis; Tendon rupture; Thrombocytopenia.

Patient educations

Treatment may cause heart problems such as low heart rate, palpitations; permanent nerve damage such as burning, numbness, tingling, weakness; Do not take aluminum or magnesium containing antacids, multivitamins, zinc or iron products at least 2 hours before or 6 hours after dose; Drink plenty of fluids.

Mycophenolate Mofetil

ATC Code: L04AA06 Antineoplastic and Immunomodulating Agents (Selective Immunosuppressants)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

- Prevention of renal transplant rejection: 1g bid.
- Prevention of heart transplant rejection: 1.5g bid.
- Prevention of hepatic transplant rejection: 1.5g bid.

Off-label uses

Mild heart transplant rejection; Moderate to severe psoriasis; Proliferative lupus nephritis; Myasthenia gravis; Graft vs host disease; Treatment of autoimmune hepatitis (refractory).

Contraindications

Hypersensitivity to mycophenolate mofetil.

Cautions

Active severe gastrointestinal disease; Neutropenia.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Mycophenolate mofetil 250mg cap
  CELLCEPT (Roche Switzerland).
- Mycophenolate mofetil 360mg tab
  MAR-Mycophenolic acid (APOTEX Canada).
- Mycophenolate mofetil 500 mg tablet
  Cellcept (Roche Switzerland).

Pharmacokinetic parameters

Absorption F=70-95%.

Distribution Vd=54±25L, 97%protein bound.

Metabolism Mycophenolate mofetil is extensively metabolized by the liver.

Elimination Renal elimination is 1% with half-life of 8-18 hours.

Drug interactions

Ampicillin: Ampicillin and mycophenolate both increases levels of the other by decreasing renal clearance.

Side effects

Common (more than 10%) Abdominal pain; Anemia; Back pain; Diarrhea; Dyspnea; Fever; Headache; Hypercholesterolemia; Hyperglycemia; Hyperkalemia; Hypertension; Hypocalcemia; Hypomagnesemia; Increased blood urea nitrogen; Increasing frequency of cough; Infection; Leukopenia; Nausea; Peripheral edema; Pleural effusion; Urinary tract infection.

Less common (1-10%) Gastrointestinal bleeding; Lymphoma; Melanoma; Neutropenia; Opportunistic infection; Progressive multifocal leukoencephalopathy; Pulmonary fibrosis.

Rare but serious (less than 1%) None.

Patient educations

Effective contraception should be used before, during, and for 6 weeks after discontinuing therapy, even if patient has a history of infertility, other than hysterectomy; Two forms of contraception must be used concurrently unless abstinence is absolute; Report unusual bleeding, sore throat, mouth sores, abdominal pain, fever; Laboratory follow-up while taking medication is important part of therapy. Malignancies may occur.

Naloxone

ATC Code: V03AB15 All Other Therapeutic Products (Antidotes)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Opioid overdose: By i.v. or i.m. injecxtion, 0.4mg -2mg every 2-3 min as needed, may repeat doses every 20-60 min.
• Reversible of respiratory depression with therapeutic opioid dosing: BY I.V. OR I.M. injection, 0.02mg-0.2mg

Off-label uses

Opioid induced pruritus.

Contraindications

Hypersensitivity to naloxone.

Cautions

Cardiac disease; Pulmonary disease; Hypertension; Arrhythmias.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Naloxone HCl inj. 400mcg/ml, (1 ml amp.)
Naloxone – Hameln (Hameln pharma GERMANY).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=200L, 45%protein bound.
Metabolism Metabolized by the liver.
Elimination Renal elimination is 25-40% with half-life of 60-90 minutes.

Drug interactions

Amoxicillin: Amoxicillin may decrease the excretion rate of naloxone which could result in a higher serum level.
Betamethasone: The metabolism of betamethasone can be decreased when combined with naloxone.

Side effects

Common (more than 10%) Nausea or vomiting; Increased heart rate; Sweating; Withdrawal reaction precipitated; Hypotension.
Less common (1-10%) Tremors or nervousness; Body aches; Diarrhea; Fever; Ventricular tachycardia.
Rare but serious (less than 1%) Seizures; Severe allergic reactions, such as difficulty breathing, swelling of your face, lips, tongue, or throat; Pulmonary edema (fluid accumulation in the lungs); Cardiac arrest.

Patient educations

Monitor vital signs especially rate, depth, rhythm of respiration, during and frequently following administration; Carefully observe patient after satisfactory response (duration of opiate may exceed duration of naloxone, resulting in recurrence of respiratory depression); Assess for increased pain with reversal of opiate.

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Nandrolone

ATC Code: A14AB01 Anabolic Agents for Systemic Use (Estren Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Osteoporosis in post-menopausal women: 50mg every three weeks.

Off-label uses

Anemia in chemotherapy patients; Anemia of chronic renal failure; Anabolic after debilitating illness.

Contraindications

Hypersensitivity to Nandrolone; Prostatic or breast carcinoma (male); Nephrosis.

Cautions

Diabetes; Migraine; Seizure disorder.
Dose adjustment in renal failure: Use with caution.
Dose adjustment in hepatic failure: Use with caution.

Dosage forms and trade names available in Iraq

- Nandrolone Decanoate 50mg/1ml ampoule
- Nandrolone Decanoate 25mg/1ml ampoule

Pharmacokinetic parameters

Absorption F=53–73%.
Distribution Vd=11.5L, 1-5%protein bound.
Metabolism Nandrolone decanoate is rapidly hydrolyzed in the blood by esterase into Nandrolone, the metabolism of Nandrolone occurs in the liver.
Elimination Nandrolone elimination half-life is 6–12 days.

Drug interactions

Insulin: Nandrolone may increase effects of insulin.
Oral anticoagulants: Nandrolone may increase effects of oral anticoagulants.

Side effects

Acne; Bladder irritability; Chills; Decreased libido; Diarrhea; Gynecomastia; Hepatic dysfunction; Hypercalcemia; Hyperpigmentation; Insomnia; Iron deficiency anemia; Nausea; Priapism; Prostatic Hyperplasia; Virilism.

Patient educations

A Patient education is not currently available for this monograph.

Naproxen

ATC Code: M01AE02 Antiinflammatory and Antirheumatic Products (Propionic Acid Derivatives)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

- Osteoarthritis, rheumatoid arthritis: 250mg-500mg bid.
- Acute gout: 250mg tid.
- Fever: 250mg-500mg bid or tid or prn.
- Pain: 500mg bid.

Off-label uses

Migraine prophylaxis.

Contraindications

Hypersensitivity to naproxen; History of asthma; Urticaria; Perioperative pain in setting of CABG surgery.

Cautions

GI bleeding; Ulcers; Fluid retention; Asthma; Heart failure; Smoking; Use of alcohol; Elderly patients.

Dose adjustment in renal failure: CrCl less than 30ml/min: Avoid.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Naproxen 25mg/ml oral suspension
- Naproxen 250 mg tablet
  NAPROSAM (SDI Iraq), **Naproxdain** (Wadi AL-Rafidain Iraq(, NAPROKIN (AL-Kindi Iraq).
- **Naproxen** 500mg tab
  NAPRON (Pioneer Iraq), **Naproken** (AL-Kindi Iraq).
- Naproxen 500mg suppository

Pharmacokinetic parameters

Absorption F=95%, food has minimal effect on absorption.

Distribution Vd=0.16L/kg, 99% protein bound.

Metabolism Extensive hepatic metabolism.

Elimination Renal elimination is 95% with a half-life of 12-17 hours.

Drug interactions

Heparin: Naproxen may enhance the anticoagulant effect of heparin, decrease the dose of heparin or naproxen if coadministration is required.

Loop diuretics: Loop diuretics may enhance the nephrotoxic effect of naproxen, monitor for evidence of kidney injury or decreased therapeutic effects of loop diuretics with concurrent use of naproxen.

Metformin: Naproxen may enhance the adverse effect of metformin.

Methotrexate: Naproxen may increase the serum concentration of methotrexate.

Side effects

Common (more than 10%) None.

Less common (1-10%) Abdominal pain; Constipation; Diarrhea; Diverticulitis; Dizziness; Drowsiness; Dyspnea; Edema; Fluid retention; Gastrointestinal tract bleeding; Gastrointestinal tract perforation; Gastrointestinal tract ulcers; Headache; Hearing disturbances; Heartburn; Lightheadedness; Nausea; Stomatitis.

Rare (less than 1%) Meaningful elevation of serum alanine aminotransferase or aspartate aminotransferase.

Patient educations

Avoid tasks that require alertness, motor skills until response to drug is established; Take with food, milk; Avoid aspirin, alcohol during therapy (increases risk of gastrointestinal bleeding).

Nebivolol

ATC Code: C07AB12 Beta Blocking Agents (Beta Blocking Agents, Selective)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Breastfed infants should be monitored for the signs and symptoms of bradycardia, respiratory distress, and hypoglycemia.

Dosage forms and trade names available in Iraq

Nebivolol 5 mg tab

NEBILET (Menarini Germany).

Indications and Dosage

• Hypertension: 5mg once daily, (max 40mg daily).

Off-label uses

Heart failure.

Contraindications

Hypersensitivity to nebivolol; Severe bradycardia; Decompensated heart failure; Cardiogenic shock; Second and third heart block; Severe hepatic impairment; Sick sinus rhythm.

Cautions

Diabetes; Acute exacerbation of coronary artery disease; Bronchospastic disease; Peripheral vascular disease; Raynaud's syndrome; Thyrotoxicosis.

Dose adjustment in renal failure: CrCl less than 30ml/min: 2.5mg once daily.

Dose adjustment in hepatic failure: Avoid.

Pharmacokinetic parameters

Absorption F=12-96%, food has no effect on absorption.

Distribution Vd=8-12L/kg, 98% protein bound.

Metabolism Hepatic metabolism.

Elimination Renal elimination is 38-67% with a half-life of 12-19 hours.

Drug interactions

Fluoxetine: CYP2D6 inhibitor (fluoxetine) may increase concentration of nebivolol.

Furosemide: Furosemide may increase hypotensive effect of nebivolol.

Side effects

Common (more than 10%) None.

Less common (1-10%) Decreased high-density lipoprotein levels; Diarrhea; Dizziness; Fatigue; Headache; Increased triglyceride levels and insulin resistance; Insomnia; Nausea; Peripheral edema; Weakness.

Rare (less than 1%) Bradycardia; Chest pain; Dyspnea.

Patient educations

Compliance with therapy regimen is essential to control hypertension; Do not use nasal decongestants, OTC cold preparations (stimulants) without physician's approval; Monitor blood pressure, pulse before taking medication; Restrict salt, alcohol intake; Do not chew, crush, dissolve, or divide tablets; Swallow whole.

Nefopam

ATC Code: N02BG06 Analgesics (Other Analgesics and Antipyretics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Acute pain including post-operative, dental, musculoskeletal, and acute traumatic pain: By i.v. or i.m. injection, 20mg prn, (max 120mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to nefopam; History of convulsive disorders.

Cautions

Angle closure glaucoma; Urinary retention; Ischemic heart disease.

Dose adjustment in renal failure: Use with caution.

Dose adjustment in hepatic failure: Use with caution.

Dosage forms and trade names available in Iraq

Nefopam Hcl 20mg/2ml ampule

Piopam (PIONEER Iraq).

Pharmacokinetic parameters

Absorption The absolute bioavailability of nefopam is low.

Distribution Vd=Undetermined, 73%protein bound.

Metabolism Extensively metabolized in the liver.

Elimination Renal elimination is 5% with half-life of 4 hours.

Drug interactions

Amitriptyline: Nefopam may cause serotonin toxicity (including serotonin syndrome) when coadministered with amitriptyline.

Side effects

Abdominal pain; Angioedema; Blurred vision; Confusion; Constipation; Convulsion; Diaphoresis; Diarrhea; Dizziness; Drowsiness; Drug dependence and abuse; Exacerbation of angina; Hallucination; Headache; Hypotension; Insomnia; Lightheadedness; Nausea; Nervousness; Palpitations; Paresthesia; Syncope; Tachycardia; Transient pink discoloration of urine; Tremor; Urinary retention; Vomiting; Xerostomia.

Patient educations

Nefopam may cause dizziness and drowsiness, if affected, do not drive or operate machinery.

Neostigmine

ATC Code: N07AA01 Other Nervous System Drugs (Anticholinesterases)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 **B2** B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Neostigmine 2.5mg/ml, (2ml Amp)
NEONEER (Pioneer Iraq).

Indications and Dosage

• Myasthenia gravis: By i.v., i.m. or s.c. injection, 0.5mg-2.5mg as needed every 1-3 hour, (max 10mg daily); Diagnosis of myasthenia gravis: By i.v. injection, 0.022mg/kg, if cholinergic reaction occurs discontinue tests and administer i.v. 0.4mg-0.6mg atropine sulfate.
• Treatment of urinary retention: By i.m. or s.c. injection, 0.5mg if urination does not occur within an hour, the patient should be catheterized. After the patient has voided, or the bladder has been emptied, continue the 0.5mg injections every three hours for at least 5 injections; Prevention of postoperative urinary retention: By i.m. or subcutaneous injection, 0.25mg every 4-6 hours for 2-3 days.
• Reversal of neuromuscular blockade (with atropine): By i.v. injection, 0.5mg-2.5mg given slowly.

Off-label uses

None.

Contraindications

Hypersensitivity to neostigmine; gastrointestinal or genitourinary obstruction; Peritonitis.

Cautions

Bronchial asthma;Bradycardia;Recent M.I;Hypotension;Peptic ulcer disease;Epilepsy;Parkinsonism; Hyperthyroidism;Recent intestinal or bladder surgery;Patient with ischemic heart disease.
Dose adjustment in renal failure: CrCl 10-50ml per minute reduce dose to 50% of normal dose; CrCl less than 10ml per minute reduce dose to 25% of normal dose.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=1-2% for the oral tablet because of poor permeation.
Distribution Vd=0.12-1.4L/kg, 15-25%protein bound.
Metabolism Neostigmine undergoes hydrolysis by cholinesterase.
Elimination Renal elimination is 50% with half-life of 52 minutes.

Drug interactions

Corticosteroids: : Concomitant use with corticosteroids may produce severe weakness in patients with myasthenia gravis, if possible, withdraw anticholinesterase agents at least 24 hours before initiating corticosteroid therapy.

Side effects

Arthralgia; Convulsions; Diaphoresis; Dizziness; Drowsiness; Dysarthria; Emesis; Flatulence; Headache; Loss of consciousness; Miosis; Muscle cramps; Nausea; Rash.

Patient educations

Tell patient drug may alter respiratory and cardiac status; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration, vision, and alertness.

Nepafenac

ATC Code: S01BC10 Ophthalmologicals (Antiinflammatory Agents, Non-Steroids)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: It's not known; caution is advised.

Dosage forms and trade names available in Iraq

Nepafenac 1mg/ml 0.1% ophthalmic suspension

Indications and Dosage

For the treatment of pain and inflammation associated with cataract surgery: 1 drop of nepafenac ophthalmic suspension 0.1% in the affected eye(s) 3 times daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period.

Off-label uses

None.

Contraindications

Hypersensitivity to nepafenac, other NSAIDs, or any component of the formulation.

Cautions

In patients with a history of bleeding disorders or who are receiving other medications which may prolong bleeding time. Also, prolonged use may increase the risk of corneal damage and infection.

Dose adjustment in renal failure: No specific guidelines

Dose adjustment in hepatic failure: No specific guidelines

Pharmacokinetic parameters

Absorption Transcorneal absorption into aqueous humor.

Distribution Unknown Vd, unknown % protein bound.

Metabolism Rapidly converted to active metabolite (amfenac) in ocular tissues.

Elimination Primarily via the kidney; elimination half-life is approximately 3 hours for amfenac.

Drug interaction

Corticosteroids: Concurrent use with NSAIDs may result in increased risk of corneal adverse events.

Other topical NSAIDs: Concurrent use may increase the potential for increased bleeding of the ocular tissues.

Side effects

Common (more than 10%) Decreased visual acuity

Less common (1-10%) Abnormal sensation in eye, conjunctival hyperemia, corneal edema, dry eye, eye pain, headache.

Rare but serious (less than 1%) Corneal decompensation, corneal melt, keratitis.

Patient educations

- Avoid touching the dropper tip against the eye or anything else; eye drops and dropper must be kept clean.
- Do not use the eye drops if the liquid has changed colors or has particles in it.
- You may feel a brief sensation of burning or stinging when you apply the eye drops.

Nifedipine

ATC Code: C08CA05 Calcium Channel Blockers (Dihydropyridine Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Variant angina, chronic stable angina: Initially, 10mg tid, maintenance, 10mg-30mg qid, (Max 180mg daily).
• Hypertension: Initially, 30mg–60mg daily, (Max 120mg daily).

Off-label uses

Treatment of Raynaud's phenomenon; Pulmonary hypertension; Preterm labor; Prevention and treatment of high altitude pulmonary edema.

Contraindications

Hypersensitivity to nifedipine; ST elevation myocardial infarction.

Cautions

Obstructive coronary disease; Heart failure; Severe aortic stenosis; Edema; Severe left ventricular dysfunction; Hypertrophic cardiomyopathy; Major surgery; Bradycardia.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use cautiously.

Dosage forms and trade names available in Iraq

- Nifedipine 20mg tab
- Nifedipine 30mg tab

Pharmacokinetic parameters

Absorption F=40-89%, food delays absorption.
Distribution Vd=1.42-2.2L/kg, 92-98% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 70-80% with half-life of 7 hours.

Drug interactions

Phenobarbital: Strong CYP3A4 Inducers (phenobarbital) may decrease concentration and effect nifedipine.

Side effects

Common (more than 10%) Dizziness; Flushing; Headache; Heartburn; Nausea; Peripheral edema.
Less common (1-10%) Chest pain; Constipation; Cough; Dyspnea; Hypotension; Nervousness; Palpitations; Pruritus; Urticaria; Wheezing.
Rare (less than 1%) None.

Patient educations

Tell patient he may take immediate release form with or without meals; If gastrointestinal upset occurs, tell him to take it with meals; Caution patient not to crush or break extended-release tablets; Tell him to swallow them whole; Advise him to take on empty stomach; Inform patient that angina attacks may occur 30 minutes after a dose, Explain that these attacks are usually temporary and don't mean that drug should be withdrawn; Tell patient to report rash immediately; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration, balance, and alertness; Instruct patient to consult prescriber before taking herbs or over-the counter drugs (especially cold remedies).

Nilotinib

ATC Code: L01EA03 Antineoplastic Agents (BCR-ABL Tyrosine Kinase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Resistant or intolerant chronic myeloid leukemia to imatinib (Chronic or accelerated phase): 400 mg bid.
• Newly diagnosed philadelphia chromosome positive chronic myeloid leukemia(Chronic phase): 300mg bid.

Off-label uses

Refractory gastrointestinal stromal tumor.

Contraindications

Hypersensitivity to nilotinib; Hypokalemia; Hypomagnesemia; Long QT syndrome.

Cautions

Myelosuppression; QT prolongation; Pancreatitis; Electrolyte abnormalities.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure:
• Newly diagnosed chronic myeloid leukemia: Reduce to 200 mg bid.
• Resistant or intolerant chronic myeloid leukemia: Reduce to 300 mg bid; may escalate to 400 mg bid depending on tolerability.

Dosage forms and trade names available in Iraq

Nilotinib 150 mg Cap
Tasigna (Novartis Switzerland).
Nilotinib 200 mg Cap
Tasigna (Novartis pharma Switzerland).

Pharmacokinetic parameters

Absorption F=30%.
Distribution Vd=Undetermined, 98%protein bound.
Metabolism Mostly metabolized by the liver, metabolites are not active.
Elimination Renal elimination is 93% with half-life of 17 hours.

Drug interactions

• **Dihydroergotamine, Dronedarone, Erythromycin, Lovastatin, Renolazine, Saquinavir, Simvastatin, Tolvaptan:** Nilotinib will increase the level or effect of these agents.
• **Indapamide, Disopyramide, Goserelin, Ibutilide, Pentamidine, Pimozide, Procainamide, Quinidine, Sotalol:** This agent nilotinib both increase QTc interval.
• **Thioridazine:** Nilotinib will increase the level or effect of thioridazine.

Side effects

Common (more than 10%) Abdominal pain; Arthralgia; Asthenia;Bone pain; Constipation; Diarrhea; Dyspnea; Fatigue; Headache; Nasopharyngitis; Nausea; Peripheral edema; Pruritus.
Less common (1-10%) Dizziness; HTN; Hyperglycemia; Hyperkalemia; Hypomagnesemia; Insomnia; Neutropenia; QT interval prolongation.
Rare but serious (less than 1%) Abscess; Amnesia; Anal abscess; Aortic valve sclerosis; Dehydration.

Patient educations

Report symptoms of infection such as body aches, burning with urination, chills, cough, fatigue, fever; Avoid those with active infection; Avoid contact with anyone who recently received live virus vaccine; do not receive vaccinations; Do not ingest food less than 2 hours before and less than 1 hour after dose is taken.

Nintedanib

ATC Code: L01EX09 Antineoplastic Agents (Other Protein Kinase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Idiopathic pulmonary fibrosis: 150mg bid.
• Systemic sclerosis associated interstitial lung disease: 150mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to nintedanib.

Cautions

Recent abdominal surgery; Peptic ulceration; Diverticular disease; Risk of bleeding; Risk factors for liver enzymes elevation; Hypertension; Coronary artery disease; Smokers.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In severe hepatic failure use of nintedanib is not recommended. required.

Dosage forms and trade names available in Iraq

Nintedanib 100mg cap
Ofev (Boehringer ingelheim Germany).

Nintedanib 150mg cap
Ofev (Boehringer ingelheim Germany).

Pharmacokinetic parameters

Absorption F=4.7%.

Distribution Vd=1050L, 97.8%protein bound.

Metabolism Nintedanib is predominantly metabolized via hydrolytic cleavage by esterase.

Elimination Renal elimination is 1% with half-life of 9-15 hours ,however it's excreted mostly via the bile and faeces.

Drug interactions

Carbamazepine: Carbamazepine decreases levels of nintedanib by P-glycoprotein efflux transporter, avoid coadministration, particularly for P-glycoprotein inducers that are also CYP3A4 inducers, nintedanib is a substrate of P-glycoprotein and to a less extent CYP3A4.

The P-glycoprotein inhibitor ketoconazole: also erythromycin or ciclosporin lead to increase blood plasma levels of nintedanib On the other hand, the P-glycoprotein inducer rifampicin, also carbamazepine, phenytoin cause reduction in plasma level of nintedanib.

Side effects

Common (more than 10%) Abdominal pain; Abdominal pain; Decreased appetite; Decreased weight; Diarrhea; Elevated liver enzymes; Fatigue; Liver enzyme elevation; Nausea; Skin ulcer; Vomiting.

Less common (1-10%) Arterial thromboembolic events; Back pain; Bleeding events; Bronchitis; Decreased appetite; Decreased weight; Dizziness; Headache; Headache; Hypertension; Hypothyroidism; Myocardial infarction; Pyrexia.

Rare but serious (less than 1%) Alopecia; Drug-induced liver injury; Gastrointestinal perforation; Lung neoplasm malignant; Pancreatitis; Pneumonia; Pruritus; Rash; Thrombocytopenia.

Patient educations

Nintedanib may cause drowsiness or dizziness, if affected, do not drive or operate machinery.

Nitrofurantoin

ATC Code: J01XE01 Antibacterial for Systemic Use (Nitrofuran Derivatives)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Urinary tract infection: 50mg-100mg qid for 7 days.

Off-label uses

None.

Contraindications

Hypersensitivity to nitrofurantoin; Anuria; Oliguria; Cholestatic jaundice.

Cautions

Diabetes; Electrolyte imbalance; Anemia; Vitamin B deficiency; Peripheral neuropathy; G6PD deficiency; Hemolytic anemia; Elderly patients.

Dose adjustment in renal failure: CrCl less than 60ml/min: Contraindicated.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Nitrofurantoin 100mg cap
  SAMAFURANTIN (SDI Iraq).
- Nitrofurantoin 25mg/5ml suspension

Pharmacokinetic parameters

Absorption F=94%, food increase absorption.
Distribution Protein bound 90%.
Metabolism Nitrofurantoin metabolized in all tissues to inactive metabolite.
Elimination Renal elimination is 40% with a half-life of 1 hour.

Drug interactions

Acetylsalicylic acid: The risk or severity of hyperkalemia can be increased when nitrofurantoin is combined with acetylsalicylic acid.

Side effects

Anorexia; Arthralgia; Chest pains; Chills; Clostridium difficile colitis; Cough; Cyanosis secondary to methemoglobinemia; Diarrhea; Dizziness; Drowsiness; Dyspnea; Exfoliative dermatitis; Fatigue; Fever; Flatulence; Headache; Hemolytic anemia; Hepatitis; Increased Liver function tests; Itching; Nausea; Numbness; Paresthesia; Rash; Sore throat; Stomach upset; Urine discoloration; Vasculitis; Vomiting; Weakness.

Patient educations

Instruct patient to take with food or milk at regular intervals around the clock; Advise patient to complete entire course of therapy; Tell patient not to take magnesium containing drugs (such as antacids) during therapy; Caution patient not to drive or perform other hazardous activities until he knows how drug affects vision, concentration, and alertness; Tell patient to immediately report fever, chills, cough, chest pain, difficulty breathing, rash, bleeding or easy bruising, dark urine, yellowing of skin or eyes, numbness or tingling of fingers or toes, or intolerable GI distress; Advise female patient to avoid taking drug during pregnancy, especially near term.

Norepinephrine

ATC Code: C01CA03 Cardiac Therapy (Adrenergic and Dopaminergic Agents)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not known

Dosage forms and trade names available in Iraq

Norepinephrine 2mg/1ml (4ml ampoule)
Noradrenaline (Laboratoire Aguttant France).

Indications and Dosage

Norepinephrine is used to treat life-threatening low blood pressure (hypotension) that can occur with certain medical conditions or surgical procedures. This medication is often used during CPR (cardio-pulmonary resuscitation). Dosage is individualized and adjusted based on response to treatment.

Off-label uses

None.

Contraindications

• In patients with hypersensitivity to it.
• In patients with mesenteric or peripheral vascular thrombosis (because of the risk of increased ischemia and extension of the area of infarction).

Cautions

In patients with heart disease, including angina and heart failure, as it can increase heart rate and blood pressure.

Dose adjustment in renal failure: Not applicable as norepinephrine is typically used in acute settings.
Dose adjustment in hepatic failure: Not applicable as norepinephrine is typically used in acute settings.

Pharmacokinetic parameters

Norepinephrine is given intravenously, so it has 100% bioavailability. The half-life is approximately 2 minutes due to rapid uptake and metabolism by adrenergic nerve terminals, the liver, and other tissues.

Drug interaction

Monoamine Oxidase Inhibitors (MAOIs): Concurrent use can result in a hypertensive crisis due to potentiation of norepinephrine's effects.
Tricyclic Antidepressants (TCAs): These can potentiate the effects of norepinephrine, leading to increased blood pressure.

Side effects

Common (more than 10%) High blood pressure, fast heart rate
Less common (1-10%) Anxiety, headaches
Rare but serious (less than 1%) Heart attack, stroke

Patient educations

• Norepinephrine is a medication used to support blood pressure during severe shock; it is typically administered in a hospital setting.
• It is administered as an infusion, and the healthcare team will closely monitor your heart rate and blood pressure.
• Alert your healthcare provider immediately if you experience severe headaches, chest pain, or irregular heartbeats.

Norethisterone

ATC Code: G03AC01 Sex Hormones and Modulators of The Genital System (Progestogens)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Endometriosis: 10–15 mg daily for 4–6 months or longer, to be started on day 5 of cycle.

• Dysfunctional uterine bleeding (to arrest bleeding): 5 mg 3 times a day for 10 days.

• Dysfunctional uterine bleeding (to prevent bleeding): 5 mg twice daily, to be taken from day 19 to day 26 of cycle.

• Dysmenorrhea: 5 mg 3 times a day for 3–4 cycles, to be taken from day 5–24 of cycle.

• Contraception: 350 micrograms daily, dose to be taken at same time each day, starting on day 1 of cycle.

Dosage forms and trade names available in Iraq

Norethisterone 5mg tab

Primolut N (Bayer Germany).

Off-label uses

Contraception.

Contraindications

documented hypersensitivity; liver diseases or liver impairment; pregnancy; current breast cancer; history of thromboembolism; undiagnosed vaginal bleeding.

Cautions

Family history of breast cancer and/or DVT/PE; depression; diabetes mellitus; hypertension; renal and hepatic impairment; bone metabolic disease; SLE; conditions exacerbated by fluid retention (eg, migraine, asthma, epilepsy).

Dose adjustment in renal failure: Use with caution.

Dose adjustment in hepatic failure: Avoid in severe or active disease.

Pharmacokinetic parameters

Absorption F=64%.

Distribution Vd=4 L/Kg, 61% protein bound.

Metabolism Norethisterone is metabolized in liver to both sulfate and glucuronide metabolites (inactive).

Elimination half-life =4-13 hr, and excreted 33-81% in urine; 35-43% in feces.

Drug interactions

Lamotrigine: Norethisterone may interfere with the metabolism of lamotrigine, plasma and tissue concentrations may decrease.

Side effects

Edema; anorexia; amenorrhea; breakthrough bleeding; DVT; depression; dizziness; headache; nervousness; breast tenderness; Galactorrhea; abdominal pain; nausea; vomiting; cholestatic jaundice.

Patient educations

A patient education is not currently available for this monograph.

Norfloxacin

ATC Code: J01MA06 Antibacterials for Systemic Use (Fluoroquinolones)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Urinary tract infections: 400mg bid for 3-21 days.
• Prostatitis: 400mg bid for 4-6 weeks.
• Uncomplicated gonococcal infections: 800mg as a single dose.
• Conjunctivitis: Instill 1-2 drops to the affected eye qid for up to 7 days, for severe infections, instill 1-2 drops to the affected eye every 2 hours while awake on the first day.

Dosage forms and trade names available in Iraq

Norfloxacin 0.3% eye drop
Norfloxacin 400mg tab

Off-label uses

None.

Contraindications

Hypersensitivity to norfloxacin; Myasthenia gravis; History of tendonitis or tendon rupture associated with the use of quinolone.

Cautions

Prolongation of QT interval; Hypokalemia; Severe cerebral arteriosclerosis; Seizures.
Dose adjustment in renal failure: CrCl less than 30ml per minute, reduce dose to 400mg once daily.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=30-40%.
Distribution Vd=Undetermined, 10-15% protein bound.
Metabolism Metabolized by the liver.
Elimination Renal elimination is 30% with half-life of 6.5 hours.

Drug interactions

Iron: Iron salts decreased therapeutic effect of norfloxacin.
Antacids: Antacid decreased therapeutic effect of norfloxacin.

Side effects

Abdominal pain; Blurred vision; Constipation; Depression; Diarrhea; Dizziness; Dry mouth; Dyspepsia; Fatigue; Flatulence; Headache; Insomnia; Nausea; Prolonged QT interval; Somnolence; Vomiting.

Patient educations

Tell patient to take on empty stomach with full glass of water, 1 hour before or 2 hours after a meal; If patient needs antacid for GI upset, instruct him not to take it within 2 hours of norfloxacin; Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness; Teach patient ways to counteract photosensitivity, such as by wearing sunglasses and avoiding excessive exposure to bright light.

Nusinersen Sodium

ATC Code: M09AX07 Musculo-Skeletal System (Other Drugs for Disorders of The Musculo-Skeletal System)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: It's unknown, so caution is advised.

Dosage forms and trade names available in Iraq

Nusinersen Sodium 2.4mg/ml (12mg/5ml vial)
Spinraza (Biogen Germany).

Indications and Dosage

Nusinersen is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. The initial dosage is typically 12 mg (5 mL) administered intrathecally (into the spinal canal) followed by maintenance doses.

Off-label uses

None.

Contraindications

In patients with a history of hypersensitivity to nusinersen or any of its components.

Cautions

Cautions include potential risks of lumbar puncture complications (such as infection or bleeding), renal toxicity, and coagulation abnormalities.

Dose adjustment in renal failure: No specific recommendations.

Dose adjustment in hepatic failure: No specific recommendations.

Pharmacokinetic parameters

Nusinersen is delivered intrathecally, so absorption is not applicable. It distributes throughout the central nervous system and peripheral tissues, with minimal metabolism and primarily renal excretion. Half-life is approximately 135-177 days in cerebrospinal fluid and 63-87 days in plasma.

Drug interaction

No known significant drug interactions.

Side effects

Common (more than 10%) Respiratory infections, constipation, headache, back pain.

Less common (1-10%) Vomiting, fever.

Rare but serious (less than 1%) Renal toxicity, coagulation abnormalities.

Patient educations

• Nusinersen is a medication used to treat spinal muscular atrophy and is administered by healthcare professionals directly into the spinal canal.

• This medication is typically well-tolerated, but side effects can include headache, back pain, and respiratory infections.

• Ensure to attend all your scheduled appointments for receiving the medication and for monitoring its effects.

Nystatin

ATC Code: A07AA02 Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents (Antibiotics)

Pregnancy category:

FDA A B **C** D X N

TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• GI candidiasis: 500000-1000000 IU tid.

• Vaginal candidiasis: insert vaginal tablet or suppository or full applicator vaginal cream into vagina once daily for 2 weeks.

• Mucocutaneous infection: Apply to affected area bid or tid until healing is complete.

Off-label uses

None.

Contraindications

Hypersensitivity to nystatin.

Cautions

Achlorhydria.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Nystatin 100,000 unit/g cream
- Nystatin 100000 IU/g ointment
  Mycodad (Wadi Al-Rafidain Iraq), **MYCODIN** (SDI Iraq).
- Nystatin 100000 IU/ml oral suspension
  NYSTADAD (Wadi Al-Rafidain Iraq),
  KINDISTATIN (Al-Kindi Iraq).
- Nystatin 100000 units, vaginal Suppositories
- Nystatin USP 500,000 I.U. tablet
  NYSTADAD (Wadi Al-Rafidain Iraq).

Pharmacokinetic parameters

Absorption Not absorbed.

Distribution Not absorbed.

Metabolism Not absorbed.

Elimination Unknown.

Drug interactions

There are no known significant interactions.

Side effects

Contact dermatitis; Diarrhea; Hypersensitivity reactions; Nausea; Stevens-Johnson syndrome; Stomach pain; Vomiting.

Patient educations

Do not miss doses; complete full length of treatment (continue vaginal use during menses); Report nausea, vomiting, diarrhea, stomach pain; Insert high in vagina, check with physician regarding douching, sexual intercourse; Rub topical nystatin well into affected areas; Avoid contact with eyes; Keep areas clean, dry and wear light clothing for ventilation; Separate personal items in contact with affected areas.

Ocrelizumab

ATC Code: L04AA36 Immunosuppressants (Selective Immunosuppressants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It's unknown

Indications and Dosage

Ocrelizumab is indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis. The standard dosage is 600 mg IV every 6 months; the first dose is given as two 300 mg IV infusions 2 weeks apart.

Off-label uses

None.

Contraindications

In patients with a history of life-threatening infusion reaction to ocrelizumab.

Cautions

• In patients with pre-existing hepatic disease
• immunocompromised patients due to potential for serious infections.

Dose adjustment in renal failure: No specific recommendations.

Dose adjustment in hepatic failure: No specific recommendations.

Dosage forms and trade names available in Iraq

Ocrelizumab 300 mg / 10 ml vial
Ocrevus (F. Hoffman – La Roche Switzerland).

Pharmacokinetic parameters

As a monoclonal antibody, ocrelizumab's pharmacokinetics do not follow traditional parameters. It's administered via IV and does not undergo traditional metabolism or elimination pathways. Its half-life is approximately 26 days.

Drug interaction

No known significant interactions.

Side effects

Common (more than 10%) Infusion reactions, upper respiratory tract infections, lower respiratory tract infections.

Less common (1-10%) Depression, insomnia.

Rare but serious (less than 1%) Progressive multifocal leukoencephalopathy, hepatitis B reactivation, severe infections.

Patient educations

• Ocrelizumab is a medication used to treat multiple sclerosis, given as an infusion by a healthcare professional.
• Infusion reactions and infections are the most common side effects, so report any symptoms such as fever, chills, or rash to your doctor.
• Regular follow-ups are crucial as your healthcare provider will need to monitor for any potential complications or side effects.

Octreotide

ATC Code: H01CB02 Pituitary and Hypothalamic Hormones and Analogues (Somatostatin and Analogues)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Octreotide acetate 30mg Vial

SANDOSTATIN LAR (Novartis Switzerland).

Indications and Dosage

• Carcinoid tumor: By i.v. injection, 50mcg–300mcg bid for 2 weeks. By subcutaneous injection, 20mg every 4 weeks for 2 months.

• Vasoactive intestinal peptic secreting tumor: By i.v. injection, 100mcg–150mcg bid. By subcutaneous injection, 20mg every 4 weeks for 2 months.

• Esophageal varices: By i.v. injection, 25mcg–100mcg followed by i.v. infusion of 25mcg–50mcg/hr for 2–5 days.

• Acromegaly: By i.v. injection, 50mcg tid, increase as needed to 300mcg-1500mcg daily.

Off-label uses

Control of bleeding esophageal varices; Treatment of AIDS-associated secretory diarrheaDiarrhea associated with graft vs host disease; Chemotherapy induced diarrhea; Insulinomas; Small bowel fistulas; Zollinger Ellison syndrome; Cushing's syndrome; Hypothalamic obesity; Malignant bowel obstruction; Post-gastrectomy dumping syndrome; Islet cell tumors; Sulfonylurea induced hypoglycemia.

Contraindications

Hypersensitivity to octreotide.

Cautions

Diabetic patients with gastroparesis; Heart failure; Elderly patients.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=33%.

Distribution Vd=13.6L, 65%protein bound.

Metabolism Extensive hepatic metabolism.

Elimination Renal elimination is 32% with half-life of 1.5 hours.

Drug interactions

Clomipramine: Clomipramine and octreotide both increase QTc interval.

Side effects

Common (more than 10%) Abdominal discomfort; Diarrhea; Hyperhidrosis; Increased blood glucose; Nausea; Osteoarthritis.

Less common (1-10%) Arrhythmia; Arthropathy; Blurred vision; Myalgia; Vomiting.

Rare but serious (less than 1%) Increased intraocular pressure; Hearing loss; Neuritis; Nephrolithiasis; Hematuria.

Patient educations

A Patient education is not currently available for this monograph.

Ofloxacin

ATC Code: J01MA01 Antibacterials for Systemic Use (Fluoroquinolones)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Ofloxacin 0.3% eye drop
Pioflox (PIONEER IRAQ).

Indications and Dosage

• Uncomplicated urinary tract infection: 200mg bid for 3-7 days.
• Complicated urinary tract infection: 200mg bid for 10 days.
• Pelvic inflammatory disease: 400mg bid for 10-14 days.
• Lower respiratory tract, skin infections: 400mg bid for 10 days.
• Acute, uncomplicated gonorrhea: 400mg as a single dose.
• Bacterial conjunctivitis: 1-2 drops every 2-4 hr for 2 days, then qid for 5 days.
• Bacterial corneal ulcers: 1-2 drops every 30 min while awake for 2 days, then every 60 min while awake for 5-7 days, then qid.
• Otitis externa: 10 drops into the affected ear once a day for 7 days.

Off-label uses

None.

Contraindications

Hypersensitivity to ofloxacin.

Cautions

Epilepsy; Severe cerebral arteriosclerosis; Seizure; Myasthenia gravis; Rheumatoid arthritis; G6PD deficiency; Congenital long QT syndrome; Hypokalaemia; Hypomagnesaemia; Heart failure; Bradycardia; Psychiatric disease; Depression; Diabetes.
Dose adjustment in renal failure: CrCl 20-50ml per minute reduce dose to 200mg once daily; CrCl less than 20ml per minute reduce dose to 100mg or half of the usual recommended dose once daily following usual initial dose.
Dose adjustment in hepatic failure: In sever hepatic failure reduce dosage to max 400mg once daily.

Pharmacokinetic parameters

Absorption F=98%.
Distribution Vd=2.4-3.5L/kg, 32%protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 70-80% with half-life of 5-7 hours.

Drug interactions

Antacids: Antacids may decrease absorption of ofloxacin.

Side effects

Common (more than 10%) Application site reaction.
Less common (1-10%) Dizziness; Earache; Paresthesia; Pruritus; Rash; Taste perversion; Vertigo.
Rare but serious (less than 1%) Diarrhea; Otorrhagia; Tinnitus; Transient hearing loss; Tremor; Xerostomia.

Patient educations

Do not skip doses; take full course of therapy; Maintain adequate hydration to prevent crystalluria; not take antacids within 2 hours of ciprofloxacin; Sugarless gum, hard candy may relieve bad taste; Avoid caffeine.

ALSAIDALY
SCIENTIFIC BUREAU

SDI

تأسست الشركة العامة لصناعة الأدوية والمستلزمات الطبية (SDI) عام 1965 بموجب العقد المبرم مع الاتحاد السوفييتي السابق للتعاون الفني والاقتصادي. بدأ المصنع بالعمل في عام 1970. في مجال الصناعات الدوائية
بامتيازات من شركات عالمية مثل: Lepetite الإيطالية، MSD، SKF، GLAXO، ASRA، و ROCHE. يقع مركز الشركة في مدينة سامراء، 50 كم جنوب مركز محافظة صلاح الدين، 120 كم شمال بغداد، وتعتبر الشركة بحد ذاتها أفضل وأكبر مصدر محلي لتوفير الأدوية البشرية وبمواصفات عالمية، والشركة تواصل مسيرة النمو حتى أصبحت واحدة من شركات الأدوية الرائدة في المنطقة. تغطي SDI نسبة كبيرة من احتياجات سوق الأدوية العراقي. ويأتي ذلك نتيجة لشراكتها الناجحة مع وكيلها التسويقي مكتب الصيدلي العلمي (من خلال شركة الناقوس الفضي). حيث يعتبر مكتب الصيدلي من أكبر المكاتب العلمية في العراق من حيث عدد الموظفين والخدمات التي يقدمها في جميع أنحاء العراق. ويهدف مكتب الصيدلي إلى تقديم دواء آمن وفعال للمستخدمين من خلال ضمان نقل الأدوية وتخزينها بالطرق الصحيحة والآمنة

The state Company for Drugs Industry and Medical Appliances(SDI) was founded in 1965 in accordance with the contract concluded with the former Soviet Unionfor technical and economic cooperation.The factory was started in1970.In the field of drugs industries with
concessions from international companies such as: Italian Lepetite,MSD,SKF,GLAXO, ASRA,and ROCHE. The center of the company is located in the city of Samarra,50km south of the center of Salahaddin province,120km north of Baghdad,The company is itself the best and largest local source for the provision of human drugs and international standards,and the company continues growth march until it becomes one of the leading pioneer drugs companies in the region. SDI covers a large proportion of the needs of the Iraqi pharmaceutical market. This comes as a result of its successful partnership with its marketing agent, the Alsaidaly Scientific Bureau (through Al-Naqoos Al-Fadhi Company). Alsaidaly Bureau is considered one of the largest scientific offices in Iraq in terms of the number of employees and the services it provides throughout Iraq. Alsaidaly Bureau aims to deliver safe and effective medicine to users by ensuring that medicines are transported and stored in the correct and safe ways.

Olanzapine

ATC Code: N05AH03 Psycholeptics (Diazepines, Oxazepines, Thiazepines and Oxepines)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Infants should be monitored for drowsiness.

Indications and Dosage

- Bipolar disorder: 5mg-20mg daily.
- Schizophrenia: 5mg-20mg daily.
- Depression: 5mg-20mg daily.

Off-label uses

Prevention of chemotherapy induced nausea and vomiting; Acute treatment of delirium; Treatment of anorexia nervosa; Tourette's syndrome; Tic disorder.

Dosage forms and trade names available in Iraq

- Olanzapine 2.5mg tablet
- Olanzapine 5 mg tab
  ZYPRAXEN (Al-Kindi Iraq).
- Olanzapine 10 mg tab
  ZYPRAXEN (Al-Kindi Iraq).

Contraindications

Hypersensitivity to olanzapine; With intramuscular use: Acute myocardial infarction, bradycardia; recent heart surgery; severe hypotension; sick sinus syndrome; unstable angina.

Cautions

Bone-marrow depression; hypereosinophilic disorders; low leucocyte count; low neutrophil count; myeloproliferative disease; paralytic ileus.

Dose adjustment in renal failure: Consider initial dose of 5mg daily.

Dose adjustment in hepatic failure: Consider initial dose of 5mg daily and cautious titration.

Pharmacokinetic parameters

Absorption Well absorbed, food has no effect on absorption.

Distribution Vd=1000L, 93% protein bound.

Metabolism Extensive hepatic metabolism.

Elimination Renal elimination is 57% with a half-life of 21-54 hr.

Drug interactions

Leflunomide: is predicted to decrease the exposure to olanzapine. Monitor and adjust dose.

Levodopa: Olanzapine decreases the effects of Levodopa; Avoid or monitor worsening parkinsonian symptoms.

Mexiletine: is predicted to increase the exposure to olanzapine. Adjust dose.

Side effects

Common (more than 10%) Accidental injury; Constipation; Dizziness; Dyspepsia; Extrapyramidal symptoms; Hypercholesterolemia; Hyperglycemia; Hyperprolactinemia; Weight gain; Xerostomia.

Less common (1-10%) Asthenia; Hypotension; Parkinsonism reactions; Postural hypotension; Tremor.

Rare (less than 1%) Pulmonary embolism; Suicidal intent; Syncope.

Patient educations

Drug may impair heat regulation; Diabetic patients should monitor and report difficulties with glycemic control; Avoid alcohol while taking olanzapine.

Olmesartan

ATC Code: C09CA08 Agents Acting on The Renin-Angiotensin System (Angiotensin II Receptor Blockers (ARBs), Plain).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: not recommended.

Dosage forms and trade names available in Iraq

- Olmesartan Medoxomil 20mg Tablet
- Olmesartan Medoxomil 40mg Tablet

Indications and Dosage

• **Hypertension:** The usual starting dose for adults is 20 mg once daily, administered orally, with or without food. The dosage may be adjusted based on individual patient response, with a maximum recommended dose of 40 mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to olmesartan or any component of the formulation, history of angioedema related to previous treatment with (ACE inhibitors), and pregnancy (Black Box Warnings).

Cautions

patients with renal impairment, hyperkalemia, heart failure, or hepatic impairment.

Dose adjustment in renal failure: CrCl<20 mL/min: Consider lower initial dose and dose not to exceed 20 mg/day.

Dose adjustment in hepatic failure: Moderate to severe impairment: Initial dose adjustment not necessary; drug exposure may increase 60% in moderate impairment.

Pharmacokinetic parameters

Absorption Bioavailability: 26%, Onset: <2 weeks, Peak response: 4-6 weeks, Duration: 24 hr, Peak plasma time: 1-2 hr.

Distribution Protein bound: 99%, Vd: 17 L; does not cross blood-brain barrier.

Metabolism primarily metabolized in the liver to inactive metabolite, olmesartan medoxomil, via ester hydrolysis.

Elimination Half-life: 13 hr, Excretion: Bile (50-65%), urine (35-50%).

Drug interactions

• Concurrent use with potassium-sparing diuretics, potassium supplements, or potassium-containing salt substitutes may increase the risk of hyperkalemia.

Side effects

Common (more than 10%): Headache, dizziness, fatigue.

Less common (1-10%): Hypotension, diarrhea, upper respiratory tract infection, Hyperglycemia.

Rare but serious (less than 1%): Angioedema, renal impairment, hyperkalemia, Rhabdomyolysis, Anaphylactic reaction.

Patient educations

• Do not stop taking olmesartan without consulting your healthcare provider, even if you feel well.

Olopatadine

ATC Code: S01GX09 Ophthalmologicals (Other Antiallergics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Olopatadine 1mg/1ml eye drop
- Olopatadine 2mg/1ml eye drop

Indications and Dosage

• Allergic conjunctivitis: 1 drop in affected eye bid.

Off-label uses

None.

Contraindications

Hypersensitivity to Olopatadine.

Cautions

Allergic conjunctivitis: 1 drop bid in affected eye(s).
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Not absorbed.
Distribution Not absorbed.
Metabolism Not absorbed.
Elimination Not absorbed.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) None.
Less common (1-10%) Asthenia; Blurred vision; Burning or stinging; Cold syndrome; Dry eye; Foreign body sensation; Headache; Hyperemia; Hypersensitivity; Keratitis; Lid edema; Nausea; Pharyngitis; Pruritus; Rhinitis; Sinusitis; Taste perversion.
Rare (less than 1%) None.

Patient educations

A Patient educations is not currently available for this monograph.

Omeprazole

ATC Code: A02BC01 Drugs For Acid Related Disorders (Proton Pump Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid; Omeprazole may suppress gastric acid secretion in the nursing infant.

Dosage forms and trade names available in Iraq

- Omeprazole 40 mg vial
- Omeprazole 20 mg Capsules
  PIOPRAZOLE (Pioneer Iraq).
- Omeprazole 40mg Capsules
  PIOPRAZOLE (Pioneer Iraq).
- Omeprazole 20mg tablet
  OPRAZON (AlKendi Iraq), **Pumpinox** (Pharma International Jorden).

Indications and Dosage

• Duodenal ulcer disease: 20mg daily for 4 weeks.
• Gastric ulcer disease: 40mg daily for 8 weeks.
• H. pylori GI infection: 20mg bid for 10-14 days in combination with amoxicillin 1000mg and clarithromycin 500mg bid.
• Erosive esophagitis, GERD: 20mg daily.
• In patients where the use of oral omeprazole is inappropriate: By i.v. infusion over 20-30 min, 40mg once daily is recommended.

Off-label uses

Prevention and treatment of NSAID induced ulcers; Stress ulcer; Prophylaxis in critically ill patients.

Contraindications

Hypersensitivity to omeprazole.

Cautions

Hypomagnesemia; Omeprazole may increase risk of fractures, Gastrointestinal infections.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=30-40%, food delays but does not reduce absorption.
Distribution Vd=0.34-0.37L/kg, 95% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 77% with a half-life of 30-60 minutes.

Drug interactions

Clopidogrel: Omeprazole may decrease concentration and effect of clopidogrel.
Diazepam: Omeprazole may increase concentration and effect of diazepam.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Acid regurgitation; Constipation; Cough; Diarrhea; Dizziness; Flatulence; Headache; Nausea; Rash; Upper respiratory infection; Vomiting.
Rare (less than 1%) None.

Patient educations

Report headache, onset of black, tarry stools, diarrhea, abdominal pain; Avoid alcohol; Swallow capsules whole; do not chew, crush, dissolve, or divide; Take before eating.

Ondansetron

ATC Code: A04AA01 Antiemetics AND Antinauseants (Serotonin (5HT3) Antagonists)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Chemotherapy induced nausea and vomiting: 8mg-24mg 30 min prior to the start of chemotherapy and repeated in 8 hr then 8mg bid 1-2 day post chemotherapy.
• Prevention of postoperative nausea and vomiting: 16mg 1 hr before anesthesia induction.
• Radiation induced nausea and vomiting: 8mg 1-2 hr prior to radiotherapy and tid after 1st dose of radiation on each day of radiotherapy.

Off-label uses

Severe hyperemesis associated with pregnancy; Bulimia; Rectal pruritus; Alcoholism.

Contraindications

Hypersensitivity to ondansetron.

Cautions

Congenital long QT prolongation, Hypokalemia; Hypomagnesemia.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Max. 8mg daily.

Dosage forms and trade names available in Iraq

Ondansetron 4mg/2ml Ampule
NO-VOMIT (PIONEER IRAQ).
Ondansetron 8mg/4ml Ampule
NO-VOMIT (PIONEER IRAQ).
Ondansetron 4mg/5ml oral solution
Stop-Vomit (SDI IRAQ), **NO-VOMIT** (PIONEER IRAQ), **ANTI-VOMIT** (Al-Kindi IRAQ), **Ondisterain** (Wadi Al-Rafidain IRAQ),
Ondansetron 4 mg tab
Ondansetron 8 mg tab
NO-VOMIT (PIONEER IRAQ).

Pharmacokinetic parameters

Absorption F=56%, food has minimal effect on absorption.
Distribution Vd=2.5L/kg.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 5% with a half-life of 4.6 hours.

Drug interactions

Tramadol: Ondansetron may enhance the serotonergic effect of tramadol; this could result in serotonin syndrome.

Side effects

Common (more than 10%) Constipation; Headache; Malaise; Fatigue.
Less common (1-10%) Anxiety; Cold sensation; Diarrhea; Dizziness; Drowsiness; Elevated liver function test results; Fever; Gynecologic disorder; Hypoxia; Injection-site pain; Paresthesia; Pruritus; Urinary retention.
Rare (less than 1%) Arrhythmias; Bradycardia; Palpitations.

Patient educations

Relief from nausea and vomiting generally occurs shortly after drug administration; Avoid alcohol, barbiturates; Report persistent vomiting; Avoid tasks that require alertness, motor skills until response to drug is established (may cause drowsiness, dizziness).

Orlistat

ATC Code: A08AB01 Antiobesity Preparations, Excl. Diet Products (Peripherally Acting Antiobesity Products)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Indications and Dosage

• Weight reduction in patients with body mass index of 27 kg/m2 or over: 120mg tid.

Off-label uses

None.

Contraindications

Hypersensitivity to orlistat; Cholestasis; Chronic malabsorption syndrome.

Cautions

Hyperoxaluria; Calcium oxalate nephrolithiasis.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=5%.
Distribution Vd=Undetermined, 99% protein bound.
Metabolism Orlistat is hydrolyzed in the intestinal wall.
Elimination Renal elimination is 3% with half-life of 1-2 hours, , fecal elimination is estimated between 95-97%.

Dosage forms and trade names available in Iraq

Orlistat 120 mg cap
Refit (Pharma International Jordan).

Drug interactions

Abacavir: Orlistat will decrease the level or effect of abacavir by inhibition of gastrointestinal absorption.
Amiodarone: Orlistat will decrease the level or effect of amiodarone.
Diazepam: Orlistat decreases levels of diazepam by inhibition of gastrointestinal absorption.
Gabapentin: Orlistat decreases levels of gabapentin by inhibition of gastrointestinal absorption.
Phenytoin: Orlistat decreases levels of phenytoin by inhibition of GI absorption.
Vitamin D: Orlistat will decrease the level or effect of vitamin D.
Warfarin: Orlistat decreases effects of warfarin; Orlistat may decrease vitamin K absorption, patients on chronic stable doses of warfarin who are prescribed orlistat should be monitored closely for changes in coagulation parameters.

Side effects

Fatty stool; Flatulence; Increased defecation; Leukocytoclastic vasculitis; Nausea; Oily spotting; Oxalate nephropathy; Reduced absorption of fat soluble vitamins and beta-carotene; Vomiting.

Patient educations

Maintain nutritionally balanced, reduced-calorie diet; Daily intake of fat, carbohydrates, protein to be distributed over 3 main meals.

Orphenadrine

ATC Code: M03BC01 Muscle Relaxants, Centrally Acting Agents (Ethers, Chemically Close to Antihistamines).

Pregnancy category:

FDA A B **C** D X N

TGA A B1 **B2** B3 C D X N

Lactation: Orphenadrine is not recommended during lactation.

Dosage forms and trade names available in Iraq

Orphenadrine 30mg/2ml ampule

Norflex (Meda pharma Germany).

Indications and Dosage

Indicated for muscle spasm and relief of discomfort associated with acute painful musculoskeletal conditions: Extended-Release Tablets: 100 mg orally twice a day OR Parenteral Injection: 60 mg IV or IM every 12 hours as needed.

Off-label uses

Leg cramps resistant to quinine, Parkinson's disease.

Contraindications

Hypersensitivity to orphenadrine or any component of the formulation, Narrow-angle glaucoma, Pyloric/duodenal obstruction, BPH, stenosing peptic ulcers, myasthenia gravis, obstructive uropathy, paralytic ileus, ulcerative colitis, toxic megacolon, achalasia.

Cautions

Hepatic impairment, cardiac arrhythmias, prostatic hypertrophy, and elderly patients.

Dose adjustment in renal failure: Dose adjustment may be necessary in patients with renal failure due to the potential for accumulation of orphenadrine metabolites.

Dose adjustment in hepatic failure: use caution in patients with hepatic impairment due to the potential for accumulation of the drug and its metabolites. Lower doses may be necessary, and close monitoring for adverse effects is recommended.

Pharmacokinetic parameters

Absorption: Orphenadrine is well absorbed after PO, with peak plasma concentrations: within 2-4 hr.

Distribution: Vd: information is not readily available; approximately 90% protein bound.

Metabolism: it undergoes extensive hepatic metabolism via cytochrome P450 enzymes, primarily CYP2D6, to active metabolites.

Elimination: primarily excreted in the urine; elimination half-life is approximately 13-24 hours.

Drug interactions

• Concurrent use with other CNS depressants, such as alcohol, opioids, or benzodiazepines, may potentiate sedative effects and increase the risk of respiratory depression.

• Concurrent use with anticholinergic medications may increase the risk of anticholinergic side effects, such as dry mouth, constipation, urinary retention, and blurred vision.

Side effects

Common (more than 10%): Dry mouth, drowsiness, dizziness, blurred vision.

Less common (1-10%): Nausea, vomiting, constipation, urinary retention, confusion.

Rare but serious (less than 1%): Severe allergic reactions, hallucinations, seizures, Aplastic anemia, cardiac arrhythmias.

Patient educations

Avoid activities requiring mental alertness or coordination, such as driving or operating machinery, until you know how orphenadrine affects you.

Oseltamivir

ATC Code: J05AH02 Antivirals for Systemic Use (Neuraminidase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Influenza virus types A and B: 75mg bid for 5 days.

Off-label uses

H1N1 influenza A (swine flu).

Contraindications

Hypersensitivity to oseltamivir.

Cautions

Chronic cardiac disease; Respiratory disorders; Elderly patients.

Dose adjustment in renal failure: CrCl 10-30ml/min: reduce dose to 75mg once daily for 5 days.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Oseltamivir phosphate 75mg cap
Flutan (Alsafaa Iraq).

Pharmacokinetic parameters

Absorption F=75%, food has minimal effect on absorption.

Distribution Vd=23-26L, 42% protein bound.

Metabolism Oseltamivir phosphate is a prodrug that is extensively metabolized to oseltamivir carboxylate by ester hydrolysis.

Elimination Renal elimination is 99% with a half-life of 1-3 hour.

Drug interactions

Acetaminophen: Oseltamivir may decrease the excretion rate of acetaminophen which could result in a higher serum level.

Side effects

Common (more than 10%) None.

Less common (1-10%) Abdominal pain; Conjunctivitis; Ear disorder; Epistaxis; Insomnia; Nausea; Vertigo; Vomiting.

Rare (less than 1%) Aggravation of diabetes; Anemia; Arrhythmia; Confusion; Delirium; Hemorrhagic colitis; Hepatitis; Humerus fracture; Peritonsillar abscess; Pneumonia; Pseudomembranous colitis; Pyrexia; Rash; Seizure; Swelling of face or tongue; Toxic epidermal necrolysis; Transaminases increased; Unstable angina.

Patient educations

Begin as soon as possible from first appearance of flu symptoms (recommended within 2 days from symptom onset); Avoid contact with those who are at high risk for influenza; Not a substitute for flu shot.

مكتب الحياة العلمي

Al-HAYAT Scientific Office

Otilonium

ATC Code: A03AB06 Drugs for Functional Gastrointestinal Disorders (Synthetic Anticholinergics)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding; Otilonium may reduce milk production.

Indications and Dosage

- Gastrointestinal tract spasm: 40mg tid.
- Irritable bowel syndrome (IBS): 40mg tid.

Off-label uses

None.

Contraindications

Hypersensitivity to otilonium or any of the excipients.

Cautions

Chronic bronchitis; patients with enlarged prostate or prostate gland; liver; kidney failure or patients with abnormal heart rhythm; hyperthyroidism.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=1%.

Distribution Undetermined.

Metabolism Undetermined.

Elimination Renal elimination is 1%.

Dosage forms and trade names available in Iraq

Otilonium bromide 40mg tab

SPASMOMEN (Menarini Italy).

Drug interactions

Azithromycin: The risk or severity of QTc prolongation can be increased when azithromycin is combined with otilonium.

Bisacodyl: The therapeutic efficacy of bisacodyl can be decreased when used in combination with otilonium.

Valsartan: The risk or severity of hyperkalemia can be increased when valsartan is combined with otilonium.

Side effects

Agranulocytosis; Anorexia; Constipation; Epigastric distress; Facial dyskinesia; Headache; Palpitation; Tremors; Urinary retention; Vertigo; Visual disturbances; Vomiting; Wheezing.

Patient educations

Take as prescribed, 30-60 minutes before meals; Avoid excessive dosage; Avoid hot environments; Avoid alcohol; wear sunglasses; impotence (reversible); difficulty urinating (empty bladder before taking drug).

Oxaliplatin

ATC Code: L01XA03 Antineoplastic Agents (Platinum Compounds)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Advanced colorectal cancer: By i.v. infusion into a vein over at least 2 hours, 85 mg/m^2 every 2 weeks along with other medications (e.g. 5-fluorouracil and leucovorin).

• Adjunctive treatment of Stage III colon cancer after resection of the primary tumor: By i.v. infusion, 85 mg/m^2 every 2 weeks for total of 6 months.

Off-label uses

Treatment of ovarian cancer; Pancreatic cancer; Hepatobiliary cancer; Testicular cancer; Esophageal cancer; Gastric cancer; Recurrent or refractory non-Hodgkin's lymphoma; Chronic lymphocytic leukemia; Breast cancer; Prostate cancer.

Contraindications

Hypersensitivity to oxaliplatin; or allergic to any platinum-containing compounds (such as cisplatin); Sever renal impairment.

Dosage forms and trade names available in Iraq

Oxaliplatin 100mg/20ml vial
Oxaliplatin (EBEWE Austria).

Oxaliplatin 50mg/10ml vial
Oxaliplatin (EBEWE Austria).

Oxaliplatin5mg/ml (100ml vial)
OXALIPLATIN MEDAC (oncotic pharma Germany).

Cautions

Patient with history of or risk for QT prolongation; Immunosuppression; Peripheral neuropathy; Pulmonary Toxicity, Elderly patients, Rhabdomyolysis.

Dose adjustment in renal failure: CrCl less than 30ml per minute reduce dose to 65 mg/m2.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption The peak serum concentration was 0.814mcg/mL.

Distribution Vd=440L, 90%protein bound.

Metabolism Undergoes rapid and extensive nonenzymatic biotransformation.

Elimination Urine (54%); feces (2%), elimination half-life is 391 hours; Clearance: 10.1L/hour.

Drug interactions

Fingolimod: Oxaliplatin increases effects of fingolimod by immunosuppressive effects; risk of infection.

Nilotinib: Oxaliplatin will increase the level or effect of nilotinib, monitor for ECG changes if therapy is initiated in patients with drugs known to prolong QT interval.

Side effects

Common (more than 10%) Abdominal pain; Anemia; Anorexia; Constipation; Cough; Diarrhea; Dyspnea; Fatigue; Fever; Leukopenia; Nausea; Peripheral neuropathy; Thrombocytopenia; Vomiting.

Less common (1-10%) Edema; Neutropenia; Pharyngolaryngeal dysesthesia.

Rare but serious (less than 1%) Anaphylactic-like reaction; Posterior leukoencephalopathy syndrome; Pulmonary fibrosis.

Patient educations

Avoid cold drinks, ice, cold objects (may produce neuropathy).

Oxybutynin

ATC Code: G04BD04 Urologicals (Drugs for Urinary Frequency and Incontinence)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: The drug may be excreted in breast milk. Caution is advised

Dosage forms and trade names available in Iraq

Oxybutynin HCL 5mg/5ml 0.1gm/100ml syrup
Oxybutin Elixir (SAFA Iraq).

Indications and Dosage

Oxybutynin is used for managing symptoms of overactive bladder such as urgency, frequency, and incontinence. The typical dose for adults is 5 mg 2-3 times per day, and the maximum daily dose is 5 mg four times a day.

Off-label uses

Hyperhidrosis (excessive sweating).

Contraindications

In patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and in patients who are at risk for these conditions.
It's also contraindicated in patients with known hypersensitivity to the drug.

Cautions

In patients with gastrointestinal obstructive disorders, severe constipation, and controlled narrow-angle glaucoma.
Dose adjustment in renal failure: Cautionis is advised, and dosage adjustment is necessary.
Dose adjustment in hepatic failure: Caution is advised and dosage adjustment is necessary.

Pharmacokinetic parameters

Absorption F= 100%
Distribution Vd= Not Available, not bound to plasma proteins.
Metabolism Hepatically metabolized, primarily via the cytochrome P450 enzyme system.
Elimination Renal excretion with half-life of approximately 2-3 hours.

Drug interaction

Oxybutynin and other anticholinergic drugs: Can increase anticholinergic side effects.
Oxybutynin and CNS depressants (like alcohol, benzodiazepines, opioids): Can increase risk of drowsiness and sedation.

Side effects

Common (more than 10%): Dry mouth; Constipation; Dizziness; Blurred vision
Less common (1-10%): Nausea; Diarrhea; Abdominal pain; Headache; Urinary tract infection
Rare but serious (less than 1%): Allergic reactions; Agitation; Confusion

Patient educations

• Take this medication exactly as prescribed. Do not increase your dose or take this more often without your doctor's approval.
• This medication can cause dizziness and blurred vision. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely.
• Limit alcoholic beverages; they can increase the risk of this drug's side effects.

Oxymetazoline

ATC Code: R01AA05 Nasal Preparations (Sympathomimetics, plain)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Nasal congestion: 2-3 drops per nostril bid for 3-5 days.

Off-label uses

None.

Contraindications

Hypersensitivity to oxymetazoline; Acute coronary disease; Angle closure glaucoma; Inflammation or lesions of the skin around the nostrils or nasal mucosa; Pheochromocytoma; Trans-sphenoidal hypophysectomy.

Cautions

Angina; Hypotension; Hypertension; Orthostatic hypotension; Cerebral or coronary insufficiency; Thromboangiitis obliterans; Raynaud's phenomenon; Scleroderma; Sjogren's syndrome; Diabetes mellitus; Hyperthyroidism; Porphyria; Prostatic hyperplasia; Urinary obstruction; Occlusive vascular disease; Angle closure glaucoma.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Oxymetazoline HCl 0.05% nose and eye drops
NAZORDIN (SDI Iraq).

Pharmacokinetic parameters

Absorption Rapidly absorbed from intranasal tissues.

Distribution Vd=Undetermined, 56.7-57.5%protein bound.

Metabolism Oxymetazoline was minimally metabolized by liver enzymes to produce mono-oxygenated and dehydrogenated metabolites.

Elimination Renal elimination is 30% with half-life of 5-8 days.

Drug interactions

Amitriptyline: Amitriptyline increase effects of sympathomimetic, by blocking reuptake of NE, or blocking uptake of indirect sympathomimetic into the adrenergic neuron.

Cabergoline: Cabergoline, increases effects of oxymetazoline by pharmacodynamic synergism, additive vasospasm and risk of hypertension.

Clomipramine: Clomipramine increase effects of oxymetazoline, by blocking reuptake of NE, or blocking uptake of indirect sympathomimetics into the adrenergic neuron.

Selegiline: Selegiline increases effects of oxymetazoline by pharmacodynamic synergism, risk of acute hypertensive episode.

Side effects

Burning; Dryness; Headache; Insomnia; Rebound congestion; Sneezing; Stinging.

Patient educations

Avoid excessive or prolonged use.

Oxytocin

ATC Code: H01BB02 Pituitary and Hypothalamic Hormones and Analogues (Oxytocin and Analogues)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding in single dose.

Dosage forms and trade names available in Iraq

- Oxytocin 5 IU/ml Ampule
- Oxytocin 10 IU/ml Ampule

Indications and Dosage

• Induction or stimulation of labor: By i.v. injection, 0.5–1 milliunit/min, may gradually increase in increments of 1–2 milliunits/min every 30–60 min until desired contraction pattern is established.

• **Abortion:** By I.V. injection, 10-20 milliunits/ min, (max 30 IU / 12hr dose).

- Control of postpartum bleeding: 10 unit intramuscularly (IM) after delivery of the placenta

- Add 10-40 units; not to exceed 40 units; to 1000 mL of non-hydrating intravenous (IV) solution and infuse at the necessary rate to control uterine atony .

• **Incomplete or Inevitable abortion:** 10-20 m Unit/ min; not to exceed 30 units/12 hours.

Off-label uses

None.

Contraindications

Hypersensitivity to oxytocin; Cephalopelvic disproportion; Fetal distress without imminent delivery; Grand multiparity; Hypertonic uterus; Obstetric emergencies that favor surgical intervention; Prematurity; Unengaged fetal head; Unfavorable fetal position or presentation; Active genital herpes infection; Invasive cervical cancer; Placenta previa; Cord presentation.

Cautions

Fetal distress; Hydramnios; Partial placental previa; Predisposition to uterine rupture.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=0.3L/kg.

Metabolism Rapidly metabolized by liver and kidneys.

Elimination Oxytocin elimination half-life is 3-9 minutes.

Drug interactions

Misoprostol: Misoprostol increases effects of oxytocin by pharmacodynamic synergism, misoprostol may augment the effects oxytocic agents, especially when given less than 4 hours before initiating oxytocin.

Side effects

Fetal death; Fetal hypercapnia; Fetal hypoxia; Low Apgar score (5 min); Neonatal jaundice; Neonatal seizure.

Patient educations

Keep patient family informed of labor progress.

Ozenoxacin

ATC Code: D06AX14 Dermatologicals (Other Antibiotics for Topical Use)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: There is no available information

Indications and Dosage

Ozenoxacin cream is indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older. Apply a thin layer to the affected area twice daily for 5 days.

Dosage forms and trade names available in Iraq

Ozenoxacine 10mg/g cream
Ozanex (Ferrer Internacional Spain).

Off-label uses

None.

Contraindications

Hypersensitivity to ozenoxacin or any component of the formulation.

Cautions

Only for topical use, avoid contact with eyes and mucous membranes.

Dose adjustment in renal failure: Not necessary, as it is for topical use only.

Dose adjustment in hepatic failure: Not necessary, as it is for topical use only.

Pharmacokinetic parameters

Due to its topical application, the pharmacokinetics of ozenoxacin has not been fully characterized.

Drug interaction

None known.

Side effects

Common (more than 10%): Rosacea-like dermatitis.

Less common (1-10%): Pruritus.

Rare but serious (less than 1%): Contact dermatitis.

Patient educations

• This medication is for external use only, apply it on the skin as directed by your healthcare provider.
• Avoid contact with eyes, nose, mouth, or other sensitive areas.
• If you notice signs of an allergic reaction (rash, itching/swelling, severe dizziness, trouble breathing), stop using the medication and seek medical attention.

Paclitaxel

ATC Code: L01CD01 Antineoplastic Agents (Taxanes)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Paclitaxel 300mg vial
ANZATAX (Pfizer Australia).

Indications and Dosage

• Ovarian cancer: By i.v. injection, 175mg/m^2/dose over 3 hr or 135mg/m^2/dose over 24 hr given, every 3 weeks.
• Breast cancer: By i.v. injection, 175mg/m2/dose over 3 hr every 3 weeks or 135 mg/m^2 over 24 hr.
• Non–small cell lung cancer: By i.v. injection, 135mg/m2 over 24 hr.
• Kaposi's sarcoma: By i.v. injection, 135mg/m^2/dose over 3 hr every 3 weeks or 100mg/m^2/dose over 3 hr every 2 weeks.

Off-label uses

Bladder cancer; Cervical cancer; Small cell lung cancer; Head and neck cancer; Treatment of adenocarcinoma.

Contraindications

Hypersensitivity to paclitaxel; Treatment of solid tumors with baseline neutrophil count less than 1500cells/mm^3; Treatment of Kaposi's sarcoma with baseline neutrophil count less than 1000cells/mm^3.

Cautions

Severe neutropenia; Peripheral neuropathy.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: In sever hepatic failure, use of paclitaxel is contraindicated.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=227-688L/m2, 89–98% protein bound.
Metabolism Highly metabolized by the liver primarily by CYP2C8 and CYP3A4.
Elimination Renal elimination is 10% with half-life of 13-52 hours.

Drug interactions

Amlodipine: The metabolism of amlodipine can be increased when combined with paclitaxel.

Side effects

Common (more than 10%) Alopecia; Anemia; Arthralgia; Diarrhea; Hypotension; Leukopenia; Mucositis; Nausea; Neutropenia; Peripheral neuropathy; Renal impairment; Thrombocytopenia.
Less common (1-10%) Bradycardia
Rare but serious (less than 1%) Congestive heart failure; Dehydration; Grand mal seizures; Left ventricular dysfunction; Pancytopenia; Pyrexia.

Patient educations

Avoid Hair loss is reversible, but new hair may have different color, texture; Do not have immunizations without physician's approval (drug lowers resistance); Avoid crowds, persons with known infections; Report signs of infection at once (fever, flu-like symptoms); Avoid tasks that may require alertness, motor skills until response to drug is established.

Palbociclib

ATC Code: L01EF01 Antineoplastic Agents (Cyclin-Dependent Kinase (CDK) Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Breast cancer: 125 mg once daily for 21 consecutive days followed by 7 days off; repeat every 28 days.

Off-label uses

None.

Contraindications

Hypersensitivity to palbociclib or any component of the formulation.

Cautions

Anemia; Lymphopenia; Neutropenia; Thrombocytopenia; History of pulmonary embolism.
Dose adjustment in renal failure: Use with caution.
Dose adjustment in hepatic failure: Use with caution.

Dosage forms and trade names available in Iraq

- Palbociclib 75mg Tablet
  Ibrance (Pfizer USA).
- Palbociclib 125mg Tablet
  Ibrance (Pfizer USA).

Pharmacokinetic parameters

Absorption F=46%, food increase absorption.
Distribution Vd=2583L, 85%protein bound.
Metabolism Palbociclib is mainly hepatically transformed.
Elimination Feces (~74%, primarily as metabolites); Urine (~18%; primarily as metabolites) with half-life elimination: 29 ± 5 hours.

Drug interactions

Dexamethasone: Dexamethasone will decrease the level or effect of palbociclib by affecting hepatic enzyme CYP3A4 metabolism, strong CYP3A inducers decrease palbociclib plasma exposure by 85%.

Side effects

Common (more than 10%) Alopecia; ALT increased; Anemia; AST increased; Asthenia; Decreased appetite; Diarrhea; Dry skin; Fatigue; Infections; Leukopenia; Nausea; Neutropenia; Neutrophils decreased; Platelets decreased; Pyrexia; Rash; Stomatitis; Thrombocytopenia; Vomiting; WBC decreased.
Less common (1-10%) Dry eye; Dysgeusia; Epistaxis; Lacrimation increased; Vision blurred.
Rare but serious (less than 1%) Febrile neutropenia.

Patient educations

Monitor full blood count prior to starting therapy, at the start of each cycle, on day 14 of the first 2 cycles and as clinically indicated. Take each dose with food. Take palbociclib at the same time each day; if a dose is missed, the missed dose should not be taken and the next dose should be taken at the usual time. Treatment may increase risk of infection; nosebleeds. Drink plenty of fluids.

Paliperidone

ATC Code: N05AX13 Psycholeptics (Other Antipsychotics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: it is excreted in human breast milk,Therefore, infants should be monitored.

Indications and Dosage

Schizophrenia in adults and adolescents aged 15-17 years: the recommended dose is 6 mg once daily in the morning. Dosage may be adjusted in increments of 3 mg/day at intervals of more than 5 days.

Off-label uses

Treatment of bipolar disorder and as an adjunctive treatment for major depressive disorder.

Contraindications

Hypersensitivity to either paliperidone, risperidone, or to any excipients in the formulation; QT Interval Prolongation; Severe Pre-existing GI Stenosis.

Dosage forms and trade names available in Iraq

- Paliperidone 3mg Extended-Release tablets **Invega** (Janssen Cilag Belgium).
- Paliperidone 6mg Extended-Release tablets **Invega** (Janssen Cilag Belgium).
- Paliperidone 9mg Extended-Release tablets **Invega** (Janssen Cilag Belgium).

Cautions

known cardiovascular disease, cerebrovascular disease, or conditions which would predispose patients to hypotension. Paliperidone may induce orthostatic hypotension. D.M.

Dose adjustment in renal failure: mild renal impairment (CrCl = 50–79 mL/min), the starting and maximum dose is 6 mg once daily. moderate to severe renal impairment (CrCl = 10–49 mL/min), the starting dose is 3 mg once daily and the maximum dose is 6 mg once daily.

Dose adjustment in hepatic failure: Not required

Pharmacokinetic parameters

Absorption The absolute oral bioavailability is 28%.

Distribution Vd = 487 L, 74% protein bound.

Metabolism Primarily hepatic, via CYP2D6 to its major active metabolite, risperidone.

Elimination Excretion primarily via urine (59%) and feces (32%) with half-life of 23 hours.

Drug interaction

Levodopa and other dopamine agonists: Paliperidone may antagonize the effect of these drugs.

Strong CYP2D6 inhibitors (e.g., fluoxetine, paroxetine): These can increase plasma concentrations of paliperidone.

Side effects

Common (more than 10%): Insomnia, agitation, anxiety, extrapyramidal symptoms (e.g., tremors, abnormal muscle movements).

Less common (1-10%): Tachycardia, orthostatic hypotension, weight gain, hyperglycemia.

Rare but serious (less than 1%) Neuroleptic malignant syndrome, tardive dyskinesia, severe allergic reactions.

Patient education

1. Paliperidone is used to manage the symptoms of schizophrenia. It won't cure the condition but will help manage symptoms.
2. It can be taken with or without food but must be swallowed whole with liquid and not chewed, crushed, or divided.
3. Notify your healthcare provider if you experience abnormal muscle movements, fever, or if you become pregnant.

Palivizumab

ATC Code: J06BD01 Immune Sera and Immunoglobulins (Antiviral Monoclonal Antibodies)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: It is not known

Indications and Dosage

Palivizumab is indicated as prophylaxis to prevent serious lower respiratory tract INFECTION caused by respiratory syncytial virus (RSV) in pediatric patients with a history of premature birth (≤35 weeks gestational age) and children with bronchopulmonary dysplasia or congenital heart disease. The recommended dosage is 15 mg/kg of body weight given monthly during RSV season.

Dosage forms and trade names available in Iraq

Palivizumab 50mg/0.5ml vial

Synagis (Boehringer Ingelheim Germany).

Palivizumab 100mg/1ml vial

Synagis (Boehringer Ingelheim Germany).

Off-label uses

None.

Contraindications

In patients with a history of severe hypersensitivity reactions to the product.

Cautions

• This drug is not intended for treatment of RSV infection.

• Hypersensitivity reactions including anaphylaxis may occur, often on re-exposure.

Dose adjustment in renal failure: Not required

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Not applicable, as it's administered intramuscularly.

Distribution Vd = 5.7 liters, not significantly protein bound.

Metabolism Metabolism is expected to be via catabolic pathways in a manner similar to endogenous IgG.

Elimination Elimination primarily through catabolism with a half-life of ~20 days.

Drug interaction

No known interactions, due to its biological nature as a monoclonal antibody.

Side effects

Common (more than 10%): Fever, rash.

Less common (1-10%): Nervousness, diarrhea, injection site reactions.

Rare but serious (less than 1%): Anaphylaxis, severe hypersensitivity reactions.

Patient education

• This medication is used to prevent severe lung infections in certain infants and children.

• If your child experiences severe allergic reactions like rash, itching, swelling, severe dizziness, trouble breathing, contact your doctor immediately.

Pancreatin

ATC Code: A09AA02 Digestives, Incl. Enzymes (Enzyme Preparations).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: It is not expected to cause harm however it is still Unknown; use caution.

Dosage forms and trade names available in Iraq

- Pancreatin 150mg (10.000) capsule
  Creon (Abbott Germany).
- Pancreatin 300mg (25.000) capsule
  Creon (Abbott Germany).

Indications and Dosage

• **Pancreatic Insufficiency:** 500 lipase units/kg per meal initially (up to the maximum dose); half the prescribed dose given for an individualized full meal often administered with each snack; total daily dose should reflect approximately 3 meals plus 2 or 3 snacks/day, THE Dose should not exceed 2,500 lipase units/kg per meal; 10,000 lipase units/kg/day; or 4,000 lipase units/g of fat ingested per day.

• **Chronic Pancreatitis or Pancreatectomy:** 72,000 lipase units per meal while consuming at least 100 g of fat per day.

Off-label uses

None.

Contraindications

Hypersensitivity to pancreatin or any component of the formulation, acute pancreatitis, and exacerbation of chronic pancreatitis.

Cautions

Caution is advised in patients with a history of intestinal obstruction, ileus, or fibrosing colonopathy.

Dose adjustment in renal failure: No specific guideline has been provided in renal failure However, monitoring for adverse effects is recommended.

Dose adjustment in hepatic failure: No specific guideline has been provided in hepatic failure, caution is advised, and monitoring for adverse effects is recommended.

Pharmacokinetic parameters

Pharmacokinetic parameters such as absorption, distribution, metabolism, and elimination are not readily available for pancreatin.

Drug interactions

Pancreatin may interact with antacids, proton pump inhibitors, or H2-receptor antagonists, potentially reducing its efficacy. Administering pancreatin at least 2 hours before or after these medications may minimize interactions.

Side effects

Common (more than 10%): Gastrointestinal disturbances such as nausea, abdominal pain, diarrhea, and bloating.

Less common (1-10%): Constipation, flatulence, allergic reactions.

Rare but serious (less than 1%): Fibrosing colonopathy (rarely reported with high doses).

Patient educations

• Take pancreatin exactly as prescribed by your healthcare provider.

• If you experience any unusual or severe gastrointestinal symptoms while taking pancreatin, contact your healthcare provider.

Pancuronium

ATC Code: M03AC01 Muscle Relaxants (Other Quaternary Ammonium Compounds)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

Pancuronium bromide 2mg/ml (2ml amp.)
Alpax (Hikma pharmaceuticals Jordan).

Indications and Dosage

• General anesthesia, cesarean section: By i.v. injection, 0.04mg-0.1mg/kg, maintenance 0.015mg-0.1mg/kg every 30-60 min or continuous infusion 0.1mg/kg/hr.
• Endotracheal intubation: By i.v. injection, 0.06mg-0.1mg/kg within 2-3 min.

Off-label uses

None.

Contraindications

Hypersensitivity to pancuronium; Lack of ventilatory support; neuromuscular disease.

Cautions

Burn injury; Biliary tract disease; Pulmonary disease; Muscular dystrophies; Myasthenia gravis; Myasthenic syndrome; Electrolyte disturbance; Altered pH; Dehydration; CV disease; Edema; Raised catecholamine concentration and those at risk of hypertension.

Dose adjustment in renal failure: CrCl 10-50ml per minute reduce dose to 50% of normal dose; CrCl less than 10ml per minute avoid use.

Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=Undetermined, 80%protein bound.

Metabolism Undergoes hepatic metabolism, converted to 3-hydroxypancuronium.

Elimination Pancuronium elimination half-life is 2 hours.

Drug interactions

Amikacin: Amikacin increases effects of pancuronium by pharmacodynamic synergism, risk of apnea.

Fentanyl: fentanyl and pancuronium. both increases effects of the other by pharmacodynamic synergism, coadministration with other CNS depressants, such as skeletal muscle relaxants, may cause respiratory depression, hypotension, profound sedation, coma.

Side effects

Dose-related tachycardia; Elevations in blood pressure; Excessive salivation; Excessive sweating (in children); Histamine release (bronchospasm, hypotension); Slight elevation in pulse rate; Transient rashes; Wheezing.

Patient educations

Patient education is not currently available for this monograph.

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SDI

Samadol

Samadol Collection, its new look

SAMARRA DRUG INDUSTRY PRODUCTION

SAMADOL (COLD&FLU) DAY
Paracetamol 500mg
Caffeine 25mg
Phenylephrine Hcl 5mg

Decongestant, runny nose, fever and headache

Samadol (ALL IN ONE)
Paracetamol 500mg
Phenylephrine Hcl 5mg
Chlorphenramine Maleate 2mg

Decongestant , runny nose, fever and headache.

Samadol (ADVANCE)
Paracetamol 500mg

For different type of pain

Samadol (RELIEF PAIN)
Paracetamol 325mg
Caffeine anhydrous 50mg
Codeine phosphate 8mg

Headache , toothache, joint pain and migraine.

Samadol (COLD&COUGH)
Paracetamol 250 mg
Phenylephrine 5 mg
Guaifenesin 100

Decongestant, runny nose, fever, chesty cough and headache

Samadol (Night)
Paracetamol 500mg
Diphenhydramine HCL 25mg

Relief of bedtime pain.

Samadol (EXTRA)
Paracetamol 500mg
Caffeine anhydrous 65mg

Relief of pain and discomfort associated with headache, tension, migraine , osteoarthritis,arthritis,cold and flu symptoms, toothache, dental

Samadol (COLD&FLU)
Paracetamol 500mg
Pseudoephedrine 20mg
Chlorpheniramine 2mg

Decongestant, runny nose, fever and headache.

Samadol (Sinus)
Paracetamol 500mg
pseudoephedrine 30mg

Decongestant, sinus pain and headache

Pantoprazole

ATC Code: A02BC02 Drugs for Acid Related Disorders (Proton Pump Inhibitors)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Pantoprazole 20mg tab
- Pantoprazole 40mg tab
- Pantoprazole 40 mg vial

Indications and Dosage

• Erosive esophagitis, GERD: 40mg once daily.
• Gastric hypersecretion: 40mg bid, may titrate to 240 mg daily.
• Zollinger-Ellison syndrome: 40mg bid, may titrate to 240 mg daily.

Off-label uses

Peptic ulcer disease; Active ulcer bleeding; Adjunct in treatment of H. pylori; Stress ulcer prophylaxis in critically ill patients.

Contraindications

Hypersensitivity to pantoprazole.

Cautions

Pantoprazole may increase risk of fractures, GI infections.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=77%, food has no effect on absorption.
Distribution Protein bound 98%.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 71% with a half-life of 1 hr.

Drug interactions

Digoxin: Pantoprazole will increase the level and effect of digoxin by increasing gastric pH.
Erlotinib: Pantoprazole decreases levels of erlotinib, concomitant use of pantoprazole with erlotinib is contraindicated because drugs that alter pH of upper gastrointestinal tract may alter the solubility of erlotinib and reduce its bioavailability.
Nilotinib: Pantoprazole will decrease the level or effect of nilotinib by increasing gastric pH. Nilotinib has a pH-dependent solubility and solubility is decreased at higher pH, separating doses may not eliminate this effect because of pantoprazole extended duration of action.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Chest pain; Constipation; Diarrhea; Facial edema; Flatulence; Generalized edema; Headache; Hyperglycemia; Nausea; Photosensitivity; Pruritus; Rash; Vomiting.
Rare (less than 1%) None.

Patient educations

Report abdominal pain, diarrhea (with or without fever) that does not resolve may indicate colon infection; Avoid alcohol; Best if given before breakfast and may give without regard to food.

Paroxetine

ATC Code: N06AB05 Psychoanaleptics (Selective Serotonin Reuptake Inhibitors)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: It is excreted in breast milk. There is potential for adverse effects in the nursing infant

Dosage forms and trade names available in Iraq

Paroxetine HCL 20mg tab
Paroxat (Hexal Austria).

Indications and Dosage

Paroxetine is indicated for major depressive disorder, panic disorder, social anxiety disorder, generalized anxiety disorder, and posttraumatic stress disorder. Usual dosage for adults is 20mg per day, titrated up according to response and tolerability, with a maximum dose of 50mg per day.

Off-label uses

Treatment of premature ejaculation, chronic headaches, hot flashes associated with menopause, and neuropathic pain.

Contraindications

Hypersensitive to paroxetine and in patients who are taking or have taken (MAOIs) within the last 14 days.

Cautions

Paroxetine may increase the risk of suicidal thoughts and behaviors in children, adolescents, and young adults, careful monitoring is advised. . The drug can also cause serotonin syndrome when used concomitantly with other serotonergic drugs.

Dose adjustment in renal failure: lower dosage or less frequent dosage should be considered because of decreased drug clearance.

Dose adjustment in hepatic failure: lower dosage or less frequent dosage should be considered because of decreased drug clearance.

Pharmacokinetic parameters

Absorption F=50%
Distribution Vd=7.5-15L/kg, 95% protein bound.
Metabolism Hepatic, primarily by CYP2D6 to active metabolite.
Elimination Excretion primarily via feces (64%) and urine (36%) with half-life of 21 hours.

Drug interaction

Monoamine oxidase inhibitors (MAOIs): Concurrent use or use within 14 days of MAOIs increases risk of serotonin syndrome.

Warfarin and other anticoagulants: Paroxetine may potentiate the effect of these drugs, leading to increased bleeding risk.

Side effects

Common (more than 10%): Nausea, dry mouth, decreased appetite, somnolence, sweating, tremor, ejaculation disorder, impotence.

Less common (1-10%): Yawning, diarrhea, abnormal dreams, dizziness, insomnia, nervousness.

Rare but serious (less than 1%): Serotonin syndrome, QT interval prolongation, suicidal thoughts and behavior, angle-closure glaucoma, akathisia.

Pegfilgrastim

ATC Code: L03AA13 Immunostimulants (Colony Stimulating Factors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is not known

Dosage forms and trade names available in Iraq

Pegfilgrastim 6mg in 0.6 ml PFS
Neulastim (Amgen USA).

Indications and Dosage

Pegfilgrastim is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. The recommended dosage is 6 mg administered subcutaneously once per chemotherapy cycle.

Off-label uses

None.

Contraindications

In patients with a history of hypersensitivity to pegfilgrastim or filgrastim.

Cautions

The drug should not be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
Dose adjustment in renal failure: Not required
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Pegfilgrastim is absorbed slowly after subcutaneous injection.
Distribution Pegfilgrastim has a volume of distribution of 150 mL/kg.
Metabolism Not extensively metabolized.
Elimination Neutrophil-mediated clearance, with a half-life of 15 to 80 hours.

Drug interaction

No known significant interactions.

Side effects

Common (more than 10%): Bone pain, extremity pain, headache, musculoskeletal pain.
Less common (1-10%): Injection site reactions, rash, chest pain, cough, dizziness.
Rare but serious (less than 1%): Splenic rupture, Acute Respiratory Distress Syndrome (ARDS), Serious Allergic Reactions, sickle cell crises.

Patient education

1. Pegfilgrastim is used to decrease the risk of infection in patients receiving certain types of chemotherapy.
2. Report symptoms such as abdominal or shoulder tip pain, difficulty breathing, allergy symptoms immediately to a healthcare provider.
3. It's administered as an injection under the skin; do not shake the medication as it may deactivate the drug.

Pembrolizumab

ATC Code: L01FF02 Antineoplastic Agents (PD1-/PDL1- (Programmed Cell Death Protein 1/Death Ligand 1) Inhibitors)
Pregnancy category:
FDA A B C D X **N**
TGA A B1 B2 B3 C **D** X N
Lactation: Avoid.

Indications and Dosage

•Classical Hodgkin lymphoma, microsatellite instability high cancer: By i.v. injection, 200mg every 3 weeks.
• Non–small cell lung, head and neck squamous cell carcinoma, melanoma, urothelial cancer, gastric cancer: By i.v. injection, 200mg every 3 weeks. Continue until disease progression or unacceptable toxicity, or in patients without disease progression for up to 24 months.

Dosage forms and trade names available in Iraq

Pembrolizumab 100mg/4ml vial
Keytruda (MSD Ireland).

Off-label uses

None.

Contraindications

Hypersensitivity to pembrolizumab.

Cautions

Thyroid disease; Interstitial lung disease; Electrolyte imbalance; Hypertriglyceridemia.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=7.5L.
Metabolism Pembrolizumab is catalyzed into small peptides and single amino acids via general protein degradation.
Elimination Pembrolizumab elimination half-life is 26 days.

Drug interactions

Clarithromycin: Clarithromycin may increase concentration and effect of pembrolizumab.
Carbamazepine: Carbamazepine may decrease effects of pembrolizumab.

Side effects

Adrenal insufficiency; Arthritis; Cellulitis; Colitis; Exfoliative dermatitis; Hemolytic anemia; Hepatitis; Hyperthyroidism; Hypophysitis; Hypothyroidism; Myasthenic syndrome; Myositis; Nephritis; Optic neuritis; Pancreatitis; Partial seizures; Pneumonia; Renal failure; Rhabdomyolysis; Sepsis.

Patient educations

Blood levels will be routinely monitored; Avoid pregnancy; treatment may cause birth defects or miscarriage.

Pemetrexed

ATC Code: L01BA04 Antineoplastic Agents (Folic Acid Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Malignant pleural mesothelioma: By i.v. injection, 500mg/m^2 on day 1 of each 21-day cycle.
• Nonsquamous non–small cell lung cancer: By i.v. injection, initial treatment 500mg/m^2 on day 1 of each 21-day cycle, maintenance or second line treatment, 500mg/m^2 on day 1 of each 21-day cycle.

Off-label uses

Treatment of bladder malignancy; Treatment cervical malignancy; Treatment ovarian malignancy; Treatment thymic malignancy; malignant pleural mesothelioma.

Contraindications

Hypersensitivity to pemetrexed.

Cautions

Preexisting myelosuppression.
Dose adjustment in renal failure: CrCl less than 45ml per minute, use of pemetrexed is not recommended.
Dose adjustment in hepatic failure: Use with caution.

Dosage forms and trade names available in Iraq

Pemetrexed 100g vial
Alimta (ELI Lilly Netherland).
Pemetrexed 500mg/20ml vial

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=16.1L, 81%protein bound.
Metabolism Minimal metabolism.
Elimination Renal elimination is 70-90% with half-life of 3.5 hours.

Drug interactions

Celecoxib: Celecoxib increases levels of pemetrexed by unspecified interaction mechanism, interrupt dosing in all patients taking NSAIDs with long elimination half-lives for at least 5 days before, the day of, and 2 days following pemetrexed administration, if coadministration of an NSAID is necessary, closely monitor patients for toxicity, especially myelosuppression, renal toxicity, and gastrointestinal toxicity.

Side effects

Common (more than 10%) Alopecia; Anemia; Anorexia; Constipation; Decreased CrCl; Diarrhea; Elevated creatinine; Fatigue; Nausea; Neutropenia; Rash; Stomatitis; Thrombocytopenia; Vomiting.
Less common (1-10%) Abdominal pain; Chest pain; Conjunctivitis; Dehydration; Dyspepsia; Erythema multiforme; Febrile neutropenia; Fever; Motor or sensory neuropathy; Pruritus; Sensory neuropathy; Taste disturbance; Urticaria.
Rare but serious (less than 1%) Supraventricular arrhythmias.

Patient educations

Maintain strict oral hygiene; Do not have immunizations without physician's approval (drug lowers resistance); Avoid crowds, those with infection; Use contraceptive measures during therapy.

Penicillin

ATC Code: J01CE Antibacterials for Systemic Use (Beta-Lactamase Sensitive Penicillins)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Benzathine benzyl penicillin 0.6 MIU vial
- Benzathine benzyl penicillin 1.2 MIU vial

Indications and Dosage

• **Pneumonia:** By i.m. injection, 1.2 MIU once daily.
• Moderately severe to severe tonsillitis, scarlet fever, upper respiratory tract, skin infections: By i.m. injection, 1 MIU once daily for at least 10 days.
• **Bacterial endocarditis:** By i.m. injection, 1 MIU once daily.
• **Syphilis:** By i.m. injection, 2.4 MIU divided and administered in 2 separate injection sites daily for 8 days.
• **Anthrax:** By i.m. injection, 1MIU once daily.
• **Prevention of rheumatic fever:** By i.m. injection, 1.2 MIU every 3-4 weeks or 0.6 MU twice monthly.

Off-label uses

None.

Contraindications

Hypersensitivity to penicillin.

Cautions

Asthma; Seizure disorder; Prolonged use may result in bacterial or fungal superinfection.

Dose adjustment in renal failure: CrCl 10-50ml per minute reduce dosage to 25% of normal dose; CrCl less than 10ml per minute reduce dosage to 50-70% of normal dose.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption IM absorption is delayed and prolonged and results in sustained therapeutic blood levels.
Distribution Vd=Undetermined, 60% protein bound.
Metabolism ~30% in liver.
Elimination Urine (60-90%), Half-Life: 20-30 minutes

Drug interactions

Cefotaxime: Cefotaxime may decrease the excretion rate of procaine penicillin which could result in a higher serum level.
Doxycycline: The therapeutic efficacy of procaine penicillin can be decreased when used in combination with doxycycline.
Methotrexate: Benzathine penicillin may increase the serum concentration of Methotrexate.
Warfarin: Benzathine penicillin may enhance the anticoagulant effect of warfarin.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Appetite loss; Diaphoresis; Dizziness; Drowsiness; Headache; Malaise; Nausea; Vomiting.
Rare but serious (less than 1%) Arrhythmia; Convulsions; Diarrhea; Eosinophilia; Fatigue; Fever; Itching; Myalgia; Pruritus; Urticaria.

Patient educations

Advise patient taking oral contraceptives to use an additional nonhormonal method of contraception during therapy with penicillin and until next menstrual period; Patient with an allergy to penicillin should be instructed to always carry an identification card with this information.

Perindopril

ATC Code: C09AA04 Agents Acting on The Renin-Angiotensin System (ACE inhibitors, plain)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Perindopril Arginine 5mg tab
  COVERSYL (Les Laboratoires Servier France).
- Perindopril Arginine 10mg tab
  COVERSYL (Les Laboratoires Servier France).

Indications and Dosage

• Hypertension: 5mg-10mg as single dose or bid. Initial dose is usually 5mg once daily for 1-2 weeks, then titrated, (max 15mg daily).

• Reduction of cardiac events and mortality in patients with CAD: Initially, 5mg once daily for 2 weeks, increase to 10mg daily if tolerated.

Off-label uses

Management of heart failure.

Contraindications

Hypersensitivity to perindopril; Idiopathic or hereditary angioedema; Bilateral renal artery stenosis.

Cautions

Hypertrophic cardiomyopathy with outflow tract obstruction; Salt or volume depletion; SLE; Scleroderma; Severe mitral valve and aortic stenosis; Ascites due to cirrhosis; Refractory ascites; Diabetes; Primary aldosteronism; Ischemic heart disease; Patients undergoing major surgery or during anesthesia; Black race.

Dose adjustment in renal failure: CrCl 30-60ml per minute use 2.5mg once daily; CrCl 15-29ml per minute use 2.5mg every other day; CrCl less than 15ml per minute use 2.5mg on dialysis days.

Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=65-75%, food reduce absorption.

Distribution Vd=0.22L/kg, 60%protein bound.

Metabolism Converted by the liver to perindoprilat.

Elimination Perindopril elimination half-life is 3-10 hours.

Drug interactions

Allopurinol: Mechanism of interaction is unknown; Risk of anaphylaxis, Stevens Johnson syndrome.

Ibuprofen: Coadministration may result in a significant decrease in renal function. The mechanism of these interactions related to the ability of NSAIDs to reduce the synthesis of vasodilating renal prostaglandins.

Side effects

Common (more than 10%) Cough; Headache.

Less common (1-10%) Abnormal ECG; ALT increased; Back pain; Chest pain; Depression; Dizziness; Edema; Flatulence; Hyperkalemia; Lower extremity pain; Menstrual disorder; Cough; Headache; Palpitation; Rash; Sexual dysfunction; Sleep disorder; Somnolence; Tinnitus; Vomiting.

Rare but serious (less than 1%) None.

Patient educations

Take this drug with meals.

Pertuzumab

ATC Code: L01FD02 Antineoplastic Agents (HER2 (Human Epidermal Growth Factor Receptor 2) Inhibitors)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Breastfeeding is not recommended during treatment with pertuzumab and for 7 months after the last dose.

Dosage forms and trade names available in Iraq

Pertuzumab 30 mg/ml 420 (14ml vial)

Perjeta (F. Hoffman – La Roche Switzerland).

Indications and Dosage

Pertuzumab is used in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer. The initial dose is a loading dose of 840 mg, followed by 420 mg every 3 weeks thereafter.

Off-label uses

None.

Contraindications

In patients with known hypersensitivity to pertuzumab or to any of its excipients.

Cautions

Pertuzumab can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased left ventricular ejection fraction.

Dose adjustment in renal failure: No adjustment is recommended for patients with mild or moderate renal impairment. There is no information available for patients with severe renal impairment.

Dose adjustment in hepatic failure: No adjustment is recommended for patients with mild or moderate hepatic impairment. There is no information available for patients with severe hepatic impairment.

Pharmacokinetic parameters

Absorption N/A (administered intravenously)

Distribution Volume of distribution (Vd) approximately 3-4 liters.

Metabolism Metabolized by proteolytic enzymes which are not specific to cytochrome P450.

Elimination Predominantly through proteolytic degradation, with a half-life of approximately 18 days.

Drug interaction

Trastuzumab: Both drugs bind to HER2 and are used together for their synergistic effects.

Docetaxel: Used in combination with pertuzumab, but may contribute to neutropenia. Close monitoring of neutrophil counts is recommended.

Side effects

Common (more than 10%): Diarrhea, hair loss, low white blood cell count, rash, fatigue.

Less common (1-10%): Febrile neutropenia, infection, decreased appetite, insomnia, neuropathy, dysgeusia, eye inflammation, palpitations, high blood pressure, epistaxis, cough, dyspnea, dyspepsia, dry skin, muscle pain, joint pain, abnormal kidney function.

Rare but serious (less than 1%): Left ventricular dysfunction, infusion reactions.

Patient education

1. Pertuzumab is used in combination with other medications to treat breast cancer; it's administered as an infusion in a healthcare setting.
2. Report any side effects like diarrhea, hair loss, fatigue or signs of infection to your healthcare provider immediately.

Pethidine

ATC Code: N02AB02 Opioids Analgesics (Phenylpiperidine Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding in single dose.

Dosage forms and trade names available in Iraq

Pethidine HCL 100mg/2ml amp
Pethidine-Hameln (SIEGFRIED Hameln Germany).

Indications and Dosage

• Pain: By i.m. or subcutaneous injection, 50mg-150mg every 3-4 hours or prn.
• Preoperative pain: By i.m. or subcutaneous injection, 50mg-100mg 30-90 min before beginning anesthesia. Continuous infusion 15mg-35mg/hour.
• Obstetrical analgesia: By i.m. or subcutaneous injection, 50mg-100mg repeated every 1-3 hours or prn.

Off-label uses

None.

Contraindications

Hypersensitivity to pethidine; Severe respiratory insufficiency.

Cautions

Sickle cell anemia; Acute alcoholism; Addison disease; CNS depression; Coma; Delirium tremens; Debilitated patients; Myxedema; Hypothyroidism.

Dose adjustment in renal failure: Use of pethidine in severe renal failure is contraindicated.

Dose adjustment in hepatic failure: Use of pethidine in severe hepatic failure is contraindicated.

Pharmacokinetic parameters

Absorption F=80-85%.

Distribution Vd=Undetermined, 60-80% protein bound.

Metabolism Pethidine is metabolized in the liver by hydrolysis to meperidinic acid followed by partial conjugation with glucuronic acid.

Elimination Renal elimination is 5% with half-life of 3-6 hours.

Drug interactions

Central nervous system depressants: central depressant effects of pethidine may be potentiated by the concurrent use of other central nervous system depressants including anxiolytics and sedatives, hypnotics, barbiturates and tricyclic antidepressants, other analgesics, alcohol and general anesthetics.

Side effects

Common (more than 10%): Dizziness or Lightheadedness; Drowsiness; Nausea or Vomiting; Sweating.

Less Common (1-10%): Constipation; Dry mouth; Headache; Mood changes; Itching or rash; Weakness

Rare but Serious (less than 1%): Slowed or difficulty breathing; Fainting; Seizures; Allergic reactions such as rash, itching.

Patient educations

Avoid alcohol, antihistamines, sedatives and tranquilizers; Report severe nausea, vomiting, constipation, shortness of breath, or difficulty breathing.

Phenobarbital

ATC Code: N03AA02 Antiepileptics (Barbiturates and Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Epilepsy: 60mg bid-tid.
• Daytime sedation: 30mg-120mg bid-tid, (max 400mg daily).

Off-label uses

Treatment of alcohol withdrawal; Sedative and hypnotic withdrawal; Prevention and treatment of hyperbilirubinemia.

Contraindications

Hypersensitivity to phenobarbital; Porphyria; Dyspnea or airway obstruction; Patients with history of sedative drug addiction.

Cautions

Acute or chronic pain; Depression; Suicidal tendencies; History of drug abuse; Elderly patients; Children; Hemodynamically unstable patients; Hypoadrenalism; Respiratory disease.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Phenobarbital 15mg tablet
  Luminal-Kindi (SDI Iraq).
- Phenobarbital 30mg tablet
  Luminal-Kindi (Alkindi Iraq).

Pharmacokinetic parameters

Absorption F=80-100%, food has no effect on absorption.
Distribution Vd=0.5-1L/kg, 20-60% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 21% with a half-life of 1.5-4.9 days.

Drug interactions

Lorazepam: Lorazepam may increase effects of phenobarbital.

Side effects

Ataxia; Constipation; Diarrhea; Dizziness; Drowsiness; Dysarthria; Fatigue; Headache; Hepatotoxicity; Hypocalcemia; Irritability; Megaloblastic anemia; Mental dullness; Nausea; Nystagmus; Osteomalacia; Paresthesia restlessness; Rash; Respiratory depression; Rickets; Stevens-Johnson syndrome; Vertigo; Vomiting.

Patient educations

Avoid alcohol, limit caffeine; May be habit-forming; Do not discontinue abruptly; May cause dizziness, drowsiness; Avoid tasks that require alertness, motor skills until response to drug is established.

Phenylephrine

ATC Code: R01AA04 Decongestants and Sympathomimetics.

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available; Phenylephrine may decrease milk production.

Indications and Dosage

• Nasal decongestant: 2-3 drops into each nostril every 4 hr or as needed, do not use for more than 3 days.

Off-label uses

Topical vasoconstriction in nasal physical examination and nasal procedures.

Contraindications

Hypersensitivity to phenylephrine; Use for > 3 days.

Cautions

Asthma; Cardiac disease; Ischemic heart disease; Hypertension; Increased intraocular pressure; Prostatic hyperplasia.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Phenylephrine Hcl 1% nasal drop
Nasofen (Pioneer Iraq).

Phenylephrine Hydrochloride 0.25% nasal drops
Nasofen (Pioneer Iraq).

Pharmacokinetic parameters

Absorption Undetermined.

Distribution Vd=340L.

Metabolism Metabolized by the liver and other tissues.

Elimination Renal elimination is 86% with half-life of 2.5 hours.

Drug interactions

Amitriptyline: Amitriptyline increase or decrease effects of phenylephrine by blocking reuptake of NE, or blocking uptake of indirect sympathomimetics into the adrenergic neuron.

Alpha1-Blockers: May diminish the vasoconstricting effect of Alpha1-Agonists. Similarly, Alpha1-Agonists may antagonize Alpha1-Blocker vasodilation.

Monoamine Oxidase Inhibitors: May enhance the hypertensive effect of Alpha1-Agonists.

Side effects

Anxiety; Burning; Decreased renal perfusion; Extravasation; Gastric irritation; Headache; Hypertension; Metabolic acidosis; Nausea; Pulmonary edema; Rebound congestion; Reduced urine output; Reflex bradycardia; Sneezing.

Patient educations

Discontinue drug if adverse reactions occur; Do not use for nasal decongestion for longer than 3 days (rebound congestion); Discontinue drug if insomnia, dizziness, weakness, tremor, palpitations occur; Discontinue medication if redness, swelling of eyelids, itching occurs.

Phenytoin

ATC Code: N03AB02 Antiepileptics (Hydantoin Derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Low concentration excreted in breast milk.

Indications and Dosage

• Seizure, generalized tonic-clonic, complex partial, or following neurosurgery: 100mg tid, may titrate to 200mg tid.

Off-label uses

Arrhythmias; Severe preeclampsia; Trigeminal neuralgia.

Contraindications

Hypersensitivity to phenytoin; Second and third degree AV block; Sinoatrial block; Sinus bradycardia; Adams Stokes syndrome.

Cautions

Porphyria; Patients at increased risk of suicidal behavior and thoughts; Elderly patients; Low serum albumin; Cardiac disease; Hypothyroidism.

Dose adjustment in renal failure: Do not use oral loading dose. Can begin with standard maintenance dose and adjust as needed.

Dose adjustment in hepatic failure: Do not use oral loading dose. Consider using decreased maintenance dose.

Lactation: Low concentration excreted in breast milk.

Dosage forms and trade names available in Iraq

Phenytoin Sodium 250mg/5ml amp

Pharmacokinetic parameters

Absorption F=70-100%, food increase absorption.

Distribution Vd=0.75L/kg, 88-93% protein bound.

Metabolism Extensive hepatic metabolism.

Elimination Renal elimination with a half-life of 7-42 hours.

Drug interactions

Calcium containing antacids: Calcium containing antacids may decrease absorption of phenytoin.

Increase metabolism of **Benzodiazepine, Abatacept, Abacavir, Acalabrutinib, Abemaciclib, Abiraterone, Abrocitinib,** increase serum concentration of **Abametapir**

Side effects

Altered taste sensation;Ataxia;Atrioventricular conduction disorder;CNS depression; Constipation;Diplopia;Dizziness;Drowsiness;Drug withdrawal seizure;Dysarthria;Dyskinesia; Encephalopathy;Headache; Hepatotoxicity; Hypertrichosis; Hypocalcemia; Hypotension;Megaloblastic anemia;Nausea;Nephrotoxicity;Nervousness; Nystagmus;Osteomalacia;Paresthesia;Pruritus;Psychosis.

Patient educations

Serum levels should be performed every month for 1 year after maintenance dose is established and every 3 months thereafter; Report sore throat, fever, glandular swelling, skin reaction (hematologic toxicity); Drowsiness usually diminishes with continued therapy; Avoid tasks that require alertness, motor skills until response to drug is established; Do not abruptly withdraw medication after long-term use (may precipitate seizures); Strict maintenance of drug therapy is essential for seizure control; Avoid alcohol; Report any unusual changes in behavior.

General
medicines

Liquid Dosage Form

Dubai Pharmaceutical Industries

DUBAI

DUFEED
Pseudoephedrine HCL 30 mg
Triprolidine HCL 1.5 mg

Dexaphar
Dexamethasone 0.5mg

SEDIPHAR
Dextromethorphan HCl 15mg

Solvohexin
Bromhexine hydrochloride 4 mg

DuAntipyro
Paracetamol 250 mg

DuAntipyro
Paracetamol 120 mg

Butaphar
Salbutamol 2mg

Du-COLDIN
Paracetamol 120mg
Chlorpheniramine maleate 2 mg

Exiphar
Theophylline 50 mg
Glyceryl guaiacolate 30 mg

DuAllerm
Diphenhydramine HCl 10 mg

DuTesseleen
Glyceryl Guaiacolate 50mg
Chlorpheniramine Maleate 1mg
Phenylephrine HCl 2.5mg

Samiluxin
Diphenhydramine HCl 13.5 mg
Ammonium Chloride 131.5 mg
Sodium Citrate 55 mg
Menthol 1 mg

Pulmocod
Glyceryl Guaiacolate 100mg
Chlorpheniramine Maleate 1mg
Phenylephrine HCl 5mg
Codeine Phosphate 10mg

Phytomenadione

ATC Code: B02BA01 Antihemorrhagics (Vitamin K).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Considered compatible with breastfeeding when used at recommended doses.

Dosage forms and trade names available in Iraq

Phytomenadione 10mg/1ml Solution for Injection

Indications and Dosage

• **Nutritional Supplementation:** Recommended daily intake (RDA): Males: 120 mcg/day PO; Females: 90 mcg/day PO.
• **Hypoprothrombinemia:** 2.5-10 mg PO/SC; may be increased PRN to 25 mg or, rarely, to 50 mg; may be repeated in 12-48 hours.
• **Reversal of Warfarin Effects:** Omit 1-2 doses, or hold warfarin; monitor INR and adjust warfarin dose accordingly.

Off-label uses

None.

Contraindications

hypersensitivity or anaphylaxis and include shock and cardiac or respiratory arrest (Black Box Warnings) and severe liver disease.

Cautions

Caution is advised in patients with a history of thromboembolic events, as excessive administration of phytomenadione may lead to hypercoagulability.
Dose adjustment in renal failure: No specific dose adjustment is typically required in renal failure. However, monitor for potential adverse effects.
Dose adjustment in hepatic failure: No specific dose adjustment is typically required in hepatic failure. However, caution is advised, and monitoring for potential adverse effects is recommended.

Pharmacokinetic parameters

Absorption Phytomenadione is absorbed from the gastrointestinal tract, Onset: 6-10 hr (PO); 1-2 hr (IV); Peak effect: 24-48 hr (PO); 12-14 hr (IV).
Distribution It is distributed to the liver and other tissues.
Metabolism Phytomenadione is metabolized in the liver.
Elimination Excretion occurs mainly via bile, with a half-life of about 1-2 hours.

Drug interactions

• Phytomenadione may antagonize the effects of oral anticoagulants such as warfarin, potentially leading to reduced anticoagulant efficacy. Close monitoring of coagulation parameters is necessary.
• Concomitant use of phenobarbital or other enzyme-inducing antiepileptic drugs may increase the metabolism of phytomenadione, leading to reduced efficacy.

Side effects

Common (more than 10%): Injection site reactions such as pain, swelling, and redness.
Less common (1-10%): Hypersensitivity reactions, flushing, transient hypotension, Taste alterations.
Rare but serious (less than 1%): Anaphylaxis, thromboembolic events, Erythematous skin eruptions, cardiac or respiratory arrest.

Pilocarpine

ATC Code: N07AX01 Parasympathomimetics (Other Parasympathomimetics).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Pilocarpine should be used cautiously during lactation.

Dosage forms and trade names available in Iraq

Pilocarpine Hcl 20mg/1ml Sterile eye drop

Indications and Dosage

• **Intraocular Hypertension:** Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension: One drop of 1%, 2%, or 4% solution applied in the eye(s) up to four times a day.
• **Glaucoma (Narrow Angle):** One drop of the 1% or 2% solution applied in the eye(s) up to three times over a 30-minute period.

Off-label uses

Xerostomia (dry mouth): (5 mg PO q8hr) and Sjogren's syndrome: (5 mg PO q6hr)

Contraindications

Hypersensitivity to pilocarpine or any component of the formulation.

Cautions

Patients with cardiovascular disease, asthma, or chronic obstructive pulmonary disease (COPD), as pilocarpine may exacerbate these conditions.
Dose adjustment in renal failure: No specific guideline has been provided in renal failure.
Dose adjustment in hepatic failure: Moderate impairment (Child-Pugh score of 7-9): 5 mg PO BID followed by adjustment based on therapeutic response and tolerability, Severe impairment (Child-Pugh score of 10-15): Not recommended.

Pharmacokinetic parameters

Absorption Pilocarpine is well-absorbed after ocular administration.
Distribution Pilocarpine distributes widely throughout the body.
Metabolism Pilocarpine undergoes hepatic metabolism.
Elimination Excretion occurs mainly via urine with a half-life of approximately 1-2 hours.

Drug interactions

• Pilocarpine may enhance the effects of other cholinergic agents, potentially leading to additive adverse effects such as bradycardia or bronchoconstriction.
• Concomitant use of anticholinergic medications may antagonize the effects of pilocarpine, reducing its efficacy in treating glaucoma.

Side effects

Common (more than 10%): Ocular irritation, brow ache, headache, visual disturbances.
Less common (1-10%): Systemic cholinergic effects such as sweating, salivation, and gastrointestinal disturbances, Asthenia, Amblyopia.
Rare but serious (less than 1%): bradycardia, bronchoconstriction, and exacerbation of asthma or COPD.

Patient educations

• Be aware of potential side effects, especially ocular irritation and systemic cholinergic effects.

Pimecrolimus

ATC Code: D11AH02 Other Dermatological Preparations (Agents for Dermatitis, Excluding Corticosteroids)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 **B3** C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Atopic dermatitis (eczema): Apply to affected area bid.

Off-label uses

None.

Contraindications

Hypersensitivity to pimecrolimus; Netherton's syndrome; Application to active cutaneous viral infections.

Cautions

Cutaneous T-cell lymphoma; Severe atopic dermatitis; Generalized erythroderma; Netherton's Syndrome.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Pimecrolimus 10mg/1g 1% cream

Elidel (MEDA Pharma Germany).

Pharmacokinetic parameters

Absorption Minimally absorbed through intact skin.

Distribution Vd=Undetermined, 74-87%protein bound.

Metabolism Systemic metabolism is negligible with local application.

Elimination Excretion is negligible with local application.

Drug interactions

Clobetasol: The risk or severity of adverse effects can be increased when pimecrolimus is combined with clobetasol.

Side effects

Common (more than 10%) Bronchitis; Fever; Cough; Burning sensation; Upper respiratory tract infection; Headache; Nasopharyngitis.

Less common (1-10%) Basal cell carcinoma of skin; Eczema; Flushing; Malignant lymphoma; Malignant melanoma; Ocular irritation; Septic arthritis; Skin discoloration; Squamous cell carcinoma.

Rare but serious (less than 1%) Application site pain; Desquamation; Dryness; Paresthesia; Rash; Skin infection.

Patient educations

• Instruct patient on correct technique for application; Apply only as directed to external areas; Wash hands following application, unless hands are areas of application; Caution patient to avoid exposure to natural sunlight while using cream; Advise patient that pimecrolimus may cause skin burning this occurs most commonly during first few days of application, is of mild to moderate severity, and improves within 5 days or as atopic dermatitis resolves; Advise patient to notify health care provider if no improvement is seen following 6 weeks of treatment or at any time if condition worsens.

• Should not discontinuation Pimecrolimus without talking with the doctor who prescribed it.

Pioglitazone

ATC Code: A10BG03 Drugs Used in Diabetes (Thiazolidinediones)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Diabetes mellitus (type 2): 15mg-30mg daily, (max 45mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to pioglitazone; Established New York Heart Association Class III or IV heart failure.

Cautions

Edema; Symptomatic heart failure; Female patients of childbearing age.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use cautiously.

Dosage forms and trade names available in Iraq

- Pioglitazone 15mg tablet
  ACTOS® (APM Jordan).
- Pioglitazone 30mg tablet
  ACTOS® (APM Jordan).

Pharmacokinetic parameters

Absorption F=50%, food delays but does not reduce absorption.
Distribution Vd=0.63L/kg, 99% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 15-30% with a half-life of 16-24 hr.

Drug interactions

Atorvastatin: Pioglitazone increases toxicity of atorvastatin by increased risk of myopathy.
Pregabalin: Pregabalin May enhance the fluid retaining effect of pioglitazone.
Topiramate: Topiramate may decrease the serum concentration of pioglitazone.

Side effects

Common (more than 10%) Edema when used in combination with sulfonylurea or insulin; Hypoglycemia; Upper respiratory infection.
Less common (1-10%) Fracture of bone; Headache; Heart failure; Myalgia; Pharyngitis; Sinusitis.
Rare but serious (less than 1%) Anemia; Hepatotoxicity; Diabetic macular edema; Bladder cancer.

Patient education

Be alert for signs and symptoms of hypoglycemia and take measures to manage it; Avoid alcohol; Report chest pain, palpitations, abdominal pain, fever, rash, hypoglycemic reactions, yellowing of skin or eyes, dark urine, light stool, nausea, vomiting; Report any change in vision; Report rapid weight gain, edema, difficulty breathing.

Piperacillin

ATC Code: J01CA12 Antibacterials for Systemic Use (Penicillins with Extended Spectrum).

Pregnancy category:

FDA A **B** C D X N

TGA A **B1** B2 B3 C D X N

Lactation: should be avoided unless the benefits outweigh the risks.

Dosage forms and trade names available in Iraq

Piperacillin sodium 1g/vial

PIPRACILLIN (Panpharma France).

Indications and Dosage

• **Urinary Tract, Uncomplicated and Community-Acquired Pneumonia:** 6-8 g/day IV/IM (100 to 125 mg/kg/day) divided q6-12 hr.

• **Acute Cholangitis:** 4 g IV q6hr.

• **Moderate Infections:** 2-3 g/dose IV/IM q6-12hr; not to exceed 2 g IM/site.

• **Severe Infections:** 3-4 g IV/IM q4-6hr; not to exceed 24 g/24 hr

• **Uncomplicated Gonorrhea:** 2 g once with 1 g probenecid 30 min before injection.

• **Pseudomonas Infections:** 4 g IV/IM q4hr.

Off-label uses

None.

Contraindication

Known hypersensitivity to piperacillin or beta-lactam antibiotics and a history of severe allergic reactions (e.g., anaphylaxis) to beta-lactams.

Caution

History of allergies or hypersensitivity reactions to other beta-lactam antibiotics, as cross-reactivity may occur.

Dose adjustment in renal failure: : CrCl 20-40 mL/min: 3-4 g q8hr and if CrCl <20 mL/min: 3-4 g q12hr.

Dose adjustment in hepatic failure: No specific dose adjustment is typically needed, but close monitoring for adverse effects is recommended.

Pharmacokinetic parameters

Absorption 70-80% (IM).

Distribution Crosses placenta, Protein Bound: 16%

Metabolism Piperacillin is primarily eliminated unchanged via renal excretion.

Elimination it has a short half-life, typically around 1 hour in adults with normal renal function.

Drug interaction

• Concurrent use of nephrotoxic drugs (e.g., aminoglycosides) may increase the risk of renal toxicity when used with piperacillin.

• piperacillin will increase the level or effect of heparin by anticoagulation. Avoid or Use Alternate Drug, as piperacillin can inhibit platelet aggregation.

Side effects

Common (more than 10%): Diarrhea,nausea, vomiting,rash,allergic reactions (e.g., pruritus, urticaria).

Less common (1-10%): Headache, dizziness, and gastrointestinal disturbances.

Rare but serious (less than 1%): anaphylaxis, pseudomembranous colitis, Interstitial nephritis.

Patient education

Be aware of potential side effects such as diarrhea, rash, or allergic reactions, and notify your healthcare provider if they occur, and take and complete the full course of treatment, even if you start to feel better.

Piracetam

ATC Code: N06BX03 Psychoanaleptics (Other Psychostimulants and Nootropics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Caution is recommended.

Indications and Dosage

• Cognitive disorders: Initial 4.8 to 9.6 g/day in 2 to 3 divided doses, may increase to a maximum of 20 g/day based on clinical response and tolerability.

Off-label uses

Some people use piracetam for memory and learning enhancement, cognitive disorders and dementia.

Contraindication

Hypersensitivity to piracetam or pyrrolidone derivatives.

Caution

In severe renal impairment, Uncontrolled hemorrhage
History of psychiatric disorders.
Dose adjustment in renal failure: reduction is required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Piracetam 333.3mg/ml Oral solution
Pacetam (Pharma Developpement France).

Pharmacokinetic parameters

Absorption Well absorbed after oral administration.
Distribution Not protein bound.
Metabolism Does not undergo metabolism.
Elimination Mainly via the kidneys; half-life is 4-5 hours in adults, but it can be prolonged in elderly patients due to decreased renal function.

Drug interaction

Anticoagulants or antiplatelet drugs: May increase the risk of bleeding.
Cytotoxic agents: May antagonize the effect of piracetam on platelet aggregation.

Side effects

Common (more than 10%): Weight gain, nervousness.
Less common (1-10%): Sleep disturbances, headache, agitation, nausea.
Rare but serious (less than 1%): Hemorrhage, depression, hallucinations.

Patient education

• Report any unusual side effects such as bleeding, depression or hallucinations to your healthcare provider immediately.
• It is important to stay hydrated while taking piracetam as it is primarily excreted in urine.

Piroxicam

ATC Code: M01AC01 Antiinflammatory and Antirheumatic Products (Oxicams)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Osteoarthritis; Short term pain; Rheumatoid arthritis; Ankylosing spondylitis: Initially, 10mg-20mg as a single dose or in divided doses (20mg orally every day or bid) no more than 30mg-40mg/day.

Off-label uses

Treatment of acute gouty arthritis.

Contraindications

Hypersensitivity to piroxicam; Active peptic ulcer disease; Gastrointestinal bleeding or ulceration; Elevated blood pressure; Ischemic heart disease; Stroke.

Cautions

Asthma; Coagulation disorders.

Dose adjustment in renal failure: Use of piroxicam in sever renal failure is not recommended.

Dose adjustment in hepatic failure: If liver disease develops or if systemic manifestations such as eosinophilia or rash occur, piroxicam should be discontinued.

Dosage forms and trade names available in Iraq

- Piroxicam 10 mg Capsule
  SAFAXICAM (SAFA IRAQ).
- Piroxicam 20mg Capsule
  SAFAXICAM (SAFA IRAQ).

Pharmacokinetic parameters

Absorption Food delayed rate of absorption.

Distribution Vd=0.14L/kg, 99%protein bound.

Metabolism Extensively metabolized in the liver via hydroxylation of the pyridyl ring side chain followed by conjugation with glucuronic acid.

Elimination Piroxicam and its biotransformation products are excreted in urine and feces, with about twice as much appearing in the urine as in the feces. Approximately 5% of a piroxicam dose is excreted unchanged.

Drug interactions

Captopril: Coadministration may result in a significant decrease in renal function. NSAIDs may diminish the antihypertensive effect of ACE inhibitors. The mechanism of these interactions is likely related to the ability of NSAIDs to reduce the synthesis of vasodilating renal prostaglandins.

Side effects

GIT upset (nausea, anorexia, vomiting, epigastric pain, heart burn; diarrhea, constipation); Dizziness; Drowsiness; Headache; Tinnitus; Elevation of blood pressure; Edema; Pruritus.

Patient educations

Avoid aspirin, alcohol during therapy (increases risk of gastrointestinal bleeding); Take without food (only patients with GIT problems are recommended to take piroxicam WITH food), milk, antacids; Avoid tasks that require alertness until response to drug is established.

Pizotifen

ATC Code: N02CX01 Analgesics (Other Antimigraine Preparations)

Pregnancy category:
FDA A B C D X **N**
TGA A **B1** B2 B3 C D X N

Lactation: It is unknown.

Indications and Dosage

• Prophylactic treatment of recurrent vascular headaches, including classical migraine, common migraine and cluster headache: 0.5mg tid, (max 4.5mg daily).
• Stimulate appetite: 0.25mg tid.

Off-label uses

Used to manage cyclic vomiting syndrome and night terrors in some cases, although evidence is limited.

Contraindications

Hypersensitivity to pizotifen, concurrent use of MAO inhibitors, gastric outlet obstruction, use in children <12 years of age.

Cautions

Angle closure glaucoma; Urinary retention; Epilepsy; prostatic hyperplasia.
Dose adjustment in renal failure: No specific guidelines available, use with caution.
Dose adjustment in hepatic failure: No specific guidelines available, use with caution.

Dosage forms and trade names available in Iraq

Pizotifen (as maleate) 0.5mg/10ml Syrup
ROUZADIN (Wadi Al-Rafidain Iraq).

Pharmacokinetic parameters

Absorption F=78%.
Distribution Vd: Parent drug: 833 L; N-glucuronide metabolite: 70 L - 90%protein bound.
Metabolism Pizotifen is extensively metabolized in the liver (mainly by glucuronidation).
Elimination Renal elimination is 1% with half-life of 23 hours.

Drug interactions

Diazepam: The central effects of sedatives may be enhanced by pizotifen.
MAOIs: Co-administration may lead to hypertensive crisis or potentially fatal reactions.

Side effects

Common (more than 10%): Appetite stimulant; Increase in body weight. Drowsiness
Less common (1-10%): Dizziness; Dry mouth; Fatigue; Nausea.
Rare but serious (less than 1%): Aggression; Agitation; Anxiety; Arthralgia; Depression; Face oedema; Hallucination; Insomnia; Myalgia; Paresthesia; Rash; Urticaria; Paresthesia; Rash; Urticaria.

Patient educations

This medication can cause drowsiness; avoid driving or operating machinery until you know how pizotifen affects you; Weight gain and increased appetite are common; maintain a healthy diet and exercise regularly; Do not stop taking this medication abruptly as it may lead to withdrawal symptoms. Always follow your doctor's instructions.

Plerixafor

ATC Code: L03AX16 Immunostimulants (Other Immunostimulants)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Caution is advised.

Indications and Dosage

Stem Cell Transplantation: 0.24 mg/kg s.c. every day; repeat up to 4 consecutive days; not to exceed 40 mg/day.

Off-label uses

None.

Contraindications

Hypersensitivity.

Cautions

patients with renal impairment.
Dose adjustment in renal failure: reduction with renal impairment.
Dose adjustment in hepatic failure: No data available.

Dosage forms and trade names available in Iraq

Plerixafor 24 mg vial

Pharmacokinetic parameters

Absorption Well absorbed, bioavailability is high.
Distribution Vd= approximately 0.3 L/kg.
Metabolism Not significantly metabolized.
Elimination Primarily excreted unchanged in urine; the half-life is 3 to 5 hours.

Drug interaction

No major interactions known for plerixafor.

Side effects

Common (more than 10%): Diarrhea, nausea, fatigue, injection site reactions, headache.
Less common (1-10%): Vomiting, dizziness, arthralgia.
Rare but serious (less than 1%): Splenic rupture, acute renal failure.

Patient education

• This drug may cause side effects such as nausea and vomiting. Report these symptoms to your healthcare provider.
• Report any unexplained pain, especially in the left upper stomach area or shoulder tip, to your healthcare provider immediately.

Potassium Chloride

ATC Code: B05XA01 Blood Substitutes and Perfusion Solutions (Electrolyte solutions)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding; Use potassium chloride only if essential.

Indications and Dosage

• Hypokalemia: By i.v. infusion, 40mEq-100mEq at a rate not exceed 10mEq-40mEq/hr.

Off-label uses

None.

Contraindications

Hyperkalemia; Conditions in which potassium retention is present.

Cautions

Cardiac disease; Acid-base disorders; Potassium altering disorders; Digitalized patients; Do not administer i.v. undiluted.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Potassium chloride 1.5gm/10ml Ampule

Potassium chloride (PIONEER IRAQ).

Pharmacokinetic parameters

Absorption Well and readily absorbed from gastrointestinal tract.

Distribution Undetermined.

Metabolism Undetermined.

Elimination Excreted by the kidneys.

Drug interactions

Spironolactone: spironolactone and potassium chloride both increase serum potassium.

Side effects

Arrhythmias; Bleeding; Diarrhea; Dyspepsia; Hyperkalemia; Nausea; Rash; Vomiting; Flatulence; Abdominal pain; Perforation; Gastrointestinal obstruction; Gastrointestinal ulceration; Gastrointestinal perforation; Hyponatremia; Hyponatremic encephalopathy.

Patient educations

Foods rich in potassium include beef, chicken, fish, milk, bananas, dates, avocados, watermelon, cantaloupe, apricots, beans, broccoli, lentils, potatoes, spinach; Report paresthesia, feeling of heaviness of lower extremities, tarry or bloody stools, weakness, unusual fatigue.

Povidone Iodine

ATC Code: D08AG02 Antiseptics and Disinfectants (Iodine Products)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C D X **N**

Lactation: Generally safe as only small amounts are absorbed.

Dosage forms and trade names available in Iraq

Povidone Iodine 10% solution
Povidone Iodine Kindi (Al-Kindi Iraq).

Povidone iodine 7.5g/100ml (7.5%) Solution
Povidone Iodine Kindi (Al-Kindi Iraq).

Indications and Dosage

• Topical antiseptic: Apply to clean wound prn.

• Treatment of acute infections of the lining of the mouth and throat, inflammation of the gums (gingivitis) and mouth ulcers, for cleansing the mouth (oral hygiene) before, during and after dental and mouth surgery: Use orally as a gargle and mouthwash undiluted for up to 30 seconds without swallowing, repeat up to qid, for up to 14 days.

Off-label uses

None.

Contraindications

Hypersensitivity to povidone iodine; thyroid disease.

Cautions

Serious wounds including burns; thyroid disease

Dose adjustment in renal failure: Not typically required.

Dose adjustment in hepatic failure: Not typically required.

Pharmacokinetic parameters

Absorption Povidone-Iodine is intended for topical application and is not absorbed.

Distribution N/A

Metabolism N/A

Elimination Not applicable for topical administration

Drug interactions

Lithium: Concurrent use can lead to additive hypothyroid effect.

Radioactive iodine: Povidone-iodine can decrease the effectiveness of radioactive iodine therapy.

Side effects

Common (more than 10%) Local skin irritation.

Less common (1-10%) Rash, itching, skin discoloration; Severe pain on application

Rare but serious (less than 1%) Severe allergic reactions, kidney problems with prolonged use. Hypothyroidism in neonates

Patient educations

Apply only to the affected area as directed by a healthcare provider; Avoid contact with the eyes; Stop use and consult a doctor if the condition persists or gets worse after 3 days.

Pramipexole

ATC Code: N04BC05 Anti-Parkinson Drugs (Dopamine Agonists)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Caution is advised.

Dosage forms and trade names available in Iraq

- Pramipexole 0.25mg tablet
- Pramipexole 0.375mg tablet
- Pramipexole 0.52mg prolonged release tablet
  Motorax (Ferrer Internacional Spain).
- Pramipexole 1.05g prolonged release tablet
  Motorax (Ferrer Internacional Spain).
- Pramipexole 2.1g prolonged release tablet
  Motorax (Ferrer Internacional Spain).

Indications and Dosage

• Parkinson's Disease: Initial, 0.375 mg/day given in three divided doses. Titrate gradually. Maintenance, 1.5-4.5 mg/day.
• Restless Legs Syndrome: Initial, 0.125 mg once daily 2-3 hours before bedtime. Maintenance, up to 0.5 mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to pramipexole.

Cautions

May cause orthostatic hypotension, hallucinations, dyskinesia, and impulse control disorders. Use with caution in patients with renal impairment.
Dose adjustment in renal failure:
• Very severe renal impairment (CrCl less than 15 mL/min): Not recommended
• Severe renal impairment (CrCl 15 to less than 30 mL/min): Initial dose: 0.125 mg orally once a day; titrate gradually at intervals of no more frequently than every 5 to 7 days to a maximum dose of 1.5 mg once a day; Maximum dose: 1.5 mg once per day
• Moderate renal impairment (CrCl 30 to 50 mL/min): Initial dose: 0.125 mg orally twice a day; titrate gradually at intervals of no more frequently than every 5 to 7 days to a maximum dose of 0.75 mg 3 times a day; Maximum dose: 2.25 mg per day
• Normal to mild renal impairment (CrCl greater than 50 mL/min): No adjustment recommended
Dose adjustment in hepatic failure: Not required

Pharmacokinetic parameters

Absorption Well absorbed, F = over 90%
Distribution Vd = approximately 500 L, less than 20% protein bound.
Metabolism Minimal metabolism.
Elimination Excreted primarily unchanged by the kidneys; the half-life is approximately 8 hours.

Drug interaction

Cimetidine: May increase the levels/effects of pramipexole. Monitor therapy.
Antipsychotics (e.g., haloperidol, risperidone): May diminish the therapeutic effect of pramipexole.

Side effects

Common (more than 10%): Nausea, dizziness, somnolence, insomnia, constipation, fatigue, and hallucination.
Less common (1-10%): Orthostatic hypotension, dyskinesia, peripheral edema, headache, dry mouth.
Rare but serious (less than 1%): Impulse control disorders, rhabdomyolysis.

Patient educations

This medication can cause drowsiness and may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert.

Prasugrel

ATC Code: B01AC22 Antithrombotic Agents (Platelet Aggregation Inhibitors Excl. Heparin)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available

Indications and Dosage

Acute coronary syndrome managed with PCI: Initial dose of 60mg, then 10mg once daily. Patients weighing less than 60kg should receive a 5mg maintenance dose.

Off-label uses

None.

Contraindications

Active pathological bleeding.
history of stroke or transient ischemic attack.

Cautions

Bleeding risk , Surgery or invasive procedures, concurrent use with drugs that increase risk of bleeding.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Prasugrel Hydrochloride 5mg Tablet
- Prasugrel Hydrochloride 10mg Tablet

Pharmacokinetic parameters

Absorption Rapid absorption, F=79%.
Distribution Vd= 44 L, 98% protein bound.
Metabolism Rapidly metabolized to active metabolite in the intestine and liver.
Elimination Eliminated in urine (68%) and feces (27%) with a half-life of 7 hours for the active metabolite.

Drug interaction

Warfarin: Increased risk of bleeding.
Nonsteroidal anti-inflammatory drugs (NSAIDs): Increased risk of bleeding.

Side effects

Common (more than 10%): Bleeding.
Less common (1-10%): Hypertension, hyperlipidemia, back pain, headache, dizziness, cough, dyspnea, nausea, diarrhea, rash, peripheral edema, fatigue.
Rare but serious (less than 1%): Severe bleeding, thrombotic thrombocytopenic purpura, intracranial hemorrhage, hypersensitivity.

Patient educations

• Do not stop taking prasugrel without first talking to your healthcare provider, as this can increase your risk of a heart attack or stroke.
• Call your healthcare provider or get medical help right away if you have any signs of bleeding, such as: severe headache, confusion, changes in vision, speech, or balance; blood in your urine or stools, black or tarry stools, or if you cough up blood or vomit that looks like coffee grounds.

Pravastatin

ATC Code: C10AA03 Lipid Modifying Agents (HMG CoA Reductase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Not recommended during breastfeeding.

Dosage forms and trade names available in Iraq

- Pravastatin sodium 20mg tablet

Indications and Dosage

• Hyperlipidemia: 10-80mg once daily.
• Primary or secondary prevention of cardiovascular disease: 40mg once daily.

Off-label uses

Certain types of stroke prevention.

Contraindications

Active liver disease or unexplained persistent elevations of serum transaminases , Hypersensitivity to pravastatin or any component of the formulation, Pregnancy or breastfeeding.

Cautions

Liver disease, heavy alcohol use, renal disease.
Dose adjustment in renal failure: A starting dose of 10 mg pravastatin once daily is recommended in patients with severe renal impairment.
Dose adjustment in hepatic failure: Use is contraindicated.

Pharmacokinetic parameters

Absorption Rapidly absorbed (F=17%)
Distribution Vd=0.36 L/kg; 50% protein bound.
Metabolism Minimal first pass metabolism.
Elimination Primarily excreted in the bile, with a half-life of 1.8 hours.

Drug interaction

Fibrates: Increased risk of myopathy/rhabdomyolysis.
Cyclosporine: Increased risk of myopathy/rhabdomyolysis.

Side effects

Common (more than 10%): Headache, dyspepsia, nausea, rash.
Less common (1-10%): Myalgia, dizziness, insomnia, cough.
Rare but serious (less than 1%): Rhabdomyolysis, liver failure, pancreatitis, anaphylaxis.

Patient education

• This medication should be taken in the evening for maximum effectiveness.
• Lifestyle changes including a heart-healthy diet, regular exercise, and smoking cessation are also important to lower cholesterol.
• Report promptly any unexplained muscle pain, tenderness, or weakness.

Claritine

BAYER

Weather is triggering your allergies?

Claritine is here to help!

Prednicarbate

ATC Code: D07AC18 Corticosteroids, Dermatological Preparations (Corticosteroids, Potent (Group III))

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Not likely to be significant

Indications and Dosage

Corticosteroid-responsive dermatoses: Apply a thin film to the affected skin areas twice daily, rubbing in gently.

Off-label uses

None.

Contraindications

Hypersensitivity

Cautions

Long-term use may lead to skin thinning and atrophy.

Dose adjustment in renal failure: Not required

Dose adjustment in hepatic failure: Not required

Pharmacokinetic parameters

Topically applied corticosteroids are systemically absorbed, but the extent is generally minimal.

Dosage forms and trade names available in Iraq

Prednicarbate 0.25% cream

Peitel (Ferrer International Spain).

Drug interaction

Not likely due to minimal systemic absorption.

Side effects

Common (more than 10%): Skin irritation at the site of application.

Less common (1-10%): Skin discoloration; dryness; acneiform eruption; skin atrophy.

Rare but serious (less than 1%): Hypothalamic-pituitary-adrenal (HPA) axis suppression; Cushing's syndrome; hyperglycemia; glucosuria.

Patient educations

• Avoid applying the medication to the face, groin, or axillae, or if there is atrophy at the treatment site.

• Do not bandage or otherwise cover or wrap the treated skin area unless directed by the physician.

Prednisolone

ATC Code: H02AB06 Corticosteroids for Systemic Use (Glucocorticoids)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

•Asthma, exfoliative erythroderma, adrenocortical insufficiency, acquired hemolytic anemia, multiple sclerosis, cerebral edema, systemic lupus erythematosus, rheumatoid arthritis; Nephrotic syndrome; Idiopathic thrombocytopenic purpura; hay fever; drug allergy; insect bites; psoriasis; Autoimmune hepatitis: 5mg-60mg daily, adjust dose according to patient response.
• Conjunctivitis: 1-2 drops bid-qid.
• Ulcerative colitis, crohns disease: Apply enema once daily at night for 2 to 4 weeks.

Off-label uses

Acute Exacerbation of COPD; Bell's palsy; Croup.

Contraindications

Hypersensitivity to prednisolone; Acute superficial herpes simplex; Keratitis; Systemic fungal infections; Varicella; Live or attenuated virus vaccines.

Dosage forms and trade names available in Iraq

- Prednisolone 15mg/5ml syrup
- Prednisolone 5mg tab
- Prednisolone 20 mg tab
- Prednisolone 10mg/ml 1% eye drop

Cautions

Hyperthyroidism; Cirrhosis; Ocular herpes simplex; Respiratory tuberculosis; Untreated systemic infections; Diabetes; Cataracts; Glaucoma; Seizure disorder; Peptic ulcer disease; Osteoporosis; Myasthenia gravis; Hypertension; Heart failure; Ulcerative colitis; Thromboembolic disorders; elderly patients.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=85%.
Distribution Vd=1.5L/kg, 70-90% protein bound.
Metabolism Hepatic metabolism.
Elimination Primarily renal elimination with a half-life of 2-4 hours.

Drug interactions

COVID-19 vaccine: Prednisolone may diminish the therapeutic effect of COVID-19 vaccine.

Side effects

Acne; Adrenal suppression; Delayed wound healing; Diabetes mellitus; Gastrointestinal tract perforation; Glucose intolerance; Hepatomegaly; Hypokalemic alkalosis; Insomnia; Menstrual irregularity; Myopathy; Neuritis; Osteoporosis; Peptic ulcer; Pituitary adrenal axis suppression; Pseudotumor cerebri; Psychosis; Seizure; Ulcerative esophagitis; Urticaria; Vertigo; Weight gain; muscle weakness; Thin skin.

Patient educations

Take once-daily doses before 9am; Do not stop taking the drug without consulting your health care provider; Avoid exposure to infections; Report unusual weight gain, swelling of the extremities, muscle weakness, black or tarry stools, fever, prolonged sore throat, colds or other infections, worsening of the disorder for which the drug is being taken.

Pregabalin

ATC Code: N02BF02 Analgesics (Gabapentinoids)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

- Neuropathic pain: 50mg-100mg tid.
- Fibromyalgia: 75mg-150mg bid, (max. 225mg bid).
- Partial seizure: 25mg-75mg bid.
- Postherpetic neuralgia: Initially, 75mg bid, maintenance 75mg-150mg bid.

Off-label uses

Moderate pain; Social anxiety disorder.

Contraindications

Hypersensitivity to pregabalin.

Cautions

Heart failure; Cardiovascular disease; Diabetes; History of angioedema, Patients at risk for suicide.

Dose adjustment in renal failure: CrCl 15-30ml/min: 25mg-150mg daily; CrCl less than 15ml/min: 25mg-75mg daily.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Pregabalin 25mg capsule
- Pregabalin 50 mg capsule
  Pregafix (PIONEER IRAQ).
- Pregabalin 75 mg capsule
  Pregafix (PIONEER IRAQ), **Zega** (Pharma International Jordan).
- Pregabalin 150mg capsule
  Pregafix (PIONEER IRAQ), **LYRIKINE** (Al-Kindi IRAQ).

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.
Distribution Vd=0.5L/kg, no protein bound.
Metabolism Negligible hepatic metabolism.
Elimination Renal elimination is 90-99% with a half-life of 5-6.5 hours.

Drug interactions

Zolpidem: Zolpidem may increase sedative effect of pregabalin.

Side effects

Common (more than 10%) Ataxia; Blurred vision; Diplopia; Dizziness; Fatigue; Peripheral edema; Somnolence; Tremor; Weight gain; Xerostomia.

Less common (1-10%) Abnormal thinking; Accidental injury; Amnesia; Asthenia; Confusion; Constipation; Disorientation; Edema; Facial edema; Hypotension; Neuropathy; Pain; Vertigo; Weight gain.

Rare (less than 1%) Addiction; Anemia; Diarrhea; Dysmenorrhea; Dystonia; Epididymitis; Esophagitis; Gynecomastia and breast enlargement; Heart failure; Hirsutism; Uveitis.

Patient educations

Do not abruptly stop taking drug; seizure frequency may be increased; Avoid tasks that require alertness, motor skills until response to drug is established; Avoid alcohol.

Prifinium Bromide

ATC Code: A03AB18 Drugs for Functional Gastrointestinal Disorders (Synthetic Anticholinergics)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Smooth muscle spasms: 30mg-60mg tid. By i.v. or i.m. injection, 7.5mg-15mg given 2-4 times daily.

Off-label uses

None.

Contraindications

Hypersensitivity to prifinium bromide; Glaucoma; Micturition disorders due to prostatic hypertrophy; Severe heart disease; Paralytic ileus.

Cautions

Prostatic hypertrophy; Hyperthyroidism; CHF; Arrhythmia; Ulcerative colitis; Exposed to high environmental temperature; May impair ability to drive or operate machinery.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Prifinium Bromide 15mg/2ml amp

Riabal (Hikma Jordan).

Prifinium bromide 30mg tab

Riaprifin (Al-Kindi Iraq).

Pharmacokinetic parameters

Absorption Undetermined.

Distribution Undetermined.

Metabolism Undetermined.

Elimination Undetermined.

Drug interactions

Amitriptyline: Amitriptyline may increase the central nervous system depressant (CNS depressant) activities of prifinium bromide

Bisacodyl: The therapeutic efficacy of Bisacodyl can be decreased when used in combination with prifinium bromide.

Side effects

Agranulocytosis; Anorexia; Constipation; Epigastric distress; Facial dyskinesia; Headache; Palpitation; Tremors; Urinary retention; Vertigo; Visual disturbances; Vomiting; Wheezing.

Patient educations

Take as prescribed, 30-60 minutes before meals; Avoid excessive dosage; Avoid hot environments; Avoid alcohol; Wear sunglasses; Impotence (reversible); Difficulty urinating (empty bladder before taking drug).

Prochlorperazine

ATC Code: N05AB04 Psycholeptics (Phenothiazines with Piperazine Structure)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

- Nausea and vomiting: 5mg-10mg tid.
- Psychosis: 5mg-10mg qid, (max 150mg daily).

Off-label uses

Behavioral syndromes in dementia; Psychosis and agitation related to Alzheimer's dementia.

Contraindications

Hypersensitivity to prochlorperazine; Coma or presence of large amounts of CNS depressants (such as alcohol, opioids); Postoperative nausea and vomiting following pediatric surgery.

Cautions

History of seizures; Parkinson's disease; Elderly, Patients at risk for pneumonia; Decreased GI motility; Urinary retention; Visual problems; Narrow angle glaucoma; Paralytic ileus; Myasthenia gravis; Cerebrovascular or cardiovascular disease.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Prochlorperazine 12.5mg/ml ampoule
Prochlorperazine 5mg tablet

Pharmacokinetic parameters

Absorption F=12.5%, food has minimal effect on absorption.
Distribution Vd=12.9-17L/kg.
Metabolism Not metabolized.
Elimination Half-life of 7-9 hr.

Drug interactions

Lorazepam: Lorazepam may increase CNS, respiratory depression, hypotensive effects prochlorperazine.

Side effects

Common (more than 10%) None.
Less common (1-10%) None.
Rare (less than 1%) Agitation; Anorexia; Anxiety; Blood dyscrasia; Cerebral edema; Constipation; Depression; Diarrhea; Dizziness; Dyspepsia; Ejaculatory disorder; Electrocardiogram changes; Euphoria; Galactorrhea; Gynecomastia; Headache; Ileus; Insomnia; Lens opacities; Orthostatic hypotension; Photosensitivity; Pruritus; Restlessness; Tachycardia; Weakness.

Patient educations

Limit caffeine; Avoid alcohol; Avoid tasks requiring alertness, motor skills until response to drug is established (may cause drowsiness, impairment).

Procyclidine

ATC Code: N04AA04 Anti-Parkinson Drugs (Tertiary amines)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Parkinson's disease: 2.5mg tid, increasing by 2.5mg-5mg daily at intervals of 2-3 days, until the optimum clinical response is achieved, maintenance 15mg-30mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to procyclidine; Myasthenia gravis; Untreated urinary retention; Closed angle glaucoma; Gastrointestinal obstruction.

Cautions

Mental disorders; Tachycardia; Cardiac arrhythmias; Hypertension; Hypotension.

Dose adjustment in renal failure: Use with caution.

Dose adjustment in hepatic failure: Therapy should not be initiated:

• In patients with clinical evidence of liver disease.

• If 2ALT or AST values are greater than the upper limit of normal.

Dosage forms and trade names available in Iraq

Procyclidine hydrochloride 5 mg tablet
KEMADRIN (Aspen Germany).

Pharmacokinetic parameters

Absorption F=75%.

Distribution Vd=1L/kg, 100% protein bound.

Metabolism Undergoes hepatic metabolism by CYP450 isoenzymes then conjugated with glucuronic acid.

Elimination Procyclidine elimination half-life is 12 hours.

Drug interactions

Antihistamines: Antihistamines may increase the anticholinergic action of procyclidine.

Side effects

Common (more than 10%) Blurred vision; Constipation; Dry mouth.

Less common (1-10%) Agitation; Anxiety; Confusion; Disorientation; Dizziness; Gingivitis; Hallucinations; Impaired cognition; Memory impairment; Nausea; Nervousness; Rash; Vomiting.

Rare but serious (less than 1%) Psychotic disorder; Urinary retention.

Patient educations

This drug may cause blurred vision, dizziness, confusion or disorientation. If affected, do not drive or operate machinery.

Progesterone

ATC Code: G03DA04 Sex Hormones and Modulators of The Genital System (Pregnen (4) Derivatives)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid; Detectable amounts of progesterone enter breast milk.

Dosage forms and trade names available in Iraq

- Progesterone 25mg vial
  Prolutex (IBSA Switzerland).
- Progesterone 100mg oral or vaginal capsule
- Progesterone 200mg oral or vaginal capsule
- Progesterone 400mg pessaries
- Progesterone 8%Vaginal gel
  Crinone (Merck Serono UK).

Indications and Dosage

• Prevention of estrogen induced endometrial hyperplasia: 200mg daily at night for 12 days per 28-day cycle while conjugated estrogens are administered.
• Amenorrhea: 400mg daily in the evening for 10 days. - Vaginal gel (90mg 8%) once/day for 6 days -Im injection 5-10 mg/ day for 6-8 days, bleeding will commence 2-3 days after last dose.
• Infertility: 90mg (8% gel) once daily. If pregnancy occurs, may continue up to 10-12 weeks.
• Heavy vaginal bleeding (DUB): 5-10 mg for 6 days to stop bleeding.

Off-label uses

Reduce risk of recurrent spontaneous preterm birth.

Contraindications

Hypersensitivity to progesterone; History of or suspected or Active breast cancer; Thromboembolic disorders; Missed abortion; Ectopic pregnancy; Undiagnosed abnormal vaginal bleeding; Use as a pregnancy test.

Cautions

Diabetes; Asthma; Epilepsy; Migraine; Cardiac dysfunction; History of mental depression.
Dose adjustment in renal failure: Not typically required.
Dose adjustment in hepatic failure: Contraindicated.

Pharmacokinetic parameters

Absorption F=10-15%, food increase AUC.
Distribution Protein bound 90%, after oral administration maximum serum concentrations is within 3 hours.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 50-60% with a half-life of 25 hr.

Drug interactions

Rifampicin: CYP3A4 inducer rifampicin may decrease effect of progesterone.
Inhibitor of cytochrome P450: 3A4 like ketoconazole or other known inhibitors of this enzyme may increase the bioavailability of Progesterone.

Side effects

Common (more than 10%) Abdominal pain; Breast enlargement; Cramps; Dizziness; Headache; Mood swings; Musculoskeletal pain; Nausea; Sleep disorder; Urinary difficulties.
Less common (1-10%) Chest pain; cholecystitis; Constipation or Diarrhea;Cough; Dizziness.
Rare (less than 1%) None.

Patient educations

Use sunscreen, protective clothing to protect from sunlight, ultraviolet light until tolerance is determined.

Promethazine

ATC Code: R06AD02 Antihistamines for Systemic Use (Phenothiazine Derivatives).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Promethazine is excreted in breast milk. Use during lactation is not recommended.

Dosage forms and trade names available in Iraq

Promethazine Hcl 5mg/5ml syrup

Indications and Dosage

•**Allergic Conditions:** PO 25 mg at bedtime or 12.5 mg before meals and at bedtime (dosage range, 6.25-12.5 mg q8hr).
•**Nausea & Vomiting:** PO 12.5-25 mg q4-6hr PRN.
•**Motion Sickness:** 25 mg PO 30-60 minutes before departure and q8-12hr PRN; on succeeding travel days, 25 mg PO every morning and every evening.
•**Preoperative Sedation:** 50 mg PO/PR on night before procedure or 25-50 mg IM combined with reduced doses of analgesics and atropine like drugs.
•**Postoperative Sedation:** 25-50 mg IM/PO/PR combined with reduced doses of analgesics and atropine like drugs.

Off-label uses

None.

Contraindications

hypersensitivity to promethazine or other phenothiazines, Coma, respiratory depression, and children under 2 years old.

Cautions

History of asthma, seizures, glaucoma, urinary retention,elderly patients.
Dose adjustment in renal failure: : Lower doses or extended dosing intervals may be necessary.
Dose adjustment in hepatic failure: Lower doses may be required.

Pharmacokinetic parameters

Absorption Promethazine is well absorbed after oral and parenteral administration.
Distribution Protein bound: 93%, Vd: 98 L/kg (syrup); 17-277 L/kg (range).
Metabolism: :extensively metabolized in the liver via sulfoxidation and glucuronidation.
Elimination: mainly via the urine. The half-life of promethazine is approximately 10 to 19 hours.

Drug interactions

Promethazine may potentiate the sedative effects of CNS depressants, including alcohol, benzodiazepines, and opioids.

Side effects

Common (more than 10%): Sedation, drowsiness, dizziness, dry mouth, and constipation.
Less common (1-10%): Blurred vision, urinary retention, and confusion, Photosensitivity, Impotence.
Rare but serious (less than 1%): Extrapyramidal symptoms, respiratory depression.

Patient educations

Be cautious when driving or operating machinery, as promethazine may cause drowsiness and impair your ability to perform these tasks safely. Avoid alcohol and other central nervous system depressants while taking promethazine, as they may enhance its sedative effects.

Propiverine

ATC Code: G04BD06 Urologicals (Drugs for Urinary Frequency and Incontinence)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Not enough data

Indications and Dosage
Urinary incontinence: 15 to 30 mg daily.

Off-label uses
None.

Contraindications
Hypersensitivity; Uncontrolled narrow-angle glaucoma; Urinary retention; severe gastro-intestinal conditions including paralytic ileus; myasthenia gravis.

Cautions
In patients with decreased gastrointestinal motility, renal impairment, hepatic impairment, or heart disease.
Dose adjustment in renal failure: Not fully established, but caution is advised due to the drug's renal excretion.
Dose adjustment in hepatic failure: Not fully established, but caution is advised due to the drug's hepatic metabolism.

Dosage forms and trade names available in Iraq
- Propiverine HCl 30mg cap
  Mictonorm XL (Losan pharma Germany).
- Propiverine HCl 45mg cap
  Mictonorm XL (Losan pharma Germany).

Pharmacokinetic parameters
Absorption Oral absorption is good.
Distribution Not readily available.
Metabolism Metabolized in the liver.
Elimination Excreted in urine and feces.

Drug interaction
Other anticholinergics: May increase the risk of anticholinergic side effects.
Drugs that prolong QT interval: May increase the risk of QT prolongation.

Side effects
Common (more than 10%): Dry mouth; constipation; blurred vision; dizziness.
Less common (1-10%): Abdominal pain; headache; fatigue; nausea.
Rare but serious (less than 1%): Allergic reactions; QT prolongation; heart failure.

Patient educations
Avoid activities requiring mental alertness or clear vision until drug effects are known as it may cause dizziness or blurred vision.

Propofol

ATC Code: N01AX10 Anesthetics (Other General Anesthetics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Breast-feeding can be resumed as soon as mother has recovered sufficiently from anesthesia.

Dosage forms and trade names available in Iraq

Propofol 200mg/20ml Emulsion for injection or IV infusion
DIPRIVAN (Aspen Italy).

Indications and Dosage

• Anesthesia: By i.v. infusion, 2mg–2.5mg/kg (approximately 40mg every 10sec until onset of anesthesia), Maintenance 100mcg–200mcg/kg/min or 6mg–12mg/kg/hr for 10–15 min.
• Sedation in ICU: By i.v. infusion, 5mcg/kg/min (0.3mg/kg/hr), increase by increments of 5mcg–10mcg/kg/min (0.3mg–0.6mg/kg/hr) every 5–10 min until desired sedation level achieved.

Off-label uses

Postoperative antiemetic; Refractory status epilepticus.

Contraindications

Hypersensitivity to propofol.

Cautions

Cardiac impairment; Respiratory depression; Not recommended for obstetric anesthesia including caesarean section deliveries.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=60L/kg, 95-99%protein bound.
Metabolism Rapidly metabolized by the liver.
Elimination Renal elimination is 88% with half-life of 3-12 hours.

Drug interactions

Fentanyl: Fentanyl, propofol both increases effects of the other by pharmacodynamic synergism; Monitor for hypotension, respiratory depression, and profound sedation.

Side effects

Common (more than 10%) Apnea; Hypotension; Injection site burning.
Less common (1-10%) Arrhythmia; Bradycardia; Cardiac output decreased; Hypertension; Hypertriglyceridemia; Pruritus; Rash; Respiratory acidosis; Tachycardia.
Rare but serious (less than 1%) Asystole; Bronchospasm; Cardiac arrest; Pancreatitis; Phlebitis; Pulmonary edema; Seizures; Thrombosis.

Patient educations

Observe patient for signs of wakefulness, agitation, monitor respiratory rate, blood pressure, heart rate, O2 saturation, depth of sedation, serum lipid, triglycerides (if used longer than 24 hours); May change urine color to green.

Propranolol

ATC Code: C07AA05 Beta Blocking Agents (Beta Blocking Agents, Non-Selective)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: present in human milk at low levels,Compatible with breastfeeding.

Indications and Dosage

• Angina pectoris: 40mg-160mg daily bid.
• Cardiac dysrhythmia: 10mg-30mg tid-qid, (max 60mg daily).
• Hypertension: 40mg bid, may titrate to 80mg tid.
• Prophylaxis migraine: 80mg daily in divided doses, (max 240mg daily).

Off-label uses

Adjunct treatment for anxiety, Tremor due to Parkinson's disease and essential tremor, Alcohol withdrawal, Schizophrenia, PTSD, Variceal hemorrhage, Acute panic attacks.

Contraindications

Hypersensitivity to propranolol; Bronchial asthma; Sinus bradycardia; Cardiogenic shock; Sick sinus syndrome, Second and third degree heart block; Uncompensated Heart failure.

Dosage forms and trade names available in Iraq

- Propranolol 10mg Tablet
  BECARDIN (SDI Iraq).
- Propranolol 40 mg Tablet
  BECARDIN (SDI Iraq), Procard (PIONEER IRAQ).

Cautions

Diabetes; Raynaud's disease; Hyperthyroidism; Myasthenia gravis; Psychiatric disease; Bronchospastic disease; Elderly patients.
Dose adjustment in renal failure: Use cautiously.
Dose adjustment in hepatic failure: Use cautiously.

Pharmacokinetic parameters

Absorption F=30-70%, food increase absorption.
Distribution Vd=6L/kg, 93% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 1% with a half-life of 3-4 hr.

Drug interactions

Diltiazem: Diltiazem and propranolol both increases toxicity of the other by unspecified interaction mechanism, diltiazem can increase risk of bradycardia of propranolol, do not use that increase heart rate and blood pressure with propranolol like epinephrine; these drugs cancel one another out, this means that neither of them will work.

Side effects

Aggravated congestive heart failure; Arthropathy; Bradycardia; Bronchospasm; Cramping; Depression; Dyspnea; Fatigue; Hyper/hypoglycemia; Hyperkalemia; Hyperlipidemia; Hypotension; Insomnia; Nausea; Paresthesia; Pruritus; Psychotic disorder; Pulmonary edema; Raynaud phenomenon; Respiratory distress; Vomiting; Wheezing; diarrhea; unusual dreams; erectile dysfunction.

Propylthiouracil

ATC Code: H03BA02 Thyroid Therapy (Thiouracils)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: It is excreted in small amounts. However, it is generally considered compatible with breastfeeding.

Indications and Dosage

Hyperthyroidism: Initial adult dosage is typically 300-600 mg daily, divided into 3 doses. Maintenance dose is usually 50-150 mg daily.

Off-label uses

Treatment of thyrotoxic crisis.

Contraindications

Hypersensitivity

Cautions

May cause severe liver injury and acute liver failure, sometimes fatal.
May cause agranulocytosis.
Dose adjustment in renal failure: Not typically required.
Dose adjustment in hepatic failure: Use is contraindicated in patients with hepatic failure.

Dosage forms and trade names available in Iraq

Propylthiouracil 50 mg tab
Prothuril (Uni-Pharma Greece).

Pharmacokinetic parameters

Absorption Rapidly absorbed from the gastrointestinal tract.
Distribution Not readily available. It's extensively bound to plasma proteins.
Metabolism Extensive first-pass metabolism in the liver to active metabolites.
Elimination Primarily via kidneys. Half-life is 1-2.5 hours.

Drug interaction

Warfarin: Propylthiouracil may enhance the anticoagulant effect of warfarin.
Digitalis Glycosides: Hyperthyroidism may cause an increased clearance of these drugs.

Side effects

Common (more than 10%): Rash; nausea; vomiting; loss of taste.
Less common (1-10%): Itching; joint/muscle pain; numbness; swelling; lymph node enlargement.
Rare but serious (less than 1%): Agranulocytosis; hepatotoxicity.

Patient educations

• Notify your healthcare provider immediately if you experience unexplained fever, sore throat, or other signs of infection.
• Contact your healthcare provider if you experience yellowing of the skin or eyes, dark urine, light-colored stools, or abdominal pain, which may be signs of liver damage.

Proximadiol

ATC Code: G04BC Urologicals (Urinary Concrement Solvents)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Best to avoid.

Indications and Dosage
As propulsive for ureteric stones; use 2 teaspoonful's or (1 sachet) in ½ glass of water 3 times daily after meals.

Off-label uses
None.

Contraindications
hypersensitivity to any of it components; first trimester of pregnancy; impairment of renal or hepatic function.

Cautions
To be used only under medical supervision.
Dose adjustment in renal failure: No data available
Dose adjustment in hepatic failure: No data available

Pharmacokinetic parameters
Absorption undetermined
Distribution undetermined
Metabolism undetermined
Elimination undetermined

Drug interaction
There is no significant known interaction.

Side effects
Rarely nausea may occur

Patient educations
The patient should be advised to drink plenty of water help explosion of the stone.

Dosage forms and trade names available in Iraq
Proximadiol 8 mg/100g effervescent granules
Proximol Simple (Kahira Egypt).

Pyridoxine

ATC Code: A11HA02 Vitamins (Other Plain Vitamin Preparations)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Generally safe. It is excreted into breast milk but is not likely to harm a nursing infant.

Dosage forms and trade names available in Iraq

Pyridoxine 50mg/ml, (2ml amp.)
VITA-6 (PIONEER IRAQ).
Pyridoxine HCl 50 mg tablet
Samavit B6 (SDI IRAQ), **Pyridoxine B6-Kindi** (Alkindi Iraq).

Indications and Dosage

• Dietary supplement: Typically (1-18 years old) 0.5-1.3 mg/day for children .
• Typically 18-50 years old 1.3mg/day for adults
• Typically >50 years old 1.7mg/day for adults
• Therapeutic uses: peripheral neuropathy: 10-20mg/day, I.V/I.M for 3 weeks
• Pyridoxine deficiency: Typically 2.5-10mg/day po

Off-label uses

Treatment of nausea and vomiting of pregnancy (dosage typically 10-25 mg three to four times daily).

Contraindications

Hypersensitivity.

Cautions

Long-term, high-dose usage can lead to sensory neuropathy.
Dose adjustment in renal failure: Not typically required.
Dose adjustment in hepatic failure: Not typically required.

Pharmacokinetic parameters

Absorption Rapidly and almost completely absorbed in the jejunum by passive diffusion.
Distribution Widely distributed throughout the body.
Metabolism Liver, converted to its active form pyridoxal phosphate.
Elimination Urine, as 4-pyridoxic acid. Half-life is 15-20 days.

Drug interaction

Levodopa: Pyridoxine may diminish the therapeutic effect of levodopa by increasing its peripheral decarboxylation. (It does not affect levodopa when given in combination with a dopa decarboxylase inhibitor.)
Isoniazid: Can cause pyridoxine deficiency, leading to peripheral neuropathy.so Pyridoxine should be given (typically 25 mg/day can go up to 50mg/day PO)
Cycloserine, hydralazine, penicillamine, theophylline: also can cause Pyridoxine deficiency

Side effects

Common (more than 10%) Not applicable (side effects at normal doses are uncommon).
Less common (1-10%) Nausea, stomach cramps (at high doses).
Rare but serious (less than 1%) Sensory neuropathy (with long-term, high-dose use).

Patient educations

If you are taking isoniazid, do not stop taking pyridoxine without first talking to your healthcare provider.
Notify your healthcare provider if you experience unusual sensory changes, like tingling in your hands or feet.

Quetiapine

ATC Code: N05AH04 Psycholeptics (Diazepines, Oxazepines, Thiazepines and Oxepines)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Not Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Quetiapine 50mg Extended Release tablet
  Asero XR (Pharma International Jordan).
- Quetiapine 100mg tablet
  Serequapine (Al-Kindi Iraq).
- Quetiapine 200mg Extended Release tablet
  Serequapine (Al-Kindi Iraq).
- Quetiapine 300mg tab
  Serequapine (Al-Kindi Iraq).

Indications and Dosage

• Bipolar disorder, schizophrenia: 50mg bid for 1-day increase 50mg daily for 3-days may titrate to 400mg-800mg daily.
• Major depressive disorder: 50mg daily at night may titrate to 300mg daily.

Off-label uses

Delirium in critically ill patients; psychosis and agitation related to Alzheimer's dementia; autism; resistant OCD.

Contraindications

Hypersensitivity to quetiapine.

Cautions

Preexisting abnormal lipid profile; Patients at risk for aspiration pneumonia; cardiovascular disease Cerebrovascular disease; Dehydration; Hypovolemia; Seizure disorder; Hypothyroidism; patients at risk for suicide; Parkinson's disease; Decreased GI motility; Urinary retention; Narrow angle glaucoma; Diabetes; Visual problems; Elderly; Orthostatic hypotension.
Dose adjustment in renal failure: Not typically required.
Dose adjustment in hepatic failure: 25mg-50mg daily.

Pharmacokinetic parameters

Absorption Well absorbed. F=100%.
Distribution Vd=14L/kg, 83% protein bound.
Metabolism Hepatic metabolism.
Elimination Primarily excreted in urine, half-life: 6 hour.

Drug interactions

Goserelin: Goserelin increases toxicity of quetiapine by QTc interval, increases risk of torsades de pointes. Medications prolonging QT interval may increase risk of QT prolongation.

Side effects

Common (more than 10%) Constipation; Dizziness; Dry mouth; Extrapyramidal symptoms; Fatigue; Headache; Increased appetite.
Less common (1-10%) Abdominal pain; Arthralgia; Back pain; Blurred vision; Dyskinesia; Dyspepsia; Postural hypotension; Rash; Rhinitis; Tachycardia; Tremor.
Rare (less than 1%) Cardiomyopathy; Epistaxis; Exfoliative dermatitis; Leukocytosis; Nightmares; Palpitation; Pancreatitis; Priapism; QTc prolongation; Rhabdomyolysis.

Patient educations

Take Quetiapine tablet with or without food. Avoid becoming dehydrated or overheated. Avoid getting up too fast from sitting or lying position.

Rabeprazole

ATC Code: A02BC04 Drugs for Acid Related Disorders (Proton Pump Inhibitors)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Rabeprazole 20 mg tablet
  Pariet (Janssen Austria).

Indications and Dosage

• Duodenal ulcer disease: 20mg daily up to 4 weeks.
• H. pylori GI infection: 20mg bid for 10-14 days in combination with amoxicillin 1000mg and clarithromycin 500mg bid.
• Gastric hypersecretion: 60mg daily may titrate to 60mg bid.
• GERD: 20mg once daily.

Off-label uses

Dyspepsia; Benign gastric ulcer; Treatment of NSAID induced ulcers.

Contraindications

Hypersensitivity to rabeprazole.

Cautions

Osteoporosis.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use cautiously.

Pharmacokinetic parameters

Absorption F=52%, food delays absorption.
Distribution Protein bound 95-98%.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 90% with a half-life of 1-2 hours.

Drug interactions

Clopidogrel: Rabeprazole May decrease concentration of clopidogrel.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Constipation; Diarrhea; Flatulence; Headache; Pain; Pharyngitis.
Rare (less than 1%) Abnormal taste; Agitation; Agranulocytosis; Alopecia; Anemia; Angioedema; Chest pain; Delirium; Erythema multiforme; Hypokalemia; Hypomagnesemia; Hyponatremia; Jaundice; Leukocytosis; Leukopenia; Migraine; Osteoporosis related fracture; Rhabdomyolysis; Stevens-Johnson syndrome; Sudden death; Toxic epidermal necrolysis.

Patient educations

Swallow tablets whole; do not break, chew, dissolve, or divide tablets; Report headache.

Baby Care
Protective Baby Ointment
For Nappy Rash[5]

Formulated for delicate baby skin[3]

0%
- PRESERVATIVES
- PERFUMES
- COLORS

Bepanthen Protective Baby Ointment Clinically proven to prevent the incidence of nappy rash on proactive use[3]

Specially formulated with:

- **Dexpanthenol that protects** the skin against irritants and accelerates the skin barrier repair[3]
- **Lanolin, a natural emollient*** that contains many lipid types present in human skin[3]
- Suitable for babies as a protective barrier against nappy wetness and for the prevention and treatment of redness and diaper rash[5]
- Oil-rich ointment base[5]

*Lanolin is one of the most physiological emollients available[3]

Rabies Antigen

ATC Code: J07BG01 Viral Vaccines (Rabies Vaccines)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Breastfeeding is not a contraindication for post-exposure prophylaxis.

Dosage forms and trade names available in Iraq

Rabies Antigen Vial

Indications and Dosage

• Adult & Pediatric Dose for Rabies Prophylaxis:
• **Preexposure prophylaxis:** 1 mL intramuscularly on days 0, 7, and 21 or 28
• Postexposure vaccination
• **Previously unvaccinated:** 1 mL intramuscularly on days 0, 3, 7, 14, and 28
• **Previously vaccinated against rabies:** 1 mL intramuscularly on days 0 and 3.

Off-label uses

None.

Contraindications

Hypersensitivity to any component of the rabies vaccine.

Cautions

Immunocompromised individuals may have a reduced response to the vaccine.
Dose adjustment in renal failure: No specific dose adjustment is typically required in renal failure.
Dose adjustment in hepatic failure: No specific dose adjustment is typically required in hepatic failure.

Pharmacokinetic parameters

Absorption Administered via intramuscular injection, ensuring systemic absorption.
Distribution No specific volume of distribution (Vd) mentioned; typically, it enters the bloodstream to elicit an immune response.
Metabolism The vaccine stimulates the body to produce an immune response against rabies; it does not undergo metabolism like conventional drugs.
Elimination Not applicable; the immune response generated is the key mechanism.

Drug interactions

• Rabies vaccine efficacy may be reduced in individuals receiving immunosuppressive therapies.
• Live vaccines, if administered simultaneously, might interfere with the immune response to the rabies vaccine.

Side effects

Common (more than 10%): Pain or redness at the injection site, mild fever, headache.
Less common (1-10%): Nausea, vomiting, muscle aches.
Rare but serious (less than 1%): Severe allergic reactions are exceedingly rare

Patient educations

1. Follow the recommended rabies vaccine schedule provided by your healthcare provider for optimal protection.
2. Report any unusual side effects or allergic reactions after vaccination to your healthcare provider promptly.
3. Consult your healthcare provider before receiving other vaccines simultaneously and inform them of any existing medical conditions or medications.

Racecadotril

ATC Code: A07XA04 Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents (Other Antidiarrheals)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Acute diarrhea: 100mg tid, continue treatment until 2 normal stools are recorded, (max duration of treatment 7 days).

Off-label uses

None.

Contraindications

Hypersensitivity to Racecadotril; Fructose intolerance; Glucose malabsorption syndrome; Sucrase-isomaltase deficiency.

Cautions

History of angioedema.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Racecadotril 10 mg sachet

Hidrasec (Abbott Germany).

Racecadotril 100 mg cap

Hidrasec (Abbott Germany).

Racecadotril 30 mg oral suspension sachet

Hidrasec (Abbott Germany).

Pharmacokinetic parameters

Absorption Rapidly absorbed.

Distribution Vd=Undetermined, 90%protein bound.

Metabolism Rapidly hydrolyzed to thiorphan.

Elimination Renal elimination is 81.4% with half-life of 3-4 hours.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) None.

Less common (1-10%) Erythema; Rash; Tonsillitis.

Rare but serious (less than 1%) None.

Patient educations

A Patient education is not currently available for this monograph.

Ramipril

ATC Code: C09AA05 Agents Acting on The Renin-Angiotensin System (ACE inhibitors, plain)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid; A decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Dosage forms and trade names available in Iraq

- Ramipril 10mg tablet
  Tritace (Sanofi Aventis ITALY).
- Ramipril 5mg tablet
  Tritace (Sanofi Aventis ITALY).
- Ramipril 2.5mg tablet
  Tritace (Sanofi Aventis ITALY).

Indications and Dosage

• Heart failure post-myocardial infarction: 1.25mg-2.5mg bid for 7 days, may titrate to 5 mg bid.

• Hypertension: 2.5mg daily, may titrate to 2.5mg-20mg daily.

Off-label uses

Delay progression of nephropathy; Reduce risks of cardiovascular events in hypertensive patients with type 1 or type 2 diabetes; nephrotic syndrome, proteinuria, glomerular disease.

Contraindications

Hypersensitivity to Ramipril; severe kidney disease; renal artery stenosis.

Cautions

Elderly patients; Collagen vascular disease; Hyperkalemia; Hypertrophic cardiomyopathy with outflow tract obstruction; Severe aortic stenosis; Major surgery.

Dose adjustment in renal failure: CrCl less than 40ml/min: reduce dose to 25%.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=50-60%, food has no effect on absorption.

Distribution Protein bound 73%.

Metabolism Ramipril metabolized in liver to active metabolite ramiprilat.

Elimination half-life 13-17hr (ramiprilat) , excretion via urine (60%) and via feces (40%)

Drug interactions

Alfuzosin: Ramipril may enhance the hypotensive effect of alfuzosin.

Allopurinol: angiotensin-converting enzyme inhibitors may enhance the potential for allergic or hypersensitivity reactions to allopurinol.

Duloxetine: Ramipril may enhance the hypotensive effect of duloxetine.

Side effects

Common (more than 10%) dry cough; drowsiness; feeling fatigued; weakness.

Less common (1-10%) Abnormal kidney function; Angina pectoris; Diarrhea; Dizziness; Headache; Nausea; Postural hypotension; Syncope; Vertigo; Vomiting.

Rare (less than 1%) Angioedema.

Patient educations

Do not discontinue medication without physician's approval; Slowly go from lying to standing to minimize hypotensive effect; Report palpitations, cough, chest pain; Dizziness may occur in first few days; Avoid tasks that require alertness, motor skills until response to drug is established; Avoid alcohol; Report swelling of the face, lips, or tongue.

Ramucirumab

ATC Code: L01FG02 Antineoplastic Agents (VEGF/VEGFR (Vascular Endothelial Growth Factor) Inhibitors)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 C **D** X N

Lactation: It is not yet known

Indications and Dosage

• Metastatic colorectal cancer, metastatic non-small cell lung cancer, hepatocellular carcinoma, metastatic gastric or gastro-esophageal junction adenocarcinoma.

• The usual dose is 8 mg/kg every two weeks or 10 mg/kg every three weeks depending on the specific condition being treated.

Off-label uses

May use it for other types of cancers that are similar to its approved indications.

Contraindications

Hypersensitivity

Cautions

• Monitor for signs and symptoms of GI perforation, impaired wound healing, hemorrhage.

• High blood pressure and infusion-related reactions can occur.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Ramucirumab 500mg/50ml injection

Cyramza (Eli lilly USA).

Ramucirumab 100mg/10ml injection

Cyramza (Eli lilly USA).

Drug interaction

Not known

Side effects

Common (more than 10%): Hypertension; fatigue; diarrhea; decreased appetite; abdominal pain.

Less common (1-10%): Proteinuria; gastrointestinal perforation; bleeding.

Rare but serious (less than 1%): Severe bleeding; severe high blood pressure; infusion reactions; reversible posterior leukoencephalopathy syndrome.

Patient educations

• Notify your healthcare provider if you experience severe abdominal pain, headaches, confusion, changes in vision, unusual bleeding or bruising.

• Ramucirumab can cause harm to a developing fetus; effective contraception is recommended during treatment and for a period after the last dose.

Ranolazine

ATC Code: C01EB18 Cardiac Therapy (Other Cardiac Preparations)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: It's not yet known. There is potential risk.

Dosage forms and trade names available in Iraq

- Ranolazine 375mg tablet
  Ranexa (Menarini Germany).
- Ranolazine 500mg tablet
  Ranexa (Menarini Germany).
- Ranolazine 750mg tablet
  Ranexa (Menarini Germany)

Indications and Dosage

It's indicated for the treatment of chronic angina. The recommended dose is 500 mg twice daily, which can be increased to a maximum of 1000 mg twice daily, if needed.

Off-label uses

potential use in heart failure and diabetic neuropathy, but these uses are not approved by the FDA.

Contraindications

• In patients with pre-existing QT interval prolongation or in combination with other drugs known to prolong the QT interval.
• Patients with hepatic cirrhosis should not use ranolazine.

Cautions

In patients with renal impairment or moderate hepatic impairment.
Dose adjustment in renal failure: In patients with severe renal impairment, a maximum dose of 500 mg twice daily should not be exceeded.
Dose adjustment in hepatic failure: In patients with moderate hepatic impairment, a maximum dose of 500 mg twice daily should not be exceeded.

Pharmacokinetic parameters

Absorption F is approximately 50-65%.
Distribution Vd is approximately 80-180 L. Protein binding is approximately 62%.
Metabolism Extensively metabolized in the liver by CYP3A4 and, to a lesser extent, CYP2D6.
Elimination Primarily excreted in the urine with a half-life of 7 hours.

Drug interaction

Strong inhibitors of CYP3A (ketoconazole, itraconazole, clarithromycin, etc.): Can significantly increase ranolazine plasma concentrations.
Drugs that prolong QT interval (amiodarone, sotalol, quinidine, etc.): Co-administration may increase the risk of serious cardiac arrhythmias.

Side effects

Common (more than 10%): Dizziness, constipation, nausea, headache
Less common (1-10%): Vomiting, ringing in ears, abdominal pain, dry mouth
Rare but serious (less than 1%): QT interval prolongation, kidney failure

Patient education

• Do not use grapefruit products while taking ranolazine, as grapefruit can increase the levels of ranolazine in your body.
• Immediately report symptoms of a serious heart rhythm problem: fast, slow, or irregular heartbeat.
• Be aware that dizziness is a common side effect, be cautious when moving to prevent falls.

Repaglinide

ATC Code: A10BX02 Rif Drugs Used in Diabetes (Other Blood Glucose Lowering Drugs, Excl. Insulins)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 **C** D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Diabetes mellitus (type 2): 0.5mg-4mg bid-qid (with meal), may titrate to 16mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to repaglinide; Diabetic ketoacidosis; Diabetes mellitus type 1.

Cautions

Elderly Patients; Malnourished patients; Adrenal dysfunction; Pituitary dysfunction.

Dose adjustment in renal failure: CrCl 20-40ml/min: Initially 0.5mg with meals.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Repaglinide 1mg Tab

NOVONORM (Boehringer Ingelheim Germany).

Pharmacokinetic parameters

Absorption F=56%, food has no effect on absorption.

Distribution Vd=24-31L, 98% protein bound.

Metabolism Hepatic metabolism.

Elimination Fecal elimination is 90% with a half-life of 1 hour.

Drug interactions

Erythromycin: Erythromycin may increase concentration and toxicity of repaglinide.

Side effects

Common (more than 10%) Headache; Hypoglycemia; Upper respiratory infection.

Less common (1-10%) Arthralgia; Back pain; Bronchitis; Chest pain; Constipation; Diarrhea; Serious Cardiovascular events; Sinusitis.

Rare (less than 1%) Anaphylactoid reactions; Hemolytic anemia; Increased Liver function tests; Leukopenia; Pancreatitis; Thrombocytopenia; Visual disturbances.

Patient educations

Diabetes requires lifelong control; Prescribed diet, exercise are principal parts of treatment; do not skip, delay meals; Continue to adhere to dietary instructions, regular exercise program, regular testing of urine or serum glucose; When taking combination drug therapy with a sulfonylurea or insulin, have source of glucose available to treat symptoms of low blood sugar.

Rho(D) Immune Globulin

ATC Code: J06BB01 Immune Sera and Immunoglobulins (Specific Immunoglobulins)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

Administer to mother to prevent hemolytic disease in newborn: i.v. or i.m. injection, 300mcg (1500 IU) within 72 hr.

Off-label uses

None.

Contraindications

Hypersensitivity to anti-D immunoglobulin.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=69%.

Distribution Vd=8.59L.

Metabolism Anti-D immunoglobulin is expected to undergo nonspecific catabolism.

Elimination Half-life is 16±4 days following i.v. administration and 18±5 days following i.m. administration.

Dosage forms and trade names available in Iraq

Anti D immunoglobulin 300 mcg prefilled syringe
WinRho (Emergent Biosolutions Canada).

Drug interactions

Cetuximab: The risk or severity of adverse effects can be increased when cetuximab is combined with human Anti-D immunoglobulin.

Estradiol valerate: Estradiol may increase the Thrombogenic activities of human Anti-D immunoglobulin.

Tibolone: Tibolone may increase the Thrombogenic activities of human Anti-D immunoglobulin.

Trastuzumab: The risk or severity of adverse effects can be increased when trastuzumab is combined with human Anti-D immunoglobulin.

Side effects

Common (more than 10%) fever, headache, pain at the site of injection, and red blood cell breakdown.

Less common (1-10%) Skin flush.

Rare but serious (less than 1%) Erythema; Increased bronchial secretions; Pruritus; Urticaria; Wheezing.

Monitoring parameters

Monitor for signs and symptoms of intravascular hemolysis (such as back pain, shaking, chills, fever, discolored urine, hematuria); Observe patient for 8 hours after administration; Monitor for systemic reactions for 20 minutes following administration.

Ribavirin

ATC Code: J05AP01 Antivirals for Systemic Use (Antivirals for Treatment of HCV Infections)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• **Chronic hepatitis C virus infection:** (Adult more than 105kg) 1400mg daily (600mg in morning, 800mg in evening), (adult weighing 81–105 kg) 1200mg daily (600mg in morning and evening), (adult weighing 66–80 kg) 1000mg daily (400mg in morning, 600mg in evening), (adult weighing less than 66 kg) 800mg daily (400mg in morning and evening).

Dosage forms and trade names available in Iraq

Ribavirin 200mg cap

Rebetol (MSD Belgium).

Ribavirin 200mg/5ml Oral Solution

Off-label uses

None.

Contraindications

Hypersensitivity to ribavirin; Sickle cell anemia.

Cautions

Cardiac disease; Pulmonary disease; Elderly patients; History of psychiatric disorders; Sarcoidosis; Severe anemia.

Dose adjustment in renal failure: CrCl less than 50ml per minute, use of ribavirin is contraindicated.

Dose adjustment in hepatic failure: In sever hepatic failure, use of ribavirin is contraindicated.

Pharmacokinetic parameters

Absorption F=64%.

Distribution Vd=2825L.

Metabolism Metabolized primarily by the liver.

Elimination Renal elimination is 61% with half-life of 120-170 hours.

Drug interactions

Antacids: Levels of ribavirin may decrease when given with antacids

Side effects

Common (more than 10%) Alopecia; Anorexia; Arthralgia; Decreased hemoglobin; Depression; Dizziness; Dyspepsia; Dyspnea; Emotional lability; Fatigue; Fever; Flu-like syndrome; Headache; Hemolysis; Hyperbilirubinemia; Impaired concentration; Insomnia; Irritability; Musculoskeletal pain; Myalgia; Nasal congestion; Nausea; Pruritus; Rash; Rigors; Sinusitis; Thrombocytopenia; Vomiting.

Less common (1-10%) Chest pain; Hemolytic anemia; Nervousness; Taste perversion; Weakness.

Rare but serious (less than 1%) Dehydration; Growth inhibition in pediatric patients; Hearing impairment; Hearing loss; Homicidal ideation; Liver and renal graft rejection; Pure red cell aplasia (PRCA); Retinal detachment; Serious skin reactions.

Patient educations

Report immediately any difficulty breathing, itching, swelling, redness of eyes, severe abdominal pain, bloody diarrhea, unusual bleeding; Female patients should take measures to avoid pregnancy; Male patients must use condoms during sexual activity.

Rifampicin

ATC Code: J04AB02 Antimycobacterials (Antibiotics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Tuberculosis: 10mg/kg/day not to exceed 600mg daily.
• Neisseria meningitides asymptomatic carrier: 600mg bid for 2 days.

Off-label uses

Prophylaxis of H. influenza type B infection; Legionella pneumonia; Serious infections caused by Staphylococcus species; Treatment of prosthetic joint infection.

Contraindications

Hypersensitivity to rifampicin or history of severe hematological disorders(thrombocytopenia, purpura) during a previous treatment of rifampicin; Jaundice.

Cautions

Alcoholism; Vitamin K deficiency; Poor nutritional status; Diabetes mellitus; Porphyria.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: In sever hepatic failure, max 8mg/kg daily.

Dosage forms and trade names available in Iraq

Rifampicin 300mg capsule

Pharmacokinetic parameters

Absorption Readily and well absorbed from the gastrointestinal tract, food delayed absorption.
Distribution Vd=Undetermined, 89% protein bound.
Metabolism Extensively metabolized in the liver mainly by CYP3A4.
Elimination Renal elimination is 30% with half-life of 3-4 hours.

Drug interactions

Atorvastatin: Rifampin will decrease the level or effect of atorvastatin by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%): Elevated liver function test.
Less common (1-10%): Anorexia; Cramps; Diarrhea; Epigastric distress; Nausea; Pancreatitis; Pseudomembranous colitis; Rash; Vomiting.
Rare but serious (less than 1%): None.

Patient educations

Preferably take on empty stomach with 240ml of water 1 hour before or 2 hours after meal (with food if gastrointestinal upset); Avoid alcohol; Do not take any other medications without consulting physician, including antacids; must take rifampin at least 1 hour before antacid; Urine, feces, sputum, sweat, tears may become red-orange; soft contact lenses may be permanently stained; Report any new symptom immediately such as yellow eyes and skin, fatigue, weakness, nausea and vomiting, sore throat, fever, flu, unusual bleeding; If taking oral contraceptives, check with physician (reliability may be affected).

Rifaximin

ATC Code: A07AA11 Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents (Antibiotics)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Avoid; Alternate therapy may be preferred.

Indications and Dosage

- Traveler's diarrhea: 200mg T.I.D for 3 days.
- Hepatic encephalopathy B.I.D.
- Irritable bowel syndrome T.I.D for 14 days.

Off-label uses

Treatment of hepatic encephalopathy; Treatment of C.difficile associated diarrhea.

Contraindications

Hypersensitivity to Rifaximin.

Cautions

Systemic bacterial infection, fever and bloody diarrhea.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Rifaximin 200mg Tablet
- Rifaximin 550mg Tablet

Pharmacokinetic parameters

Absorption F=0.4%, action is primarily in gastrointestinal tract.

Distribution Gut 80-90%, 67.5% protein bound.

Metabolism Extensively metabolized in the liver and mainly by CYP3A4.

Elimination Feces >90%, renal elimination is 0.32% with half-life of 6 hours.

Drug interactions

Azithromycin: Azithromycin increases levels of rifaximin by P-glycoprotein efflux transporter.

Side effects

Common (more than 10%) Flatulence.

Less common (1-10%) Abdominal pain; Constipation; Defecation urgency; Headache; Nausea; Pyrexia; Rectal tenesmus; Vomiting.

Rare but serious (less than 1%) Allergic dermatitis; Pruritus; Rash; Rhabdomyolysis (patients with cirrhosis).

Patient educations

Avoid Report if diarrhea worsens or if blood occurs in stool, fever develops within 48 hours.

Anti Tussive Syrups Line By Pioneer

Piospan
Cough Syrup
100ml

Mucosolve
Syrups
100ml

Exvent
Syrups
100ml

X-Cough
Syrups
100ml

PIONEER PIONEER CO.
FOR PHARMACEUTICAL INDUSTRIES

Risedronate

ATC Code: M05BA07 Drugs for Treatment of Bone Diseases (Bisphosphonates)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Risedronate Sodium 35mg Tablets

Indications and Dosage

• Paget's disease: 35mg once daily for 2 months.
•Treatment and prophylaxis of postmenopausal osteoporosis: 35mg once weekly.
• Treatment of male osteoporosis: 35mg once weekly.

Off-label uses

None.

Contraindications

Hypersensitivity to risedronate; Inability to stand or sit upright for at least 30 minutes; Abnormalities of esophagus that delays esophageal emptying.

Cautions

Duodenitis; Dysphagia; Esophagitis; Gastritis; Ulcers; Hypocalcemia.
Dose adjustment in renal failure: CrCl less than 30ml per minute, use of risedronate is not recommended.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F= 0.63%, food decrease absorption.
Distribution Vd=13.8L/kg, 24%protein bound.
Metabolism Not metabolized.
Elimination Renal elimination is 40% with half-life of 480 hours.

Drug interactions

Famotidine: Famotidine will increase the level or effect of risedronate by increasing gastric pH.

Side effects

Common (more than 10%) Hypertension; Arthralgia; Constipation; Headache; Nausea; Diarrhea; Dyspepsia; Abdominal pain; Rash.
Less common (1-10%) Arrhythmia; Chest pain; Depression; Dizziness; Dyspnea; Flulike syndrome; Gastritis; Hypocalcemia; Hypophosphatemia; Nephrolithiasis; Pharyngitis; Prostatic hyperplasia; Rhinitis.
Rare but serious (less than 1%) Diaphyseal femur; Dysphagia; Esophageal cancer; Esophageal ulcer; Femur fracture; Gastric and duodenal ulcer; Osteonecrosis.

Patient educations

Expected benefits occur only when risedronate is taken with full glass (240ml) of plain water first thing in the morning and at least 30 minutes before first food, beverage, medication of the day; Any other beverage (mineral water, orange juice, coffee) significantly reduces absorption of risedronate; Do not lie down for at least 30 minutes after taking risedronate.

Risperidone

ATC Code: N05AX08 Psycholeptics (Other Antipsychotics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

- Autistic disorder, irritability: 0.25mg-0.5mg daily.
- Bipolar I disorder: 2mg-3mg daily, may titrate to 6mg daily.
- Schizophrenia: 1mg bid, may titrate to 18mg daily.

Off-label uses

Tourette syndrome; Post-traumatic stress syndrome; Major depressive disorder.

Contraindications

Hypersensitivity to risperidone.

Cautions

Seizure disorder; Cardiac disease; Recent myocardial infarction; Breast cancer; Patients at risk for aspiration pneumonia; Parkinson's disease; Orthostatic hypotension, Elderly patients; Diabetes; Decreased GI motility; Urinary retention; Xerostomia; Visual problems; Narrow angle glaucoma; Patient with high risk of suicide.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Risperidone 1mg/1ml oral solution
  Risperodel (Al-Kindi Iraq).
- Risperidone 0.5mg tab
  Rispharm (Pharma international Jordan).
- Risperidone 1mg tab
  Rispharm (Pharma international Jordan).
- Risperidone 2mg tablet
  RIPREDON (Al-Kindi Iraq), **Rispharm** (Pharma international Jordan).
- Risperidone 4mg tablet
  Rispharm (Pharma international Jordan).

Pharmacokinetic parameters

Absorption F=70%, food has no effect on absorption.

Distribution Vd=1-2L/kg, 90% protein bound.

Metabolism Hepatic metabolism.

Elimination Renal elimination is 70% with a half-life of 3-20 hr.

Drug interactions

Fluoxetine: Fluoxetine may increase concentration of risperidone and risk of extrapyramidal symptoms.

Lisinopril: Risperidone may increase hypotensive effect of lisinopril.

Lorazepam: Lorazepam may increase CNS depression of risperidone.

Side effects

Common (more than 10%): Agitation; Fatigue; Headache; Increased appetite; Increased weight; Tremor; Urinary incontinence; Vomiting.

Less common (1-10%): Abdominal pain; Acne; Aggressive reaction; Agitation; Bradycardia; Constipation; Dry mouth; Dyspepsia; Extrapyramidal disorder; Facial edema; Gynecomastia in children; Hyperprolactinemia; dysfunction; Syncope; Tachycardia; Xerostomia.

Rare (less than 1%): Agranulocytosis; Cholesterol increased; Delirium; Ketoacidosis; Orthostatic hypotension; Seizures.

Patient educations

Avoid tasks that may require alertness, motor skills until response to risperidone is established (may cause dizziness and drowsiness); Avoid alcohol; Go from lying to standing slowly.

Rituximab

ATC Code: L01FA01 Antineoplastic Agents (CD20 (Clusters of Differentiation 20) Inhibitors)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 **C** D X N

Lactation: Avoid; Breastfeeding discontinue 6 months after the last dose.

Dosage forms and trade names available in Iraq

Rituximab 100mg/10ml vial

MabThera (Roche Germany), **Ruxience** (Pfizer Belgium).

Rituximab 500mg/50ml vial

MabThera (Roche Germany), **Ruxience** (Pfizer Belgium).

Indications and Dosage

• Non-Hodgkin's lymphoma: By i.v. infusion, 375mg/m2 once weekly for 4 weeks.

• Rheumatoid arthritis: By i.v. infusion, 1000mg on days 1 and 15 in combination with methotrexate, give every 24 weeks or based on response, but not sooner than every 16 weeks.

•Wegener's granulomatosis and microscopic polyangiitis: By i.v. infusion, 375 mg/m^2 once weekly for 4 weeks.

Off-label uses

Treatment of autoimmune hemolytic anemia; Chronic immune thrombocytopenic purpura; Systemic autoimmune disease; Burkitt's lymphoma; CNS lymphoma; Hodgkin's lymphoma.

Contraindications

Hypersensitivity to rituximab.

Cautions

Tumor lysis syndrome; Cardiac disease; Elderly patients; Pulmonary disease; Severe active infection; History of hepatitis B virus infection.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=3-4.5L.

Metabolism Most likely removed via the reticuloendothelial system.

Elimination Rituximab elimination half-life is 20 days.

Drug interactions

There are no known significant interactions.

Side effects

Abdominal pain; Altered taste; Anemia; Arrhythmias; Arthralgia; Back pain; Bronchospasm; Chills; Cough; Dyspepsia; Dyspnea; Fever; Flushing; Headache; Hepatitis B reactivation; Hyperglycemia; Hypocalcemia; Hypotension; Infusion reactions; Mucocutaneous skin reactions; Neutropenia; Peripheral edema; Progressive multifocal leukoencephalopathy; Renal failure; Rigors; Thrombocytopenia; Tumor lysis syndrome; Urticaria.

Patient educations

Inform patient of the purpose of the medication; Advise patient to report infusion related events or symptoms of hypersensitivity reactions immediately; Caution patient to avoid crowds and persons with known infections; Instruct patient to use soft toothbrush and electric razor and to avoid falls; Caution patient not to drink alcoholic beverages or take medication containing aspirin or NSAIDs may precipitate gastric bleeding; Advise patient to consult health care professional prior to receiving any vaccinations.

Rivaroxaban

ATC Code: B01AF01 Antithrombotic Agents (Direct Factor Xa Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

- Rivaroxaban 10 mg tablet
- Rivaroxaban 15 mg tablet
  Revma (Pharma International Jordan).
- Rivaroxaban 20 mg tablet
  Rivaroxam (SDI Iraq).

Indications and Dosage

• Prevention of thromboembolism in patients after orthopedic surgery: 10mg daily beginning at least 6hr. after surgery for 12-14 days for knee replacement or 35 days for hip replacement.
• Prevention of thromboembolism in patients with nonvalvular atrial fibrillation: 20mg daily.
• Treatment and secondary prevention of DVT or pulmonary embolism: 15mg bid for 21 days, then 20mg once daily.

Off-label uses

Acute coronary syndrome (after stabilization with initial management).

Contraindications

Hypersensitivity to rivaroxaban; Active major bleeding.

Cautions

Thrombocytopenia; Stroke; Severe hypertension.
Dose adjustment in renal failure: CrCl 15-50ml/min: 15mg once daily with evening meal in nonvalvular atrial fibrillation; CrCl less than 30ml/min: avoid use in DVT or pulmonary embolism; CrCl less than 15ml/min: avoid.
Dose adjustment in hepatic failure: Avoid.

Pharmacokinetic parameters

Absorption F=66-100%, food increase extent of absorption at higher doses.
Distribution Vd=50L, 95% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 66% with a half-life of 5-9 hr.

Drug interactions

Clarithromycin: Clarithromycin increases levels of rivaroxaban by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) None.
Less common (1-10%) Abdominal pain; Back pain; Blister; Hematoma; Muscle spasm; Pain in extremity; Pruritus; Syncope; Wound secretion.
Rare (less than 1%) None.

Patient educations

Avoid alcohol, aspirin, NSAIDs; Consult physician before surgery, dental work; Use electric razor, soft toothbrush to prevent bleeding; Report any unusual bleeding or bruising, spinal hematomas (such as tingling, numbness, muscular weakness).

Rocuronium Bromide

ATC Code: M03AC09 Muscle Relaxants (Other Quaternary Ammonium Compounds)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

Rocuronium 50mg/5ml ampoule
ROCUNEER (Pioneer Iraq).

Rocuronium bromide 100mg vial
Rocuronium-Hameln (Siegfried Hameln GERMANY).

Indications and Dosage

• Rapid sequence intubation: By i.v. injection, 0.6mg-1.2mg/kg.

• Tracheal intubation: By i.v. injection, 0.45mg-0.6mg/kg, maintenance 0.1mg-0.2mg/kg repeat prn or continuous infusion 0.01mg-0.012mg/kg/min.

Off-label uses

None.

Contraindications

Hypersensitivity to rocuronium bromide; Lack of ventilatory support, Neuromuscular disease.

Cautions

Biliary tract disease; Neuromuscular disease; Previous poliomyelitis; Burn injury; Severe electrolyte disturbances; Eaton-Lambert syndrome; Myasthenia gravis; Respiratory disease; Pulmonary hypertension; Obese patients.

Dose adjustment in renal failure: CrCl less than 30ml per minute, prolongation of action has been observed with doses of 0.6mg/kg; The recommended maintenance dose for these patients is 0.075-0.1 mg/kg rocuronium bromide, and the recommended infusion rate is 0.3-0.4mg/kg/hours regardless of the anesthetic technique used.

Dose adjustment in hepatic failure: The influence of hepatic failure on the pharmacodynamics of a 0.6mg/kg dose of rocuronium bromide was investigated in a study in which 9 patients with alcoholic cirrhosis were compared to 10 patients with normal hepatic function. Relative to the normal group, the patients with hepatic failure exhibited an increased clinical duration of action (60 versus 42 minutes). The recovery index (time for recovery from 25-75% T1 suppression) was also prolonged in the cirrhotic patients (53 versus 20 minutes).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=0.25L/kg, 30%protein bound.
Metabolism Rocuronium is metabolized to a less active metabolite, 17-desacetyl rocuronium.
Elimination Renal elimination is 40% with half-life of 60-70 minutes.

Drug interactions

Amikacin: Amikacin increases effects of rocuronium by pharmacodynamic synergism. risk of apnea.

Side effects

Common (more than 10%) None.
Less common (1-10%) Hypertension; Transient hypotension.
Rare but serious (less than 1%) Apnea; Hiccups; Pruritus.

Patient educations

A Patient educations is not currently available for this monograph.

Romiplostim

ATC Code: B02BX04 Antihemorrhagics (Other Systemic Hemostatics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Adult or Children (more than 1 year) thrombocytopenia: By subcutaneous injection, 1mcg/kg once weekly, adjust weekly doses by increments of 1mcg/kg to achieve platelet count 50000/mm^3 or greater and reduce risk of bleeding, (max 10mcg/kg weekly).

Dosage forms and trade names available in Iraq

Romiplostim 250mcg vial
Nplate (Amgen Ireland).

Off-label uses

None.

Contraindications

Hypersensitivity to romiplostim.

Cautions

Myelodysplastic syndrome; Hematologic malignancy; History of cerebrovascular disease.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Slowly absorbed, time to peak plasma concentration 14 hours.
Distribution Vd=0.05-0.12L/kg.
Metabolism Undetermined.
Elimination Romiplostim elimination half-life is 3.5 days.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) Abdominal pain; Arthralgia; Contusion; Diarrhea; Dizziness; Headache; Insomnia; Myalgia; Oropharyngeal pain; Pain in extremity; Pyrexia; Rash; Upper abdominal pain; Upper respiratory tract infection.
Less common (1-10%) Arthralgia; Bronchitis; Cough; Diarrhea; Dizziness; Dyspepsia; Ear infection; Gastroenteritis; Headache; Myalgia; Nausea; Oropharyngeal pain; Paresthesia; Peripheral swelling; Purpura; Should pain; Sinusitis; Thrombocytosis; Upper respiratory tract infection; Urticaria; Vomiting.
Rare but serious (less than 1%) Erythromelalgia; Hypersensitivity reactions including angioedema and anaphylaxis.

Patient educations

Report if bruising, bleeding occur; Essential to receive drug therapy at scheduled times or risk of bleeding may occur.

Note

People may have increased bone marrow reticulin, sever thrombocytopenia upon discontinuation.

Rosuvastatin

ATC Code: C10AA07 Lipid Modifying Agents (HMG CoA Reductase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding

Indications and Dosage

● Hyperlipidemia, primary prevention of cardiovascular disease, dyslipidemia, dysbetalipoproteinemia, atherosclerosis: 10mg-20mg daily, may titrate to 40mg daily.

Off-label uses

Rosuvastatin is suggested following kidney transplant to reduce cardiovascular events; Rosuvastatin is effective and recommended following heart transplant regardless of cholesterol levels.

Contraindications

Hypersensitivity to rosuvastatin.

Cautions

Substantial alcohol consumption; Elective major surgery; Hypothyroidism; Elderly patients.

Dose adjustment in renal failure: CrCl less than 30ml/min: initially 5mg daily, maintenance 10mg daily.

Dose adjustment in hepatic failure: Contraindicated in active in liver disease.

Dosage forms and trade names available in Iraq

- Rosuvastatin 5mg tablet
  CRESTOR (AstraZeneca UK).
- Rosuvastatin 10mg tablet
  CRESTOSAM (SDI IRAQ), **ROSVA** (PIONEER IRAQ), Eveness (Pharma international Jordan).
- Rosuvastatin 20mg tablet
  CRESTOSAM (SDI IRAQ), **ROSVA** (PIONEER IRAQ), Eveness (Pharma international Jordan).
- Rosuvastatin 40mg tablet
  ROUVASTATIN KINDI (Al-Kindi Iraq).

Pharmacokinetic parameters

Absorption F=20%, food slows absorption.
Distribution Vd=134L, 88% protein bound.
Metabolism Minimal hepatic metabolism.
Elimination Fecal elimination is 90% with a half-life of 13-20 hours.

Drug interactions

Clarithromycin: Clarithromycin increases toxicity of rosuvastatin by OATP1B1 inhibitors, this interaction may increase risk of myopathy.

Fenofibrate: Fenofibrate may further increase risk for rhabdomyolysis when added to optimal statin regimen to further decrease TG and increase HDLs.

Side effects

Common (more than 10%) Myalgia.

Less common (1-10%) Abdominal pain; ALT increased; Arthralgia; Asthenia; Constipation; Creatine phosphokinase increased; Diabetes mellitus; Dizziness; Flulike illness; Headache; Nausea; Pharyngitis; Urinary tract infection.

Rare (less than 1%) Jaundice; Myopathy; Rhabdomyolysis.

Patient educations

Use appropriate contraceptive measures; Periodic lab tests are essential part of therapy; Maintain appropriate diet (important part of treatment); Report unexplained muscle pain, tenderness, weakness, especially if associated with fever, malaise.

Roxithromycin

ATC Code: J01FA06 Antibacterials for Systemic Use (Macrolides)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Small amounts of roxithromycin are excreted in the breast milk. Breastfeeding or treatment of the mother should be discontinued as necessary.

Dosage forms and trade names available in Iraq

- Roxithromycin 150mg tablet
- Roxithromycin 300mg tablet

Indications and Dosage

• Upper respiratory tract infection, acute pharyngitis, tonsillitis, sinusitis, dental infections, lower respiratory tract infection, acute bronchitis, community acquired pneumonia, skin infections, non-gonococcal urethritis: 300mg once daily or 150mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to macrolides, including erythromycin; severely impaired hepatic function; concomitant therapy with vasoconstrictive ergot alkaloids.

Cautions

Congenital prolongation of QT interval; Cardiac diseases; Myasthenia gravis.

Dose adjustment in renal failure: In the elderly and those with renal failure, dosage reduction is not required for the normally short course of treatment.

Dose adjustment in hepatic failure: In severe hepatic insufficiency (e.g. hepatic cirrhosis with jaundice and/or ascites), the dose should be reduced by half to 150 mg once daily.

Pharmacokinetic parameters

Absorption F=50%, Food delays absorption.

Distribution Vd=Undetermined, 96%protein bound.

Metabolism Roxithromycin is only partially hepatic metabolized.

Elimination Renal elimination is 7% and 13% by lungs with half-life of 12 hours and 20 h in children.

Drug interactions

Simvastatin: Roxithromycin will increase the level or effect of simvastatin by affecting hepatic enzyme CYP3A4 metabolism, increased risk for rhabdomyolysis with drugs that increase simvastatin systemic exposure.

Side effects

Abdominal pain; Cholestatic hepatitis; Confusion; Diarrhea; Dyspepsia; Fever; Flatulence; Hallucinations; Headache; Hearing loss; Hypertrophic pyloric stenosis; Hypotension; Interstitial nephritis; Nausea; Seizures; Pain; Pruritus; Pseudomembranous colitis; QT prolongation; Rash; Skin eruptions; Tinnitus; Torsades de pointes; Urticaria; Ventricular arrhythmias; Ventricular tachycardia; Vertigo; Vomiting.

Patient educations

Instruct patient to take with 240ml of water 1 hour before or 2 hours after meals; If drug causes GI upset, encourage patient to take it with food; Advise patient to immediately report irregular heartbeats, unusual tiredness, yellowing of skin or eyes, or signs and symptoms of new infection; Tell patient he'll undergo periodic blood tests to monitor liver function; Roxithromycin not addictive and it is similar to erythromycin (derived from erythromycin).

Ruxolitinib

ATC Code: L01EJ01 Antineoplastic Agents (Janus-Associated Kinase (JAK) Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoid.

Indications and Dosage

• Myelofibrosis: 20mg bid if platelets greater than 200000 cells/mm^3, or 15mg bid if platelets 100000–200000 cells/mm^3, or 5mg bid if platelets 50000 to less than 100000 cells/mm^3, (max 25mg bid).
• Polycythemia vera: Initially, 10mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to ruxolitinib.

Cautions

Patients at risk for developing bacterial, fungal, or viral infections; History of bradycardia; Conduction disturbances; ischemic heart disease; Heart failure.
Dose adjustment in renal failure: CrCl 15-60ml per minute, avoid use; CrCl less than 15ml per minute use 15mg after dialysis on days of dialysis.
Dose adjustment in hepatic failure: If platelets 100000–150000 cells/mm^3 use 10mg bid; If platelets less than 100000 cells/mm^3 avoid use.

Dosage forms and trade names available in Iraq

- Ruxolitinib 5mg tab
  JAKAVI (Novartis Switzerland).
- Ruxolitinib 15mg tab
  JAKAVI (Novartis Switzerland).

Pharmacokinetic parameters

Absorption F=95%.
Distribution Vd=72-75L, 97%protein bound.
Metabolism Ruxolitinib undergoes metabolism by CYP3A4 and CYP2C9.
Elimination Renal elimination is 74% with half-life of 3 hours.

Drug interactions

Clarithromycin: Clarithromycin will increase the level or effect of ruxolitinib by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Anemia; Bacterial infections; Bruising; Dizziness; Edema; Fatigue; Headache; Hemorrhage; Hypertriglyceridemia; Neutropenia; Thrombocytopenia.
Less common (1-10%) Flatulence; Herpes zoster; Hypertriglyceridemia; Urinary tract infection; Weight gain.
Rare but serious (less than 1%) None.

Patient educations

Report any new bleeding, bloody stools or urine, fever, chills, rash, painful urination, suspected infection, fatigue, shortness of breath; Do not breastfeed; Open skin lesions, blisters may signal herpes infection.

Saccharomyces Boulardii

ATC Code: A07FA02 Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents (Antidiarrheal Microorganisms)
Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: No data available, but it is likely safe due to the nature of the substance.

Dosage forms and trade names available in Iraq

Saccharomyces boulardii 100mg Powder for Oral Suspension sachet
Floratil (Biocodex France).

Saccharomyces boulardii 200mg capsule
Floratil (Biocodex France).

Indications and Dosage

• Diarrhea associated with antibiotics: 100-200 mg (in powder or capsule form) orally twice daily.
• Traveler's diarrhea: 200 mg (in powder or capsule form) orally daily, starting 5 days before travel and continuing through the end of travel.

Off-label uses

Inflammatory bowel disease, Clostridium difficile infection.

Contraindications

Patients with central venous catheters due to risk of fungemia.

Cautions

• Immuno-compromised patients, critically ill patients
• Patients with a central venous catheter.

Dose adjustment in renal failure: No adjustment needed.

Dose adjustment in hepatic failure: No adjustment needed.

Pharmacokinetic parameters

As a probiotic, Saccharomyces boulardii is not digested or absorbed and does not have traditional pharmacokinetic parameters such as **absorption**, **distribution**, **metabolism**, and **elimination**.

Drug interaction

Antifungal medications: May decrease the effectiveness of Saccharomyces boulardii.
Immunosuppressive therapy: May increase the risk of fungemia in these patients.

Side effects

Common (more than 10%): Bloating and gas.
Less common (1-10%): Increased thirst.
Rare but serious (less than 1%): Fungemia in critically ill or immunocompromised patients.

Patient educations

• Can be taken with or without food.
• If you are taking antifungal medications, consult with your doctor before taking Saccharomyces boulardii.
• Report any signs of infection, such as fever or persistent cough, to your healthcare provider.

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Salbutamol

ATC Code: R03AC02 Drugs for Obstructive Airway Diseases (Adrenergics for Systemic Use)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Treatment and prevent bronchospasm in patients with reversible obstructive airway disease: 2mg-4mg tid-qid, (max 32mg daily), Aerosol, 1-2 inhalations qid to relieve bronchospasm, solution for inhalation 2.5mg tid-qid by nebulization delivered over 5 to 15 min.
• Prevent exercise induced bronchospasm: 2 inhalations 15 min before exercise.

Off-label uses

Chronic obstructive pulmonary disease; Hyperkalemia with renal failure; Preterm labor management.

Contraindications

Hypersensitivity to salbutamol.

Cautions

Hypertension; Cardiovascular disease; Hyperthyroidism; Diabetes; Heart failure; Convulsive disorders; Glaucoma; Hypokalemia; Arrhythmias.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Salbutamol 5mg/ml solution for nebulizer
  VENTODAD (Wadi AL-Rafidain Iraq).
- salbutamol 100µg/dose inhaler
  Ventolin Evohaler (GSK France).
- Salbutamol 2mg/5ml Syrup
  BUTADIN (SDI Iraq), **VENTODAD** (Wadi AL-Rafidain Iraq), **SALBUTIN** (Al-Kindi Iraq), **butaphar** (Dubai Co. Iraq), VentoWay (AL-MANSOUR Iraq).
- Salbutamol 2mg tab
  BUTAMOL (Al-Kindi Iraq).

Pharmacokinetic parameters

Absorption F=50-85%, food decrease rate of absorption.
Distribution Vd=156L, 10% protein bound.
Metabolism 20% via sulfotransferase.
Elimination Renal elimination is 80% with a half-life of 3.7-5 hours.

Drug interactions

Metoprolol: Metoprolol antagonize effect of salbutamol, metoprolol may produce bronchospasm.

Side effects

Common (more than 10%) Dyskinesia; Nausea.
Less common (1-10%) Abdominal pain; Dry mouth.
Rare but serious (less than 1%) Activation of mania; Arrhythmias; Blood pressure elevation; Confusion; External heat; Generalized pain; Hallucinations; Headache; Insomnia; Mood changes; Orthostatic hypotension; Serotonin syndrome; Suicidal thoughts and behaviors; Syncope; Urinary retention; Vomiting.

Patient educations

Tolerance to dizziness, light-headedness develops during therapy; To reduce hypotensive effect, slowly go from lying to standing; Avoid tasks that require alertness, motor skills until response to drug is established; Dry mouth, drowsiness, dizziness may be an expected response to drug; Avoid alcohol; Report worsening depression, unusual behavior, thoughts of suicide; Avoid tyramine-rich foods; Do not take herbal supplements.

Saxagliptin

ATC Code: A10BH03 Drugs Used in Diabetes (Dipeptidyl Peptidase 4 (DPP4-) Inhibitors)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: Compatible with breastfeeding; Monitoring of the breastfed infant's blood glucose is advisable during maternal therapy with saxagliptin.

Dosage forms and trade names available in Iraq

- Saxagliptin 2.5mg tablet
  Onglyza (Astra Zeneca UK).
- Saxagliptin 5mg tablet
  Onglyza (Astra Zeneca UK).

Indications and Dosage

• **Diabetes mellitus:** 2.5mg-5mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to saxagliptin; Type 1 diabetes; Ketoacidosis.

Cautions

History of pancreatitis.

Dose adjustment in renal failure: CrCl less than 50ml/min: 2.5mg once daily.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=50-75%, food has no effect on absorption.

Distribution Vd=2.7L/kg, negligible protein bound.

Metabolism Hepatic metabolism.

Elimination Renal elimination is 60% with a half-life of 2.5 hr.

Drug interactions

Clarithromycin: Strong CYP3A4 inhibitors clarithromycin may increase the serum concentration of saxagliptin, limit the saxagliptin dose to 2.5mg daily when combined with clarithromycin.

Diltiazem: Diltiazem CYP3A4 inhibitors may increase the serum concentration of saxagliptin.

Side effects

Common (more than 10%) None.

Less common (1-10%) Gastroenteritis; Headache; Hypoglycemia; Peripheral edema; Upper respiratory tract infection; Urinary tract infection.

Rare (less than 1%) None.

Patient educations

Explain to patient that saxagliptin helps control hyperglycemia but does not cure diabetes, therapy is usually long term; Encourage patient to follow prescribed diet, medication, and exercise regimen to prevent hyperglycemic or hypoglycemic episodes; Review signs of hypoglycemia and hyperglycemia with patient. If hypoglycemia occurs, advise patient to take a glass of orange juice or 2–3 tablespoonful of sugar or honey dissolved in water, and notify health care professional.

Semaglutide

ATC Code: A10BJ06 Drugs Used in Diabetes (Glucagon-like Peptide1- (GLP1-) Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Not recommended

Dosage forms and trade names available in Iraq

Semaglutide 0.25 mg pre-filled pen
Ozempic (Novo Nordisk Denmark).

Semaglutide 0.5 mg pre-filled pen
Ozempic (Novo Nordisk Denmark).

Semaglutide 1 mg pre-filled pen
Ozempic (Novo Nordisk Denmark).

Indications and Dosage

• Type 2 Diabetes: Start with 0.25 mg subcutaneously once weekly for 4 weeks, then increase to 0.5 mg once weekly. If additional glycemic control is needed, may increase dose to 1 mg once weekly.

• Obesity: Start with 0.25 mg subcutaneously once weekly for 4 weeks, then gradually increase the dose by 0.25 mg weekly, up to a dose of 2.4 mg once weekly.

Off-label uses

None.

Contraindications

Personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Cautions

Risk of thyroid C-cell tumors; Pancreatitis; diabetic retinopathy, hypoglycemia.

Dose adjustment in renal failure: Not needed.

Dose adjustment in hepatic failure: Not needed.

Pharmacokinetic parameters

Absorption F= ~94%

Distribution Vd= 12.6 L, 0% protein bound.

Metabolism Minimal, mainly by proteolytic cleavage

Elimination Renal excretion of metabolites, with half-life of ~ 1 week.

Drug interaction

Insulin or sulfonylureas: Increased risk of hypoglycemia. May require dose reduction of insulin or sulfonylureas.

Any medication that slows gastric emptying: Semaglutide may alter the absorption of these medications.

Side effects

Common (more than 10%): Nausea, diarrhea, vomiting, constipation, abdominal pain.

Less common (1-10%): Decreased appetite, dyspepsia, eructation, hypoglycemia.

Rare but serious (less than 1%): Pancreatitis, diabetic retinopathy, acute gallbladder disease.

Patient educations

• Administer the injection once weekly, on the same day each week, at any time of day, with or without meals.

• Inform your doctor if you experience severe stomach pain, vision changes or persistent vomiting/diarrhea.

• Store unopened pens in the refrigerator, opened pens can be kept at room temperature. Don't freeze or use if it has been frozen.

Senna

ATC Code: A06AB06 Drugs for Constipation (Contact Laxatives)

Pregnancy category:
FDA A B **C** D X N
TGA **A** B1 B2 B3 C D X N

Lactation: Considered safe to use during lactation

Indications and Dosage

Indicated for the treatment of constipation. Dosage: Adults and children over 12 years, 13.5 mg (1 tablet) orally once a day; increase to 2 tablets if necessary.

Off-label uses

bowel preparation prior to medical procedures.

Contraindications

Individuals with intestinal obstruction, acute intestinal inflammation (e.g., Crohn's disease, ulcerative colitis); abdominal pain of unknown origin.

Cautions

Prolonged use may lead to electrolyte imbalance and dependence.

Dose adjustment in renal failure: Not necessary.

Dose adjustment in hepatic failure: Not necessary.

Dosage forms and trade names available in Iraq

- Sennosides as Calcium Salts 12mg tablet

Pharmacokinetic parameters

Absorption Minimal systemic absorption (F=N/A%).

Distribution N/A.

Metabolism Undergoes bacterial metabolism in the colon.

Elimination Excretion in the feces.

Drug interaction

Senna and Diuretics: Concomitant use can increase the risk of electrolyte imbalance.

Senna and Corticosteroids: Concomitant use can increase the risk of electrolyte imbalance.

Side effects

Common (more than 10%): Abdominal cramps; Diarrhea.

Less common (1-10%): Nausea; Discolored urine.

Rare but serious (less than 1%): Electrolyte imbalance.

Patient educations

• Do not use Senna for more than one week without consulting your healthcare provider.

• Drink plenty of fluids and maintain a balanced diet while taking senna to avoid dehydration and electrolyte imbalance.

• Contact your healthcare provider if you experience severe abdominal pain, cramps, or persistent nausea and diarrhea.

Sertaconazole Nitrate

ATC Code: D01AC14 Antifungals for Dermatological Use (Imidazole and Triazole Derivatives))

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Not yet known. Caution should be exercised

Dosage forms and trade names available in Iraq

Sertaconazole nitrate 20 mg/g cream

Dermofix (Ferrer Internacional Spain).

Indications and Dosage

Sertaconazole cream is indicated for the topical treatment of interdigital tinea pedis (athlete's foot) caused by Trichophyton rubrum, Trichophyton mentagrophytes, and Epidermophyton floccosum. Apply twice daily (morning and evening) for 4 weeks.

Off-label uses

Treatment of tinea cruris and tinea corporis.

Contraindications

Hypersensitivity to sertaconazole nitrate.

Cautions

If irritation or sensitivity develops with the use of sertaconazole, treatment should be discontinued.

Dose adjustment in renal failure: None, topical use only and systemic absorption is minimal.

Dose adjustment in hepatic failure: None, topical use only and systemic absorption is minimal.

Pharmacokinetic parameters

Absorption Minimal systemic absorption through intact skin.

Distribution None determined

Metabolism Minimal systemic metabolism.

Elimination Presumably through desquamation of the skin.

Drug interaction

No known major interactions.

Side effects

Common (more than 10%): Application site burning.

Less common (1-10%): Skin irritation; Pruritus.

Rare but serious (less than 1%): Contact dermatitis.

Patient educations

• Wash and dry the affected area before applying sertaconazole cream.

• Avoid the use of occlusive dressings or wrappings unless directed by a doctor.

• If irritation or sensitivity develops, stop using the cream and consult your healthcare provider.

Sertraline

ATC Code: N06AB06 Psychoanaleptics (Selective Serotonin Reuptake Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Depression: 50mg-200mg daily.
• Panic disorder, post-traumatic stress disorder, social phobia disorder: 25mg daily for 1 week then titrate to 50mg daily, (max 200 mg daily).
• Premenstrual dysphoric disorder: 50mg-100mg daily.

Off-label uses

Eating disorders; Bulimia nervosa; Generalized anxiety disorder.

Contraindications

Hypersensitivity to sertraline.

Cautions

Seizures disorders; Increased risk for suicide; History of mania.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use cautiously.

Dosage forms and trade names available in Iraq

- Sertraline 100mg tablet
  Seralin (Pharma International Jordan).
- Sertraline 50mg tablet
  Seralin (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=100%, food has minimal effect on absorption.
Distribution Vd=20L/kg, 99% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 40-45% with a half-life of 24 hours.

Drug interactions

Selegiline: Selegiline and sertraline both increase serotonin levels, at least 14 days should elapse between discontinuation of selegiline and initiation of treatment with a serotonergic drug.

Side effects

Common (more than 10%) Diarrhea; Dizziness; Drowsiness; Dry mouth; Ejaculation disorder; Fatigue; Headache; Insomnia; Nausea.
Less common (1-10%) Agitation; Anorexia; Anxiety; Constipation; Impotence; Malaise; Pain; Paresthesia; Sweating; Vomiting.
Rare (less than 1%) Agitation; Anorexia; Anxiety; Constipation; Impotence; Malaise; Pain; Paresthesia; Sweating; Vomiting.

Patient educations

Dry mouth may be relieved by sugarless gum, sips of water; Report headache, fatigue, tremor, sexual dysfunction; Avoid tasks that require alertness, motor skills until response to drug is established (may cause dizziness, drowsiness); Take with food if nausea occurs; Inform physician if pregnancy occurs; Avoid alcohol; Do not take OTC medications without consulting physician; Report worsening of depression, suicidal ideation.

Sevelamer

ATC Code: V03AE02 All Other Therapeutic Products (Drugs for Treatment Of Hyperkalemia And Hyperphosphatemia)
Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N
Lactation: Compatible with breastfeeding.

Indications and Dosage

•Treatment of hyperphosphatemia: 800mg-1600mg with each meal, depending on severity of hyperphosphatemia (5.5-7.4mg/dL: 800mg tid; 7.5-8.9mg/dL: 1200-1600mg tid; 9mg/dL or greater: 1600mg tid; Maintenance based on serum phosphorus concentrations, goal range: 3.5–5.5mg/dL.

Off-label uses

None.

Contraindications

Hypersensitivity to sevelamer; Bowel obstruction.

Cautions

Dysphagia; Major gastrointestinal tract surgery; Severe gastrointestinal tract motility disorders.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Sevelamer carbonate 800mg Tablet
Renvela (Genzyme Ireland).

Pharmacokinetic parameters

Absorption Not absorbed following oral administration; Sevelamer may bind to dietary phosphates and prevent its gastrointestinal absorption when sevelamer is administered in combination with food.
Distribution Not Available.
Metabolism Not Available.
Elimination Not Available

Drug interactions

Acetazolamide: Sevelamer decreases levels of acetazolamide by increasing elimination.
Ciprofloxacin: Sevelamer decreases levels of ciprofloxacin by inhibition of gastrointestinal absorption, administer ciprofloxacin at least 1 hour before or 3 hours after sevelamer.
Diazepam: Sevelamer decreases levels of diazepam by increasing elimination.
Roxadustat: Sevelamer modestly decreases the exposure to roxadustat, roxadustat should be taken at least 1 hour after sevelamer.

Side effects

Common (more than 10%) Arthralgia; Bronchitis; Diarrhea; Dyspepsia; Dyspnea; Hypertension; Limb pain; Nasopharyngitis; Nausea; Pruritus; Vomiting.
Less common (1-10%) Abdominal pain; Constipation; Flatulence; Hypercalcemia; Peritonitis.
Rare but serious (less than 1%) None.

Patient educations

• Take with meals; swallow tablets whole; do not chew, crush, dissolve, or divide tablets; Report persistent headache, nausea, vomiting, diarrhea, hypotension.
• Oral powder sachets, Manufacturer advises each sachet should be dispersed in 60mL water, or mixed with a small amount of cool food (100 g), prior to administration and discarded if unused after 30 minutes.

Sevofluorane

ATC Code: N01AB08 Anesthetics (Halogenated Hydrocarbons)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation: Safe for use in lactating women. However, breastfeeding should be avoided for at least 24 hours after administration due to potential transmission in breast milk.

Dosage forms and trade names available in Iraq

Sevofluorane 250ml inhalation anesthetic **Sevoflurane** (ABBVIE Italy).

Indications and Dosage

Sevoflurane is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery. Dosage varies by patient, procedure, and anesthesiologist discretion, generally 0.5 - 8.0% inhaled, adjusted as necessary.

Off-label uses

sedation for ICU patients.

Contraindications

• Sensitivity to Sevoflurane or to other halogenated inhalation anesthetics.
• Patients with known or suspected genetic susceptibility to malignant hyperthermia.

Cautions

• Should be administered by trained individuals familiar with the use of general anesthesia.
• Care should be taken in patients with hepatic and renal disease, and the elderly.
Dose adjustment in renal failure: No specific guidelines have been provided, but use with caution.
Dose adjustment in hepatic failure: No specific guidelines have been provided, but use with caution.

Pharmacokinetic parameters

Absorption Almost complete (F=100%)
Distribution Rapid equilibration with blood and tissues, Vd= 185 L/kg, minimal protein binding.
Metabolism Minimal (less than 5%) hepatic metabolism
Elimination Exhaled unchanged via lungs, with a half-life of 1-2 hours.

Drug interaction

Sevoflurane and Benzodiazepines: The combination may enhance the CNS depressive effect.
Sevoflurane and Opioids: The combination may lead to profound respiratory depression.

Side effects

Common (more than 10%): Nausea; Vomiting.
Less common (1-10%): Hypotension; Dizziness.
Rare but serious (less than 1%): Malignant hyperthermia; Seizures.

Patient educations

• Do not eat or drink anything after midnight on the night before your surgery, unless otherwise instructed by your doctor.
• Report any history of malignant hyperthermia in you or your family members to your doctor.

Sildenafil

ATC Code: G04BE03 Urologicals (Drugs Used in Erectile Dysfunction)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Erectile dysfunction: 25mg-100mg prn 1 hour prior to anticipated sexual activity.
• Pulmonary hypertension (WHO group I): 5mg-20mg tid.

Off-label uses

Pulmonary hypertension (WHO group II-IV).

Contraindications

Hypersensitivity to sildenafil.

Cautions

Myocardial infarction; Cerebrovascular accident; Serious arrhythmia within past 6 months; Coronary artery disease; Heart failure; Bleeding disorder; Active peptic ulcer; Anatomic penile deformity; Retinitis pigmentosa; Sickle cell anemia; Multiple myeloma; Leukemia; Hypertension; Hypotension.

Dose adjustment in renal failure: CrCl less than 30ml/min: 25mg if used for erectile dysfunction, dose not required if used for pulmonary hypertension.

Dose adjustment in hepatic failure: Avoid in sever liver disease.

Dosage forms and trade names available in Iraq

- Sildenafil (as citrate) 100mg tablet
  VIAGRA (Pfizer France).
- sildenafil (as citrate) 50mg tablet
  SAMAGRA (SDI Iraq).
- sildenafil 25mg tablet
  VIAGRA (Pfizer Europe France).

Pharmacokinetic parameters

Absorption F=41%, food has minimal effect on absorption.
Distribution Vd=105L, 96% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 13% with a half-life of 4 hr.

Drug interactions

Isosorbide: Isosorbide and sildenafil have additive vasodilation, potentially fatal hypotension.

Side effects

Common (more than 10%) Headache
Less common (1-10%) Diarrhea; Dizziness; Dyspepsia; Epistaxis; Erythema; Flushing; Insomnia; Skin rash.
Rare (less than 1%) None

.

Patient educations

Instruct patient to take sildenafil as directed; For erectile dysfunction, take approximately 1 hour before sexual activity and not more than once per day; If taking sildenafil for pulmonary arterial hypertension, take missed doses as soon as remembered unless almost time for next dose; do not double doses; Advise patient that sildenafil is not indicated for use in women; Caution patient not to take sildenafil concurrently with alpha-adrenergic blockers (unless on a stable dose) or nitrates; If chest pain occurs after taking sildenafil, instruct patient to seek immediate medical attention.

Silver Sulfadiazine

ATC Code: D06BA01 Antibiotics and Chemotherapeutics for Dermatological Use (Sulfonamides)

Pregnancy category:

FDA A **B** C D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Can be used during breastfeeding but avoid the baby coming into contact with areas of skin being treated with the cream.

Dosage forms and trade names available in Iraq

Silver Sulfadiazine 10mg/1g Cream

Flamadain (Wadi Al-Rafidain Iraq).

Indications and Dosage

• Prevention and treatment of wound sepsis in patients with second- and third-degree burns; Apply once or twice daily. The burn areas should be covered with cream at all times.

Off-label uses

Treatment of various skin and soft tissue infections.

Contraindications

Hypersensitive

Cautions

Avoid contact with the eyes; Prolonged use may lead to fungal or bacterial overgrowth.

Dose adjustment in renal failure: Not necessary, but monitor patients for systemic sulfonamide toxicity.

Dose adjustment in hepatic failure: Not necessary, but monitor patients for systemic sulfonamide toxicity.

Pharmacokinetic parameters

Absorption Minimal absorption through unbroken skin.

Distribution None determined.

Metabolism Minimal systemic metabolism.

Elimination Renal excretion for any systemically absorbed drug.

Drug interaction

Silver Sulfadiazine and Sulfonylureas: May increase the hypoglycemic action of sulfonylureas.

Silver Sulfadiazine and Cimetidine: Cimetidine may inhibit the renal excretion of silver sulfadiazine, leading to potential accumulation and toxicity.

Side effects

Common (more than 10%): Skin discoloration; Burning sensation at application site.

Less common (1-10%): Rash; Itching.

Rare but serious (less than 1%): Severe allergic reactions; Leukopenia.

Patient educations

• Apply cream once or twice a day.

• Do not apply this medication in or around the eyes.

• If you notice any severe side effects such as rash, itching, or unusual tiredness, contact your healthcare provider immediately.

Simethicone

ATC Code: A03AX13 Drugs for Functional Gastrointestinal Disorders (Other Drugs for Functional Gastrointestinal Disorders)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Antiflatulent: 40mg-360mg after meals and at bedtime, (max 500mg daily).

Off-label uses

Adjunct to bowel radiography and gastroscopy.

Contraindications

Hypersensitivity to simethicone.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption No systemic absorption occurs.

Distribution Simethicone is not systemically absorbed.

Metabolism Simethicone is not systemically absorbed.

Elimination Excreted unchanged in the feces.

Dosage forms and trade names available in Iraq

Simethicone 40mg/1ml Oral Drop

Colic out (Wadi AL-Rafidain Iraq), **GASES- OUT** (Al-Kindi Iraq).

Drug interactions

There are no known significant interactions.

Side effects

Abdominal pain; Diarrhea; Dizziness; Dry mouth; Fatigue; Headache; Nausea; Pancreatitis; Vomiting.

Patient educations

Explain to patient the importance of diet and exercise in the prevention of gas, also explain that this medication does not prevent the formation of gas; Take drug after each meal and at bedtime; Chew chewable tablets thoroughly before swallowing, shake; Parents may want to add drops to 30 milliliters of cool water, infant formula or other liquid to ease administration.

Simvastatin

ATC Code: C10AA01 Agents Acting on The Renin-Angiotensin System (ACE Inhibitors, Plain)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Hyperlipidemias, prevention of cardiovascular disease: 10mg-40mg once daily.

Off-label uses

Prophylaxis of adverse cardiovascular outcomes post-acute coronary syndrome hospitalization; Prophylaxis of atrial fibrillation among patients with stable coronary artery disease.

Contraindications

Hypersensitivity to simvastatin. Active hepatic disease.

Cautions

Diabetes; Substantial alcohol consumption; Rhabdomyolysis.

Dose adjustment in renal failure: CrCl less than 30ml/min: initially 5mg daily.

Dose adjustment in hepatic failure: Contraindicated in active hepatic disease.

Dosage forms and trade names available in Iraq

- Simvastatin 20mg tab
- Simvastatin tab 40mg

Pharmacokinetic parameters

Absorption F=5%.

Distribution Protein bound 95%.

Metabolism Extensive hepatic metabolism into 3 active metabolites.

Elimination Fecal elimination is 60%.

Drug interactions

Diltiazem: Diltiazem will increase the level or effect of simvastatin by affecting hepatic enzyme CYP3A4 metabolism, benefits of combination therapy should be carefully weighed against the potential risks of combination. Limit simvastatin dose to no more than 10mg/day and diltiazem dose to no more than 240mg/day when used concurrently.

Side effects

Common (more than 10%) None.

Less common (1-10%) Constipation; Creatine phosphokinase elevation; Eczema; Flatulence; Headache; Transaminases increased; Upper respiratory infection; Vertigo; hair loss; difficulty in sleep; liver problems; decrease in the sexual activity (erectile dysfunction).

Rare (less than 1%) Abdominal pain; Angioedema; Arthralgia; Arthritis; Chills; Eosinophilia; Myalgia; Myopathy; Rhabdomyolysis.

Patient educations

Use appropriate contraceptive measures; Periodic lab tests are essential part of therapy; Maintain appropriate diet; Avoid grapefruit products; Report unexplained muscle pain, tenderness, weakness.

Sirolimus

ATC Code: L04AA10 Immunosuppressants (Selective Immunosuppressants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Prevention of organ transplant rejection: 6mg as loading dose, maintenance 2mg daily.

Off-label uses

Prevention and Treatment of refractory acute or chronic graft-vs-host disease; Rescue agent for acute and chronic organ rejection.

Contraindications

Hypersensitivity to sirolimus.

Cautions

Heart failure; Hypertension; Pulmonary disease; Hyperlipidemia; Perioperative period due to increased chance of surgical complications from impaired wound and tissue healing.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Is reduced by approximately 31% in patients with mild or moderate hepatic impairment and by approximately 50% in patients with severe hepatic failure.

Dosage forms and trade names available in Iraq

- Sirolimus 1mg tablet
  Rapamune (PFIZER Germany).
- Sirolimus 2mg tablet
  Rapamune (PFIZER Germany).

Pharmacokinetic parameters

Absorption F=27%.
Distribution Vd=4-20L/kg, 92% protein bound.
Metabolism Extensively metabolized by P450 3A4.
Elimination Renal elimination is 2.2%, 91% by feces with half-life of 62 hours.

Drug interactions

Azathioprine: Azathioprine and sirolimus both increase immunosuppressive effects, risk of infection.

Use with Cyclosporine: Was demonstrated to increase sirolimus concentrations when co-administered with sirolimus.

Strong Inducers and Strong Inhibitors of CYP3A4 and P-gp: Avoid concomitant use of sirolimus with strong inducers (e.g., rifampin, rifabutin) and strong inhibitors (e.g., ketoconazole, voriconazole, itraconazole, erythromycin, telithromycin, clarithromycin) of CYP3A4 and P-gp.

Side effects

Common (more than 10%) Abdominal pain; Abnormal healing; Acne; Anemia; Arthralgia; Arthralgia; Basal cell carcinoma; Bone necrosis; Constipation; Diabetes mellitus; Diarrhea; Edema; Epistaxis; Fever.

Less common (1-10%) gingivitis; gum hyperplasia; weight changes; neck pain; fever; abscess; chills; facial edema; flu-like symptoms.

Rare but serious (less than 1%) None.

Patient educations

Avoid those with colds, other infections; Avoid exposure to sunlight; Strict monitoring is essential in identifying, preventing symptoms of organ rejection; Do not chew, crush, dissolve, or divide tablets.

Sitagliptin

ATC Code: A10BH01 Drugs Used in Diabetes (Dipeptidyl Peptidase 4 (DPP4-) Inhibitors)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: Compatible with breastfeeding; Monitoring of the breastfed infant's blood glucose is advisable during maternal therapy with sitagliptin.

Dosage forms and trade names available in Iraq

- Sitagliptin 50mg tab
  Sitavia (PIONEER IRAQ).
- Sitagliptin 100mg tab
  Sitavia (PIONEER IRAQ).

Indications and Dosage

• Diabetes mellitus: 100mg once daily.

Off-label uses

None.

Contraindications

Hypersensitivity to sitagliptin.

Cautions

Diabetes type 1; Diabetic ketoacidosis, History of pancreatitis; Angioedema with other DPP-4 inhibitors.
Dose adjustment in renal failure: CrCl 30-50ml/min: 50mg daily; CrCl less than 30ml/min: 25mg daily.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=87%, food has no effect on absorption.
Distribution Vd=198L, 38% protein bound.
Metabolism Not metabolized.
Elimination Renal elimination is 87% with a half-life of 12 hr.

Drug interactions

Amitriptyline: Amitriptyline increases effects of sitagliptin by pharmacodynamic synergism.
Ciprofloxacin: Ciprofloxacin increases effects of sitagliptin by pharmacodynamic synergism. Hyper and hypoglycemia have been reported in patients treated concomitantly with ciprofloxacin and sitagliptin, careful monitoring of blood glucose is recommended.

Side effects

Common (more than 10%) None.
Less common (1-10%) Headache; Nasopharyngitis; Upper respiratory tract infection.
Rare (less than 1%) None.

Patient educations

Diabetes requires lifelong control; Prescribed diet, exercise are principal part of treatment; do not skip, delay meals; Continue to adhere to dietary instructions, regular exercise program, regular testing of serum glucose; When taking combination drug therapy or when glucose demands are altered (fever, infection, trauma, stress, heavy physical activity), have source of glucose available to treat symptoms of hypoglycemia; Report nausea, vomiting, anorexia, severe abdominal pain, pancreatitis.

Sodium Bicarbonate

ATC Code: B05XA02 Blood Substitutes and Perfusion Solutions (Electrolyte Solutions)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Generally considered safe, but caution is advised

Indications and Dosage

Used to correct metabolic acidosis. Dosage is based on the individual's medical condition.

Off-label uses

Treatment of certain drug intoxications, and in certain cases of mushroom poisoning.

Contraindications

• Metabolic or respiratory alkalosis
• Hypocalcemia, hypernatremia, hypertension, congestive heart failure, renal impairment, edema, and certain drug interactions.

Cautions

In patients with congestive heart failure, renal impairment, or edema.
Dose adjustment in renal failure: Use with caution, adjust dosage based on patient's acid-base status and serum electrolyte levels.
Dose adjustment in hepatic failure: Not typically required.

Dosage forms and trade names available in Iraq

Sodium bicarbonate 8.4% 25ml Infusion
Sodium bicarbonate 8.4% 50ml Infusion
Sodium bicarbonate 84g/1L (5L) Infusion
Basic hemodialysis concentrate (National health factory Iraq).
Sodium bicarbonate powder sachets
Sodium Bicarbonate (WRC Iraq), **Sodium Bicarbonate** (AlMansur Iraq).

Pharmacokinetic parameters

Absorption Rapid and complete.
Distribution Throughout the extracellular space
Metabolism Not metabolized.
Elimination Renal excretion, half-life depends on urinary pH.

Drug interaction

• Sodium bicarbonate can interact with certain heart medications, causing them to be less effective.
• May also interact with certain antifungal medications, affecting their absorption.

Side effects

Common (more than 10%): Metabolic alkalosis if overdosed.
Less common (1-10%): Hypernatremia; hypokalemia.
Rare but serious (less than 1%): Heart failure due to sodium overload.

Patient educations

Notify healthcare provider immediately if you experience shortness of breath, swelling of ankles/feet, or sudden weight gain.

Sodium Chloride

ATC Code: B05XA03 Blood Substitutes and Perfusion Solutions (Electrolyte Solutions).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Generally considered safe.

Dosage forms and trade names available in Iraq

Sodium Chloride 0.9% (9mg/1ml) nasal drops
Physoneer (Pioneer Iraq).

sodium chloride 0.9g/100ml 0.9%
Normal saline (SDI IRAQ), **Sodium Chloride** (Pioneer Iraq).

Indications and Dosage

For nasal congestion, 1-2 drops in each nostril as needed.

Off-label uses

None.

Contraindications

Hypersensitive sodium chloride.

Cautions

Avoid use if nasal passage is completely blocked, If there is an ear infection.
Dose adjustment in renal failure: None
Dose adjustment in hepatic failure: None

Pharmacokinetic parameters

Absorption Minimal
Distribution Local
Metabolism Not applicable
Elimination Not applicable

Drug interaction

No known significant interactions.

Side effects

Common (more than 10%): No common side effects.
Less common (1-10%): Minor nose irritation or stinging.
Rare but serious (less than 1%): Allergic reaction.

Patient educations

• Do not share this medication with others as it may spread infection.
• To apply, tilt head back and drop solution into each nostril.

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Sodium Hyaluronate

ATC Code: S01KA01 Ophthalmologicals (Viscoelastic Substances).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: It is not yet known.

Indications and Dosage

For the treatment of dry eye syndrome, usually 1-2 drops in the affected eye(s) as needed.

Off-label uses

None.

Contraindications

Hypersensitivity to sodium hyaluronate.

Cautions

Contact lens wearers should remove their lenses before applying the drops and wait at least 15 minutes before reinserting.

Dose adjustment in renal failure: None.

Dose adjustment in hepatic failure: None.

Dosage forms and trade names available in Iraq

Sodium hyaluronate 2mg/ml eye drop
Piofresh (Pioneer Iraq).

Pharmacokinetic parameters

Absorption Minimally absorbed systemically.
Distribution Not applicable, not protein bound.
Metabolism Not metabolized.
Elimination Any absorbed drug is likely excreted unchanged in the urine, with the half-life unknown.

Drug interaction

Other Eye Drops: Wait at least 5 minutes between using Sodium Hyaluronate and any other eye medication to prevent diluting the drugs.

Contact Lenses: Sodium Hyaluronate may interact with soft contact lenses.

Side effects

Common (more than 10%): Temporary blurred vision.

Less common (1-10%): Mild eye irritation.

Rare but serious (less than 1%): Serious allergic reaction.

Patient educations

• Do not touch the dropper tip or let it touch your eye or any other surface to avoid contamination.
• If you are using another kind of eye medication (e.g., drops or ointments), wait at least 5 minutes before applying other medications.
• Use this medication regularly to get the most benefit from it.
• To help you remember, use it at the same times each day.

Sodium Picosulphate

ATC Code: A06AB08 Alimentary Tract and Metabolism (Contact Laxatives).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Not yet known, use with caution.

Indications and Dosage

Used for bowel cleansing before colonoscopy or surgery; adult dosage is typically 10 mg (or 20 drops) per day.

Off-label uses

None.

Contraindications

• Hypersensitivity to sodium picosulphate; Ileus, intestinal obstruction; Acute surgical abdominal conditions; Severe dehydration; Severe electrolyte imbalance.

Cautions

Do not use for more than one week, unless supervised by a doctor.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Sodium Picosulphate 7.5mg/1ml oral drop

Pharmacokinetic parameters

Absorption Rapidly absorbed.
Distribution Vd= not available, not protein bound.
Metabolism In the colon by gut bacteria.
Elimination Excreted mostly in the feces, with a half-life of approximately 6.5 hours.

Drug interaction

Antacids: May decrease the effect of Sodium Picosulfate.
Diuretics or corticosteroids: Concurrent use may increase the risk of electrolyte imbalance.

Side effects

Common (more than 10%): Abdominal cramps; diarrhea.
Less common (1-10%): Nausea; vomiting.
Rare but serious (less than 1%): Allergic reactions; electrolyte imbalance.

Patient educations

• Drink plenty of clear liquids before, during, and after taking this medication.
• This medication may cause you to have a bowel movement within 6 to 12 hours.

Sodium Valproate

ATC Code: N03AG01 Antiepileptics (Fatty acid derivatives)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

● Seizures: 10mg-15mg/kg/day in 2-3 divided doses, may increase by 5mg-10mg/kg/day at weekly intervals up to 30mg-60mg/kg/day, usual adult dosage 1000mg-2500mg/day. By i.v. injection same oral dose but given every 6 hours.

Off-label uses

Refractory status epilepticus; Diabetic neuropathy; Mood stabilizer for behaviors in dementia.

Contraindications

Hypersensitivity to sodium valproate; Active hepatic disease; Urea cycle disorders; Known mitochondrial disorders; Migraine prevention in pregnant women.

Cautions

Children younger than 2 years; Patients at risk for hepatotoxicity; History of hepatic impairment; Bleeding abnormalities; Patients at high risk for suicide; Elderly patients.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Use of sodium valproate in severe hepatic failure is contraindicated.

Dosage forms and trade names available in Iraq

- Sodium valproate 500mg tablet
  DEPAKIN CHRONO (Sanofi France).
- sodium valproate 200 mg tab
  DEPAKINE (Sanofi France).
- Sodium valproate 200mg /1ml oral solution
  DEPAKIN (Sanofi France).
- Sodium valproate 200mg/5ml Syrup

Pharmacokinetic parameters

Absorption F=90%.

Distribution Vd=11L/1.73m2, 80-90%protein bound.

Metabolism Mostly metabolized by the liver.

Elimination Sodium valproate elimination half-life is 9-16 hours.

Drug interactions

Aspirin: Aspirin increases levels of valproic acid by plasma protein binding competition.

Side effects

Common (more than 10%) Alopecia; Diarrhea; Diplopia; Dizziness; Dyspepsia; Headache; Nausea; Nystagmus; Somnolence; Thrombocytopenia; Tinnitus; Tremor; Vomiting.

Less common (1-10%) Abdominal pain; Abnormal gait; Anxiety; Ataxia; Back pain; Hallucinations; Increased appetite; Irregular menses; Mood changes; Paresthesia; Rash; Tardive dyskinesia; Tremor; Weight gain.

Rare but serious (less than 1%) Acute pancreatitis (may be life-threatening); Anorexia; Cerebral pseudoatrophy (acute or subacute cognitive decline and behavioral changes (apathy or irritability); Decreased bone mineral density; Fractures; Hepatic toxicity; Hyperammonemia; Osteopenia; Osteoporosis; Weight loss.

Patient educations

Do not abruptly discontinue medication after long term use (may precipitate seizures); Avoid tasks that require alertness, motor skills until response to drug is established.

Solifenacin

ATC Code: G04BD08 Urologicals (Drugs for Urinary Frequency and Incontinence)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Overactive bladder: 5mg daily, may titrate to 10mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to solifenacin; Gastric retention; Narrow angle glaucoma; Urinary retention.

Cautions

Bladder outflow obstruction; GI obstructive disorders; Decreased GI motility; Congenital or acquired QT prolongation; Hypokalemia Hypomagnesemia; Hot weather; Exercise.

Dose adjustment in renal failure: CrCl less than 30ml/min: max. 5mg daily.

Dose adjustment in hepatic failure: Not recommended use in severe hepatic impairment.

Dosage forms and trade names available in Iraq

- Solifenacin Succinate 5mg tab
- Solifenacin Succinate 10mg tab

Pharmacokinetic parameters

Absorption F=90%, food has no effect on absorption.
Distribution Vd=600L, 98% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 70% with a half-life of 45-68 hours.

Drug interactions

Acetaminophen: The metabolism of solifenacin can be decreased when combined with acetaminophen.
Amitriptyline: The metabolism of solifenacin can be decreased when combined with amitriptyline.
Topiramate: Solifenacin may enhance the adverse effect of Topiramate.
Antifungal agents (Azole derivatives, systemic): May increase the serum concentration of Solifenacin (e.g Ketokanazole) Maximum dose: 5mg/day.
Valsartan: Solifenacin may decrease the antihypertensive activities of valsartan.

Side effects

Common (more than 10%) Constipation; Dry mouth.
Less common (1-10%) Abdominal pain; Blurred vision; Cough; Depression; Dizziness; Dry eyes; Dyspepsia; Edema lower limb; Fatigue; Hypertension; Influenza; Nausea; Positive urinalysis bacterial test; Somnolence; Upper abdominal pain; Urinary retention; Urinary tract infection; Vomiting.
Rare (less than 1%) None.

Patient educations

Avoid tasks requiring alertness, motor skills until response to solifenacin is established; Anticholinergic side effects include constipation, urinary retention, blurred vision, heat prostration in hot environment; Use caution during exercise, exposure to heat.

Somatropin

ATC Code: H01AC01 Pituitary and Hypothalamic Hormones and Analogues (Somatropin and Somatropin Agonists).

Pregnancy category:

FDA A B **C** D X N

TGA A B1 **B2** B3 C D X N

Lactation: Unknown, use with caution.

Indications and Dosage

• Somatotropin is a recombinant human growth hormone used as replacement therapy in various conditions of growth failure, growth hormone deficiency, and weakness in children and adults

• Dosage is highly variable and individualized based on diagnosis, patient response, and tolerance. A common starting dose is 0.004-0.01 mg/kg/day subcutaneously for pediatric patients and 0.2-0.3 mg/day for adult patients, which can be titrated based on IGF-1 levels.

Off-label uses

Anti-aging; bodybuilding; short stature in children without growth hormone deficiency, Turner syndrome, and chronic renal failure-associated growth failure.

Contraindications

Active malignancy, diabetic retinopathy, acute critical illness (e.g. post open-heart or abdominal surgery, multiple accidental trauma, acute respiratory failure); Prader-Willi syndrome with obesity and respiratory impairment; Hypersensitivity to somatropin or any of its excipients.

Dosage forms and trade names available in Iraq

- Somatropin 5mg/1.5ml PFP
  Omnitrope (Sandoz Austria).
- Somatropin 10mg/1.5ml PFP
  Norditropin NordiFlex (Novo Nordisk Denmark).
- Somatropin 15mg/1.5ml PFP
  Norditropin NordiFlex (Novo Nordisk Denmark).
- Somatropin 12mg/1ml PFP
  Genotropin (PFIZER Belgium).
- Somatropin 5.3mg/1ml PFP
  Genotropin (PFIZER Belgium).

Cautions

Increased risk of neoplasms; monitor glucose levels in diabetics; monitor for hypothyroidism; monitor for intracranial hypertension.

Dose adjustment in renal failure: Lower dose may be required.

Dose adjustment in hepatic failure: Lower dose may be required.

Pharmacokinetic parameters

Absorption Well-absorbed after subcutaneous administration.

Distribution Vd= ~50 L, minimally protein bound.

Metabolism Liver, kidney, and extrahepatic tissues via the GH receptor.

Elimination Kidney and liver with half-life of 2-3 hours.

Drug interaction

Glucocorticoids: May inhibit the growth-promoting effect of somatropin. Closely monitor growth rate when glucocorticoid therapy is instituted in growth hormone-treated patients.

Insulin and/or oral hypoglycemic agents: Patients with diabetes mellitus may require adjustment of their doses of insulin and/or other hypoglycemic agents.

Side effects

Common (more than 10%): Injection site reactions; headaches; fluid retention; joint or muscle aches/pains.

Less common (1-10%): Abdominal pain; hypothyroidism; increased appetite; edema; nausea/vomiting.

Rare but serious (less than 1%): Leukemia; recurrence of brain tumors; severe allergic reactions.

Patient educations

• Do not shake the vial before use; gently swirl the vial to dissolve the powder.

• Monitor blood sugar levels if you are a diabetic; notify your doctor if you experience increased thirst or urination.

• If you experience any allergic reactions like rash, itching, or severe dizziness, seek immediate medical help.

• Store somatropin as recommended by the manufacturer.

Sorafenib

ATC Code: L01EX02 Antineoplastic Agents (Other Protein Kinase Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Sorafenib as tosylate 200mg tab
Nexavar (Bayer Germany).

Indications and Dosage

• Advanced renal cell or hepatocellular cancer: 400mg bid on an empty stomach.
• Thyroid Cancer, indicated for locally recurrent or metastatic, progressive, differentiated thyroid cancer that is refractory to radioactive iodine treatment the dosage is determined by the doctor.

Off-label uses

Recurrent or metastatic angiosarcoma; Resistant gastrointestinal stromal tumor.

Contraindications

Hypersensitivity to sorafenib.

Cautions

Hypertension; Congenital long QT syndrome; Hypokalemia; Hypomagnesemia; Unstable coronary artery disease; Recent myocardial infarction; Heart failure.

Dose adjustment in renal failure: CrCl 20-40ml per minute, use 200mg bid; CrCl less than 20ml per minute, use 200mg once daily.

Dose adjustment in hepatic failure: Bilirubin greater than 1.5 to 3 times, use 200mg bid; Albumin less than 2.5g/dL, use 200mg once daily.

Pharmacokinetic parameters

Absorption F=38-49%.
Distribution Vd=Undetermined, 99.5%protein bound.
Metabolism Sorafenib is metabolized primarily in the liver by CYP3A4.
Elimination Renal elimination is 19% with half-life of 25-48 hours.

Drug interactions

Voriconazole: Voriconazole will increase the level or effect of sorafenib by affecting hepatic enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Abdominal pain; Alopecia; Anemia; Anorexia; Constipation; Dry skin; Fatigue: Hand foot skin reaction; Hemorrhage; Hypertension; lymphadenopathy; nausea; neutropenia; rash; thrombocytopenia; vomiting; weight loss.
Less common (1-10%) Congestive heart failure; MI; Headache; Joint pain; QT prolongation.
Rare but serious (less than 1%) Acute renal failure; Angioedema and arrhythmia may occur; Bone pain reported.

Patient educations

Report any episode of chest pain, do not have immunizations without physician's approval (drug lowers resistance), Avoid contact with those who have recently taken live virus vaccine: Promptly report fever, sore throat, signs of local infection, unusual bleeding from any site. swallow whole; do not chew, crush, dissolve, or divide tablet; Avoid administration after high fat meals.

Spiramycin

ATC Code: J01FA01 Antibacterials For Systemic Use (Macrolides)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Avoid.

Indications and Dosage

• Toxoplasmosis, Protozoal infections (cryptospriddiosis): 3000000-6000000 IU bid, or 1500000-3000000 IU tid, for severe infections, the dose is 6000000-7500000 IU bid.

Off-label uses

None.

Contraindications

Hypersensitivity to spiramycin.

Cautions

History of arrhythmias or predisposition to QT interval prolongation.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=30-39%.
Distribution Vd=300L, 10-25%protein bound.
Metabolism Metabolized hepatically to active metabolites.
Elimination Renal elimination is 10% with half-life of 5-8 hours.

Dosage forms and trade names available in Iraq

Spiramycin 3.000.000 IU tablet
Rovamycin 3M (Sanofi Aventis France).

Drug interactions

Atorvastatin: The risk or severity of adverse effects can be increased when spiramycin is combined with atorvastatin.
Betamethasone: The serum concentration of betamethasone can be increased when it is combined with spiramycin.
Digoxin: The serum concentration of digoxin can be increased when it is combined with spiramycin.
Warfarin: The risk or severity of bleeding can be increased when spiramycin is combined with Warfarin.

Side effects

Abdominal pain; Diarrhea; Macular rashes; Nausea; Neuromuscular blockade; Prolongation of QT interval; Pruritus; Pseudomembranous colitis; Transient paresthesia; Urticaria; Ventricular arrhythmias; Vomiting.

Patient educations

Continue therapy for full length of treatment; Doses should be evenly spaced. Instruct patient to take with large amount of water, spiramycin is best taken on an empty stomach if drug causes gastrointestinal upset, encourage patient to take it with food.

Spironolactone

ATC Code: C03DA01 Diuretics (Aldosterone Antagonists)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Spironolactone 25 mg tab
- Spironolactone 50 mg tab

Indications and Dosage

• Heart failure: 12.5mg-25mg daily, (max 50mg daily).
• Edema associated with heart failure, nephrotic syndrome: 100mg daily in single or divided doses may titrate to 400mg daily.
• Hypertension: 50mg-100mg daily in single or divided doses.
• Hypokalemia: 25mg-100mg daily.

Off-label uses

Ascites; Cirrhosis of liver; Acne vulgaris; Hirsutism.

Contraindications

Hypersensitivity to spironolactone; Anuria; Hyperkalemia; Addison's disease.

Cautions

Dehydration; Hyponatremia; Elderly patients.
Dose adjustment in renal failure: CrCl less than 30ml/min: Not recommended.
Dose adjustment in hepatic failure: Alternate day dosing may be considered.

Pharmacokinetic parameters

Absorption F=73%, food increase absorption.
Distribution Protein bound 90%.
Metabolism Hepatic to active metabolite.
Elimination Renal elimination is 47-57% with a half-life of 1.4 hours.

Drug interactions

Furosemide: Spironolactone increases and furosemide decreases serum potassium, effect of interaction is not clear, use caution.

Side effects

Common (More than 10%) Hyperkalemia, hyponatremia.
Less common (1-10%) Acidosis in patients with liver problems
Rare (less than 1%) Dehydration, porphyria, hyperuricemia

Patient educations

Expect increase in volume, frequency of urination; Therapeutic effect takes several days to begin and can last for several days when drug is discontinued; Avoid foods high in potassium, such as whole grains (cereals), meat, bananas, apricots, orange juice, potatoes; Avoid alcohol; Avoid tasks that require alertness, motor skills until response to drug is established (may cause drowsiness).

Sugammadex

ATC Code: V03AB35 All Other Therapeutic Products (Antidotes)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Reversal of neuromuscular blockers: By i.v. injection, 4mg/kg.

Off-label uses

None.

Contraindications

Hypersensitivity to sugammadex; Patients on hemodialysis.

Cautions

Impaired hemostasis; Hepatic impairment particularly if accompanied by coagulopathy or severe edema.
Dose adjustment in renal failure: CrCl less than 30ml per minute, use of sugammadex is contraindicated.
Dose adjustment in hepatic failure: Use with caution particularly if accompanied by coagulopathy or severe edema.

Dosage forms and trade names available in Iraq

Sugammadex 200mg/2ml vial
Biomadex (Pioneer Iraq).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=11-14L.
Metabolism Not metabolized.
Elimination Renal elimination is 96% with half-life of 2 hours.

Drug interactions

Medroxyprogesterone: Sugammadex sodium decreases effects of medroxyprogesterone by receptor binding competition, in vitro binding studies showed that sugammadex may bind to progestogen, thereby decreasing progestogen exposure. Therefore, a sugammadex bolus dose is considered to be equivalent to missing dose of hormonal contraceptives containing an estrogen or progestogen. If an oral contraceptive is taken on the same day of sugammadex, the patient must use an additional, nonhormonal contraceptive method or back-up method of contraception (such as condoms and spermicides) for the next 7 days.

Side effects

Common (more than 10%) Hypotension; Nausea; Pain; Vomiting.
Less common (1-10%) Abdominal pain; Airway complication of anesthesia; Anesthetic complication; Anxiety; Bradycardia; Chills; Cough; Decreased RBCs; Depression; Dizziness; Dry mouth; Erythema; Flatulence; Headache; Hypertension; Hypocalcemia; Hypoesthesia; Incision site pain; Increased CPK; Insomnia; Musculoskeletal pain; Myalgia; Oropharyngeal pain; Pain in extremity; Procedural complication; Pruritus; Pyrexia; QT interval abnormal; Restlessness; Tachycardia; Wound hemorrhage;
Rare but serious (less than 1%) None.

Patient educations

A Patient education is not currently available for this monograph.

Sumatriptan

ATC Code: N02CC01 Analgesics (Selective Serotonin (5HT1) Agonists).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It is excreted in breast milk. Consider a delay in breastfeeding after administration of the drug, in case of need.

Dosage forms and trade names available in Iraq

Sumatriptan as Succinate 6mg/0.5ml Pre-Filled Syringes

Indications and Dosage

Treatment of acute migraine or cluster headache attacks. Typically, the dose for subcutaneous injection is 6mg once, if symptoms persist, the dose can be repeated once after 1 hour, up to a maximum of 12mg per day.

Off-label uses

for severe tension headaches.

Contraindications

Hypersensitivity to Sumatriptan; Coronary artery disease (CAD) or coronary artery vasospasm, including Prinzmetal's angina, Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders.

Cautions

In patients with uncontrolled hypertension; history of seizure; liver disease.

Dose adjustment in renal failure: Use with caution, may require adjustment but specific guidelines are not available.

Dose adjustment in hepatic failure: Use with caution, may require adjustment but specific guidelines are not available.

Pharmacokinetic parameters

Absorption After subcutaneous administration, sumatriptan is rapidly absorbed, with a bioavailability of ~96%.
Distribution Vd= 2.4L/kg, 14-21% protein bound.
Metabolism Monoamine oxidase A (MAO-A) major enzyme responsible for metabolism.
Elimination Primarily renal excretion with a half-life of ~2 hours.

Drug interaction

With ergot-type medications (like dihydroergotamine, ergotamine): May cause prolonged vasoconstrictive reactions. Do not use within 24 hours of each other.
With MAO inhibitors: Increased levels of sumatriptan. Avoid concurrent use.

Side effects

Common (more than 10%): Injection site reactions; tingling; dizziness; warm/hot sensation.
Less common (1-10%): Vertigo; fatigue; flushing; discomfort in the nasal cavity.
Rare but serious (less than 1%): Coronary artery vasospasm; transient ischemic attacks; stroke; seizures.

Patient educations

• Sumatriptan should only be used during a migraine attack and must not be used to prevent attacks.
• Don't use more than your doctor has prescribed; overuse can cause headaches to get worse.
• Seek immediate medical attention if you have symptoms of a stroke (such as weakness on one side of your body, slurred speech, sudden vision changes, confusion).

Sunitinib

ATC Code: L01XE04 Antineoplastic Agents (Other Protein Kinase Inhibitors)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• GI stromal tumor, renal cell carcinoma: 50mg once daily for 4 weeks, followed by 2 weeks off in 6weeks cycle.

Off-label uses

Non-gastrointestinal stromal tumor; Soft tissue sarcomas; Advanced thyroid cancer.

Contraindications

Hypersensitivity to sunitinib.

Cautions

Cardiac dysfunction; Bradycardia; Electrolyte imbalance; Bleeding tendencies; Hypertension; History of prolonged QT interval; Hypokalemia; Hypomagnesemia; Heart failure.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Use of sunitinib in severe hepatic failure is contraindicated.

Dosage forms and trade names available in Iraq

- Sunitinib maleate 12.5mg capsule
- Sunitinib maleate 25mg capsule
- Sunitinib maleate 50mg capsule

Pharmacokinetic parameters

Absorption Well absorbed following oral administration, food has no effect on absorption.

Distribution Vd=2230L, 95%protein bound.

Metabolism Metabolized by the CYP3A4.

Elimination Excretion is primarily fecal with half-life of 40-60 hours.

Drug interactions

Bevacizumab: Coadministration of bevacizumab and sunitinib is not recommended, cases of microangiopathic hemolytic anemia (MAHA) have been reported.

Side effects

Common (more than 10%) Abdominal pain; Alopecia; Altered taste; Anorexia; Arthralgia; Asthenia; Back pain; Constipation; Cough; Dehydration; Diarrhea; Dizziness; Dry skin; Dyspepsia; Dyspnea; Fatigue; Fever; Flatulence; Hair color change; Headache; Hyperpigmentation; Hypertension; Limb pain; Mucositis; Myalgia; Nausea; Periorbital edema; Peripheral; Rash; Renal carcinoma; Stomatitis; Stromal tumor; Tongue pain; Vomiting.

Less common (1-10%) None.

Rare but serious (less than 1%) None.

Patient educations

Avoid crowds, those with known infection; Avoid contact with anyone who recently received live virus vaccine; Do not have immunizations without physician's approval (drug lowers resistance); Avoid pregnancy; use effective contraceptive measures; Promptly report fever, unusual bleeding from any site.

Tacrolimus

ATC Code: L04AD02 Immunosuppressants (Calcineurin Inhibitors)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Avoided, Excreted in breast milk.

Dosage forms and trade names available in Iraq

- Tacrolimus 0.3mg/g ointment
  Protopic (Leo Ireland).
- Tacrolimus 1mg/g 0.1% ointment
  Protopic (Leo Ireland).
- Tacrolimus 0.5mg capsule
- Tacrolimus 1mg capsule
  Prograf (Astellas Ireland).
- Tacrolimus 5mg capsule

Indications and Dosage

• Liver transplant rejection: 0.1mg/kg daily in 2 divided doses, may titrate based on clinical response.
• Renal transplant rejection: 0.2mg/kg daily in 2 divided doses, may titrate based on serum levels and tolerability.
• Atopic Dermatitis: Apply thin layer to affected area bid.

Off-label uses

Prevention of organ rejection in lung, small bowel recipients.

Contraindications

Hypersensitivity to tacrolimus or hydrogenated castor oil.

Cautions

Pure red cell aplasia; Patients at risk for QT prolongation; Hypokalemia Hypomagnesemia; Exposure to sunlight.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=14-32%, food decrease absorption.
Distribution Vd=5-65L/kg, 99% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is less than 1% with a half-life of 11 hours.

Drug interactions

Amikacin: Amikacin and tacrolimus both increase nephrotoxicity and ototoxicity.

Side effects

Common (more than 10%) Abdominal pain; Anemia; Arthralgia; Asthenia; Back pain; Chest Pain; Constipation; Diabetes mellitus; Diarrhea; Dizziness; Dyspepsia; Dyspnea; Edema; Fever; Headache; Hyperglycemia; Hyperkalemia; Hyperlipidemia; Hypertension; Hypokalemia; Hypomagnesemia; Hypophosphatemia; Increased cough; Increased creatinine; Infection; Insomnia; Leukopenia; Nausea; Pain; Paresthesia; Peripheral edema; Pruritus; Skin rash; Tremor; Urinary tract infection; Vomiting.
Less common (1-10%) None.
Rare (less than 1%) None.

Patient educations

Avoid crowds, those with infection; Report decreased urination, chest pain, headache, dizziness, respiratory infection, rash, unusual bleeding/bruising; Avoid exposure to sun, (may cause photosensitivity reaction); Do not take within 2 hours of taking antacids.

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Tadalafil

ATC Code: G04BE08 Urologicals (Drugs used in Erectile Dysfunction)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Tadalafil is not indicated for use in women.

Indications and Dosage

• Erectile dysfunction: 2.5mg-5mg daily or prn use 10mg-20mg 30 min prior to anticipated sexual activity, (max frequency is once daily).
• Benign prostatic hyperplasia: 5mg daily, when combined with finasteride, tadalafil administration should be discontinued at or before 26 weeks.
• Pulmonary hypertension: 40mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to tadalafil.

Cautions

Cardiac risk that makes sexual activity inadvisable; Left ventricular outflow obstruction; Myocardial infarction within last 90 days; Unstable angina or angina occurring during sexual intercourse; Uncontrolled arrhythmias; Stroke within last 6 months.
Dose adjustment in renal failure: CrCl 30-50ml/min: max. 10mg every 48 hr; CrCl less than 30ml/min: max. 5mg every 72 hr.
Dose adjustment in hepatic failure: Avoid.

Dosage forms and trade names available in Iraq

- Tadalafil 5mg tablet
  Cialis (Eli Lilly Netherland), **Adams** (Pharma international Jordan).
- Tadalafil 10mg tablet
- Tadalafil 20mg tablet
  Cialis (Eli Lilly Netherland), **Adams** (Pharma international Jordan).

Pharmacokinetic parameters

Absorption Well absorbed, food has no effect on absorption.
Distribution Vd=63-77L, 94% protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 36% with a half-life of 15-35 hours.

Drug interactions

Bidil (Hydralazine and Isosorbide Dinitrate): Additive vasodilation, potentially fatal hypotension, allow 48 hours after last tadalafil dose before nitrate administration.
Alcohol: additive vasodilation, severe orthostatic hypotension, avoid or limit alcohol consumption to one or two drinks

Side effects

Common (more than 10%) Back pain; Dyspepsia; Flushing; Headache; Myalgia; Nasopharyngitis; Nausea; Respiratory tract infection.
Less common (1-10%) Nasal congestion; Gastroesophageal reflux disease; Hypertension; Bronchitis; Genitourinary tract infection.
Rare (less than 1%) Amnesia; Angina pectoris; Arthralgia; Change in color vision; Conjunctival hyperemia; Dyspnea; Epistaxis.

Patient educations

Instruct patient to take tadalafil as needed for erectile dysfunction at least 30 minutes before sexual activity and not more than once per day; Inform patient that sexual stimulation is required for an erection to occur after taking tadalafil; Advise patient that tadalafil is not indicated for use in women.

Tafluprost

ATC Code: S01EE03 Ophthalmologicals (Prostaglandin Analogues)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Better to be avoided.

Indications and Dosage

• Open angle glaucoma or ocular hypertension: Instill 1 eye drop container in affected eye once daily in the evening.

Off-label uses

None.

Contraindications

Hypersensitivity to tafluprost.

Cautions

Eye surgery, inflammatory eye conditions (uveitis, iritis, aphakia, pseudoaphakia, cystoid macular edema, herpetic keratitis), and severe asthma

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Tafluprost 15µg/ml eye drop

Pharmacokinetic parameters

Absorption Absorbed through the cornea, time to peak plasma concentration 10 minutes.

Distribution Vd=Undetermined, 99%protein bound.

Metabolism Tafluprost is an ester prodrug which is rapidly hydrolyzed by corneal esterase to form its biologically active acid metabolite.

Elimination Renal elimination is 27-38%.

Drug interactions

Latanoprost: Combined use of 2 or more ophthalmic prostaglandins may decrease the IOP lowering effect or cause paradoxical elevations in IOP.

Side effects

Common (more than 10%) Conjunctival hyperemia.

Less common (1-10%) ocular stinging/irritation, ocular pruritus including allergic conjunctivitis, cataract, dry eye, ocular pain, eyelash darkening, growth of eyelashes, increase iris pigmentation, and blurred vision.

Rare but serious (less than 1%) Iritis; uveitis; Periorbital and lid changes including deepening of the eyelid sulcus observed with prostaglandin analogs; Exacerbation of asthma; Dyspnea.

Patient educations

• Not exceeding once-daily dosing; more frequent administration may decrease IOP-lowering effect of tafluprost.

• Administering tafluprost ophthalmic solution immediately after opening single-use container and discarding any unused portion immediately after administration.

• If using more than one topical ophthalmic preparation, importance of administering the preparations at least 5 minutes apart.

Tamsulosin

ATC Code: G04CA02 Urologicals (Alpha-Adrenoreceptor Antagonists)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Tamsulosin is not indicated for use in female patients.

Indications and Dosage

• Benign prostatic hyperplasia: 0.4mg daily may titrate to 0.8mg daily.

Off-label uses

Neurogenic bladder; Bladder outlet obstruction symptoms; Ureteral stones expulsion.

Contraindications

Hypersensitivity to tamsulosin.

Cautions

Orthostatic hypotension.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%, fasting increase F by 30%.
Distribution Vd=16L, 94-99% protein bound.
Metabolism Extensive hepatic metabolism.
Elimination Renal elimination is 10% with a half-life of 9-13 hr.

Dosage forms and trade names available in Iraq

Tamsulosin Hydrochloride 0.4mg tablet
OMNIC OCAS (Astellas Pharma Netherlands).

Drug interactions

Alfuzosin: Alfuzosin and tamsulosin both increases effects of the other by additive vasodilation, risk of hypotension.
Clomipramine: Clomipramine increases levels of tamsulosin by affecting hepatic enzyme CYP2D6 metabolism.
Erythromycin: Erythromycin base increases levels of tamsulosin by affecting hepatic and intestinal enzyme CYP3A4 metabolism, Dose reduction may be needed for coadministered drugs that are predominantly metabolized by CYP3A.
Rifampin: Rifampin will decrease the level or effect of tamsulosin by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects

Common (more than 10%) Abnormal ejaculation; Arthralgia; Dizziness; Headache; Infection; Orthostatic hypotension; Rhinitis.
Less common (1-10%) Abdominal discomfort; Asthenia; Back pain; Bitter taste; Chest pain; Cough; Decreased libido; Diarrhea; Insomnia; Myalgia; Nausea; Pharyngitis; Sinusitis; Skin rash; Somnolence.
Rare (less than 1%) None.

Patient educations

Take at same time each day, 30 minutes after the same meal; Go from lying to standing slowly; Avoid tasks that require alertness, motor skills until response to drug is established; Do not break, crush, open capsule.

Teicoplanin

ATC CODE: J01XA02 Antibacterials for Systemic Use (Glycopeptide Antibacterials)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: No data available.

Dosage forms and trade names available in Iraq

Teicoplanin 200mg/3ml vial
TARGOCID (SANOFI Italia).
Teicoplanin 400 mg vial
Teicoplanin (Sandoz Slovenia).

Indications and Dosage

• Moderate infections caused by susceptible gram positive bacteria such as skin infections, respiratory infections and urinary tract infections: By i.v. injection, 400mg on first day, maintenance 200mg once daily.
• Sever infections (endocarditis, septicemia): By i.v. injection, 400mg twice daily for 3 doses, then maintenance 400mg once daily.
• Antibiotic associated diarrhea caused by clostridium difficile: 200mg twice daily.

Off-label uses

None.

Contraindications

Hypersensitivity to teicoplanin.

Cautions

History of red man syndrome.
Dose adjustment in renal failure: CrCl 30-80ml per minute, use 200mg once daily; CrCl less than 30ml per minute, use 100mg once daily.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=90%.
Distribution Vd=0.7-1.4L/kg, 90-95%protein bound.
Metabolism Minimally metabolized via hydroxylation.
Elimination Renal elimination is 80% with half-life of 70-100 hours.

Drug interactions

Aminoglycoside: Teicoplanin and aminoglycoside solutions are incompatible and must not be mixed for injection.

Side effects

Common (more than 10%) Erythema; Pain; Pruritus; Pyrexia; Rash.
Less common (1-10%) Bronchospasm; Diarrhea; Dizziness; Eosinophilia; Headache; Leucopenia; Nausea; Phlebitis; Thrombocytopenia; Vomiting.
Rare but serious (less than 1%) Abscess; Red man syndrome (e.g. Flushing of the upper part of the body).

Patient educations

A Patient educations is not currently available for this monograph.

Telmisartan

ATC Code: C09CA07 Agents Acting on The Renin-Angiotensin System (Angiotensin II Receptor Blockers (ARBS), Plain)

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Hypertension: Initially, 40mg once daily, usual range 40mg–80mg daily.

• Cardiovascular risk reduction: 80mg once daily.

Off-label uses

Treatment of congestive heart failure.

Contraindications

Hypersensitivity to telmisartan.

Cautions

Hypovolemia; Hyperkalemia; Renal artery stenosis; Biliary obstructive disease; Significant aortic or mitral stenosis; Avoid potassium supplements.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Use with caution.

Dosage forms and trade names available in Iraq

- Telmisartan 40mg tablet
  Micardis (Boehringer ingelheim Germany).
- Telmisartan 80mg tablet
  Micardis (Boehringer ingelheim Germany).

Pharmacokinetic parameters

Absorption F=42-58%.

Distribution Vd=500L, 90%protein bound.

Metabolism Minimally metabolized by conjugation to form a pharmacologically inactive acylglucuronide.

Elimination Telmisartan elimination half-life is 24 hours.

Drug interactions

Aspirin: Telmisartan and aspirin both increase serum potassium, aspirin decreases effects of telmisartan by pharmacodynamic antagonism.

Captopril: Dual blockade of renin-angiotensin system increases risks of hypotension, hyperkalemia, and renal impairment.

Side effects

Common (more than 10%) None.

Less common (1-10%) Abdominal pain; Back pain; Chest pain; Cough; Diarrhea; Dizziness; Dyspepsia; Fatigue; Headache; Hypertension; Influenza-like symptoms; Myalgia; Nausea; Pain; Peripheral edema; Pharyngitis; Sinusitis; Upper respiratory tract infection; Urinary tract infection.

Rare but serious (less than 1%) None.

Patient educations

Avoid tasks that require alertness, motor skills until response to drug is established (possible dizziness effect); Maintain proper hydration; Avoid pregnancy; Report any sign of infection (sore throat, fever); Avoid excessive exertion during hot weather (risk of dehydration, hypotension).

Temozolomide

ATC Code: L01AX03 Antineoplastic Agents (Other Alkylating Agents)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

- Temozolomide 100mg capsule
  Temomedac (Haupt Pharma Germany).
- Temozolomide 20mg capsule
  Temomedac (Haupt Pharma Germany).

Indications and Dosage

• Anaplastic astrocytoma: By i.v. infusion, 150mg/m^2/day for 5 consecutive days of 28-day treatment cycle, subsequent doses of 100mg–200mg/m^2/day based on platelet count, absolute neutrophil count during previous cycle, maintenance 200mg/m^2/day for 5 days every 4 weeks.
• Glioblastoma multiforme: 75mg/m^2 daily for 42 days.

Off-label uses

Metastatic melanoma; Soft tissue sarcoma; Pediatric neuroblastoma; Ewing's sarcoma.

Contraindications

Hypersensitivity to temozolomide; bone marrow suppression,Dacabazine(DTIC) hypersensitivity to gelatin & mannitol hypersensitivity; hepatic disease/toxicity; Renal disease/impairment.

Cautions

None.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Use with caution.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=0.4L/kg, 15%protein bound.
Metabolism it undergoes non enzymatic chemical conversion to the active metabolite (MTIC) plus carbon dioxide and to a temozolomide acid metabolite.
Elimination Renal elimination is 38% with half-life of 1.8 hours.

Drug interactions

Methotrexate: The risk or severity of adverse effects can be increased when Methotrexate is combined with Temozolomide.
Ciprofloxacin: Ciprofloxacin may decrease the excretion rate of Temozolomide which could result in a higher serum level.
Live Vaccines: Concurrent use with temozolomide may increase the risk of systemic viral infection as temozolomide can reduce the body's immune response to the vaccine

Side effects

Common (more than 10%) Alopecia; Anorexia; Asthenia; Constipation; Convulsions; Diarrhea; Fatigue; Fever; Headache; Hemiparesis; Lymphopenia; Rash; Thrombocytopenia; Vomiting.
Less common (1-10%) Abdominal pain; Abnormal vision; Amnesia; Anemia; Ataxia; Back pain; Breast pain; Confusion; Depression; Erythema; Insomnia; Pruritus; Urinary incontinence; Weight gain.
Rare but serious (less than 1%) Diabetes insipidus; Interstitial pneumonitis; Pulmonary fibrosis.

Tenofovir Disoproxil Fumarate

ATC Code: J05AF07 Direct Acting Antivirals (Nucleoside and Nucleotide Reverse Transcriptase Inhibitors).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: It's recommended to avoid breastfeeding to prevent transmission of HIV.

Dosage forms and trade names available in Iraq

Tenofovir disoproxil fumarate 245mg caplets

Indications and Dosage

• For HIV infection, the typical dosage for adults and pediatric patients weighing at least 35 kg is 300 mg orally once daily.

• For chronic hepatitis B, the typical dosage is 300 mg orally once daily.

Off-label uses

Used as a component of post-exposure prophylaxis for non-occupational or occupational exposure to HIV.

Contraindications

Hypersensitivity to tenofovir disoproxil fumarate.

Cautions

It can cause severe or life-threatening side effects, including lactic acidosis; liver problems.

Dose adjustment in renal failure: required for patients with creatinine clearance below 50 ml/min.

Dose adjustment in hepatic failure: No adjustment is required in mild or moderate hepatic impairment.

Pharmacokinetic parameters

Absorption Rapidly converted to tenofovir and absorbed with a bioavailability of 25%.

Distribution Vd= 1.3 ± 0.6 L/kg, less than 0.7% protein bound.

Metabolism Tenofovir is not a substrate of CYP enzymes.

Elimination Predominantly renal excretion via glomerular filtration and active tubular secretion with a half-life of ~17 hours.

Drug interaction

With didanosine: Increased didanosine levels. Use together cautiously, and consider didanosine dose reduction.

With drugs affecting renal function: Increased risk of tenofovir-associated renal toxicity.

Side effects

Common (more than 10%): Diarrhea; nausea; vomiting; flatulence and weakness.

Less common (1-10%): Dizziness; insomnia and rash.

Rare but serious (less than 1%): Lactic acidosis; severe hepatomegaly with steatosis; acute renal failure and HIV resistance.

Patient education

• It's important to take tenofovir regularly to keep your HIV under control.

• Let your doctor know if you have kidney problems or take other medications that can harm your kidneys.

• Although tenofovir can help manage HIV infection, it does not cure HIV or AIDS, so you should continue to take precautions to avoid transmitting HIV to others.

Terbinafin

ATC Code: D01BA02 Antifungals for Dermatological Use (Antifungals for Systemic Use)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Onychomycosis due to dermatophyte: 250mg daily for 6 weeks for fingernails and for 12 weeks for toe nails.
• Tinea corporis and cruris: Apply once daily for 1 week, (max 4 weeks).

Off-label uses

Treatment of tinea pedis (athlete's foot); Tinea versicolor.

Contraindications

Hypersensitivity to terbinafin; Chronic or active hepatic disease.

Cautions

None.

Dose adjustment in renal failure: CrCl less than 50ml/min: not recommended.

Dose adjustment in hepatic failure: Not recommended in patients with active or chronic hepatic disease.

Dosage forms and trade names available in Iraq

- Terbinafin HCl 1% cream
- Terbinafine HCl 1% topical spray
- Terbinafin 250mg tablet

Pharmacokinetic parameters

Absorption F=40%, food increase AUC by 20%.
Distribution Vd=948L, 99% protein bound.
Metabolism Rapid and extensive hepatic metabolism.
Elimination Renal elimination is 70% with a half-life of 22-26 hours.

Drug interactions

Cyclosporine: Terbinafin increases the clearance of cyclosporine.

Side effects

Common (more than 10%) Headache.
Less common (1-10%) Abdominal pain; Burning; Dryness; Flatulence; Irritation; Pruritus; Urticaria; Visual disturbance.
Rare (less than 1%) Altered taste; Diarrhea; Dyspepsia; Nausea; Pruritus; Rash.

Patient educations

Keep areas clean, dry; wear light clothing to promote ventilation; Avoid topical cream contact with eyes, nose, mouth, other mucous membranes; Rub well into affected, surrounding area; Do not cover with occlusive dressing; Report rash, dark urine, abdominal pain, anorexia, yellowing of skin.

EYE LUBRICANT

STERILE OPHTHALMIC SOLUTION FOR EYE DRYNESS

PIONEER PIONEER Co. FOR PHARMACEUTICAL INDUSTRIES

Teriflunomide

ATC Code: L04AA31 Immunosuppressants (Selective Immunosuppressants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Not recommended due to potential for serious adverse reactions in breastfed infants.

Indications and Dosage

Treatment of patients with relapsing forms of multiple sclerosis. The typical dosage is 14 mg orally once daily.

Off-label uses

None.

Contraindications

• Hypersensitivity to teriflunomide;In patients with severe hepatic impairment; Pregnant women or women of childbearing potential not using reliable contraception.

Cautions

Monitor for hepatic injury; Hypertension; risk of infections.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Avoid in severe hepatic impairment.

Dosage forms and trade names available in Iraq

Teriflunomide 14mg tablet

Aubagio (Sanofi-Aventis France).

Pharmacokinetic parameters

Absorption Slowly but adequately absorbed after oral administration.

Distribution Highly protein bound (~99%).

Metabolism Primarily metabolized by hepatic CYP1A2.

Elimination Primarily via feces and less in urine, with a half-life of 15-18 days.

Drug interaction

With leflunomide: Risk of increased concentrations due to shared active metabolite.

With CYP1A2 substrates: Possible increased concentrations of CYP1A2 substrates.

Side effects

Common (more than 10%): Elevated liver enzymes; alopecia; diarrhea; nausea; influenza; paresthesia and upper respiratory tract infection.

Less common (1-10%): Hypertension; rash; neutropenia and peripheral neuropathy.

Rare but serious (less than 1%): Serious infections; acute renal failure; Stevens-Johnson syndrome/toxic epidermal necrolysis.

Patient educations

• Notify your healthcare provider immediately if you become pregnant.

• Contact your healthcare provider if you develop any signs of liver problems, such as yellowing of the skin or eyes, dark urine, or persistent nausea/vomiting.

• You will need regular laboratory tests (blood tests, blood pressure, liver function) to monitor your progress and check for side effects.

Tetracaine

ATC Code: S01HA03 Ophthalmologicals (Local Anesthetics).

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation: It is not yet known caution is advised.

Dosage forms and trade names available in Iraq

Tetracaine hydrochloride 0.5% eye drop

Indications and Dosage

local anesthesia of the eye. Typical usage involves one or two drops in the affected eye(s).

Off-label uses

None.

Contraindications

Hypersensitivity to tetracaine.

Cautions

Prolonged use of tetracaine eye drops can lead to corneal desensitization and potentially corneal epithelial damage.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Specific pharmacokinetic parameters have not been clearly defined.

Drug interaction

There are no major known interactions.

Side effects

Common (more than 10%): Transient burning or stinging upon application.

Less common (1-10%): Allergic reactions; redness; pain; itching.

Rare but serious (less than 1%): Corneal epithelial damage with prolonged use.

Patient education

• Avoid touching the tip of the dropper to the eye, fingers, or any other surface to avoid contamination.

• Do not use this medication more frequently or for longer than prescribed as it may lead to prolonged numbness and potential corneal damage.

• Temporary blurred vision may occur after using this medication. Do not drive, use machinery, or do any activity that requires clear vision until you are sure you can perform such activities safely.

Tetracycline

ATC Code: J01AA07 Antibacterials for Systemic USE (Tetracyclines)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding; Although absorption and therefore discoloration of teeth in the infant is probably usually prevented by chelation with calcium in milk.

Dosage forms and trade names available in Iraq

Tetracycline HCl 250mg capsule
SAMACYCLIN (SDI Iraq).

Tetracycline Hcl 10mg/1g 1% ophthalmic ointment

Tetracycline HCl 30mg/1g 3% ointment
SAMACYCLINE (SDI Iraq), **Tetracycline** (Dubai Co. Iraq), **TETRACIN** (Wadi Al-Rafidain Iraq).

Indications and Dosage

• Inflammatory acne vulgaris, chlamydial infections in patients with gonorrhea: 250mg-500mg four times daily, (max 3g daily).
•Helicobacter pylori infections: 500mg twice daily (in combination with another antibiotic and acid suppressant therapy).
• For eye infections: Apply eye ointment into affected eye every 2-4 hr.
• For skin infections: Apply skin ointment on affected skin once daily or twice daily.

Off-label uses

None.

Contraindications

Hypersensitivity to tetracycline; Children 8 years and younger.

Cautions

Sun or ultraviolet light exposure lead to severe photosensitivity reaction; Avoid use during tooth development (children 8 years or younger).
Dose adjustment in renal failure: Use of tetracycline in severe renal failure is contraindicated.
Dose adjustment in hepatic failure: In severe hepatic failure max 1g daily.

Pharmacokinetic parameters

Absorption F=60-80% (fasting), food and milk decrease absorption.
Distribution Vd=4.5±1.06L/kg, 20-67%protein bound.
Metabolism They are concentrated by the liver in the bile.
Elimination Renal elimination is 55% with half-life of 6-12 hours.

Drug interactions

Calcium carbonate: Calcium carbonate and tetracycline both decreases levels of the other by inhibition of gastrointestinal absorption.

Side effects

Black hairy tongue; Diarrhea; Dysphagia; Enamel hypoplasia; Esophageal ulceration; Hemolytic anemia; Permanent discoloration of teeth; Thrombocytopenia; Urticaria; Vomiting.

Patient educations

Take oral doses on empty stomach (1 hour before or 2 hours after food); Avoid antacids, dairy products within 3 hours of tetracycline; Drink full glass of water with capsules; avoid bedtime doses.

Theophylline

ATC Code: R03DA04 Drugs for Obstructive Airway Diseases (Xanthines)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Chronic lung diseases: 5mg/kg, maintenance 10mg/kg/day (max 600mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to theophylline; Porphyria; Recent myocardial infarction; Acute tachyarrhythmia.

Cautions

CHF; Cardiac arrhythmias except bradyarrhythmias; Hypertension; Corpulmonale; Acute pulmonary edema; Hypothyroidism; Hyperthyroidism; Acute febrile illness; Cirrhosis; Acute hepatitis; Cholestasis; Sepsis with multi-organ failure; Shock; Cystic fibrosis; Seizure disorders; Active peptic ulcer; Chronic alcoholism; Prostatic enlargement particularly in elderly males; Viral infections; Severe asthma; Smokers.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Reduction dose may be necessary.

Dosage forms and trade names available in Iraq

Theophylline Anhydrous 120mg tab
ASMASAM (SDI Iraq).

Pharmacokinetic parameters

Absorption F=77.1±5.4%.
Distribution Vd=0.3±0.7L/kg, 40%protein bound.
Metabolism Metabolized in the liver via demethylation by CYP1A2.
Elimination Renal elimination is 10% with half-life of 8 hours.

Drug interactions

Allopurinol: Allopurinol increases levels of theophylline by decreasing metabolism.

Side effects

Common (more than 10%) Nausea/vomiting; Abdominal discomfort; Headache-Insomnia; Nervousness.
Less common (1-10%) Diarrhea; Increased heart rate; Irregular heartbeat; Tremors-Restlessness; Irritability.
Rare but serious (less than 1%) Seizures; Allergic reactions (such as rash, itching/swelling, severe dizziness, and trouble breathing); Severe nausea/vomiting; Dark urine; Persistent stomach/abdominal pain; Yellowing of eyes or skin (jaundice).

Patient educations

Theophylline may be taken with or without food, may be taken with meals to reduce GI discomfort; Avoid excessive intake of coffee, tea, cocoa, cola beverages, and chocolate; Smoking cigarettes or other tobacco products impacts the theophylline effectiveness. Try not to smoke.

Thiamine

ATC Code: A11DA01 Vitamins (Vitamin B1, Plain).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No known risk when used appropriately.

Dosage forms and trade names available in Iraq

Thiamine HCl (Vitamin B1) 100mg tab
SAMAVIT-B1 (SDI Iraq).
Thiamine HCl (Vitamin B1) 100mg/2ml amp
VITAMINE B1 STEROP (LABORATOIRES STEROP Belgium).

Indications and Dosage

Treatment and prevention of thiamine deficiency, including beriberi and Wernicke's encephalopathy. The typical dosage for adults ranges from 5 to 100 mg per day.

Off-label uses

None.

Contraindications

Hypersensitivity to thiamine.

Cautions

High doses can cause adverse effects, particularly with intravenous administration.
Dose adjustment in renal failure: No specific guidelines.
Dose adjustment in hepatic failure: No specific guidelines.

Pharmacokinetic parameters

Absorption Well absorbed in the small intestine.
Distribution, Metabolism, Elimination Thiamine is widely distributed to most body tissues. It's metabolized to its active form, thiamine pyrophosphate, in the liver. Excess thiamine is excreted in the urine.

Drug interaction

Loop diuretics (like furosemide): They can decrease thiamine levels leading to deficiency.
Chronic alcohol use: Can lead to thiamine deficiency by reducing absorption and increasing excretion.

Side effects

Common (more than 10%): Generally well-tolerated.
Less common (1-10%): Allergic reactions (e.g., rash, pruritus).
Rare but serious (less than 1%): Anaphylaxis.

Patient education

- This medication should be taken with food.
- If you experience any allergic reaction such as rash or itching, contact your healthcare provider.
- Do not to exceed the maximum daily dose.

Thioctic Acid

ATC Code: A16AX01 Other Alimentary Tract and Metabolism Products (Various Alimentary Tract and Metabolism Products).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: It is not yet known, caution is advised.

Indications and Dosage

Thioctic acid is often used as a dietary supplement for its antioxidant properties. Typical dosages range from 300 to 600 mg per day.

Off-label uses

Diabetic peripheral neuropathy; weight loss supplement.

Contraindications

Hypersensitivity to thioctic.

Cautions

With diabetes as it may lower blood sugar levels; It may also interact with certain types of chemotherapy.

Dose adjustment in renal failure: No specific guidelines.

Dose adjustment in hepatic failure: No specific guidelines.

Dosage forms and trade names available in Iraq

- Thioctic acid 300mg tablet

Pharmacokinetic parameters

Specific pharmacokinetic parameters have not been clearly defined.

Drug interaction

Antidiabetic drugs: Thioctic acid may enhance the hypoglycemic effect of antidiabetic drugs.

Levothyroxine: Thioctic acid may decrease the serum concentration of levothyroxine.

Side effects

Common (more than 10%): Generally well tolerated, but may cause gastrointestinal upset.

Less common (1-10%): Rash.

Rare but serious (less than 1%): Allergic reactions.

Patient education

• Thioctic acid may lower blood sugar levels. Monitor for signs of hypoglycemia.

• This supplement may interact with certain medications, including insulin or other diabetes drugs and levothyroxine. Discuss with your healthcare provider.

• Report any unusual side effects like rash or severe gastrointestinal upset to your healthcare provider.

Thyrotropin Alfa

ATC Code: H01AB01 Pituitary and Hypothalamic Hormones and Analogues (Thyrotropin).

Pregnancy category:

FDA A B C D X N

TGA A B1 B2 B3 C D X N

Lactation: It is not yet known, caution is advised.

Indications and Dosage

Thyrotropin alfa is indicated to stimulate thyroid function for radioactive iodine uptake or thyroglobulin testing in the follow-up of patients with well-differentiated thyroid cancer. The typical dosage is 0.9 mg injected intramuscularly daily for two consecutive days.

Off-label uses

None.

Contraindications

Hypersensitivity to thyrotropin alfa.

Cautions

In patients with endogenous thyroid tissue; In patients with a known history of thyroid cancer.

Dose adjustment in renal failure: No specific guidelines caution is advised.

Dose adjustment in hepatic failure: No specific guidelines caution is advised.

Dosage forms and trade names available in Iraq

Thyrotropin Alfa 0.9mg /ml vial

Thyrogen (Genzyme Europe Netherlands).

Pharmacokinetic parameters

Absorption The bioavailability of thyrotropin alfa is complete when administered intramuscularly.

Distribution, Metabolism, Elimination These pharmacokinetic parameters are not well defined for thyrotropin alfa.

Drug interaction

Radioactive iodine: Thyrotropin alfa increases the uptake of radioactive iodine in thyroid cells.

Thyroid hormone replacement: Patients should temporarily withhold thyroid hormone replacement therapy prior to and during use of thyrotropin alfa.

Side effects

Common (more than 10%): Nausea; headache; asthenia (weakness); vomiting.

Less common (1-10%): Dizziness; flushing and pain at the injection site.

Rare but serious (less than 1%): Serious allergic reactions.

Patient education

• Report any allergic reactions or symptoms of hyperthyroidism such as rapid heartbeat, sweating, and nervousness to your healthcare provider.

• Do not drive or operate machinery until you know how this medication affects you as it may cause dizziness.

Ticagrelor

ATC Code: B01AC24 Antithrombotic Agents (Platelet Aggregation Inhibitors Excl. Heparin)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid; Monitor the infant for bruising and bleeding.

Dosage forms and trade names available in Iraq

Ticagrelor 90mg tab
PIOLINTA (Pioneer Iraq).

Indications and Dosage

• Acute coronary syndrome: Initially, 180mg once then 90mg twice daily; Give with aspirin 325 mg once (loading dose), then maintain with aspirin 75mg-100mg daily, continue for up to one year then decrease dose to 60mg twice daily.

Off-label uses

None.

Contraindications

Hypersensitivity to ticagrelor; History of intracranial hemorrhage; Active pathologic bleeding.

Cautions

Hyperuricemia; Bradycardia; Elderly patients; Trauma; Peptic ulcer disease.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Avoid.

Pharmacokinetic parameters

Absorption F=36%, food has no effect on absorption.
Distribution Vd=88L/kg, 99% protein bound.
Metabolism Hepatic metabolism 84%.
Elimination Renal elimination is less than 1% with a half-life of 7 hours.

Drug interactions

Itraconazole: Itraconazole increases levels of ticagrelor by affecting hepatic and intestinal enzyme CYP3A4 metabolism, contraindicated during and 2 weeks after itraconazole treatment.
Morphine: Morphine will decrease the level or effect of ticagrelor by inhibition of GI absorption, co-administration of morphine delay and reduce absorption of ticagrelor and its active metabolite presumably by slowing gastric emptying.

Side effects

Common (more than 10%) Bleeding; Dyspnea.
Less common (1-10%) Diarrhea; Dizziness; Nausea; Ventricular pauses.
Rare (less than 1%) None.

Patient educations

It may take longer to stop bleeding during therapy; Do not vigorously blow nose; Use soft toothbrush, electric razor to decrease risk of bleeding; Immediately report bloody stool, urine, or nosebleeds; Inform physician of any planned dental procedures or surgeries.

Tigecycline

ATC Code: J01AA12 Antibacterials for Systemic Use (Tetracyclines)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

• Systemic infections: By i.v. injection, 100mg initially, followed by 50mg bid for 5–14 days.

Off-label uses

None.

Contraindications

Hypersensitivity to Tigecycline.

Cautions

Monotherapy for patients with intestinal perforation; Do not use for diabetic foot infections; Hospital acquired pneumonia; Ventilator associated pneumonia.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: In sever hepatic failure, initially 100mg followed by 25mg.

Dosage forms and trade names available in Iraq

Tigecycline 50mg vial
Tygacil (Pfizer UK).

Pharmacokinetic parameters

Absorption F=100%.
Distribution Vd=7-9 L/kg, 71-89%protein bound.
Metabolism Not extensively metabolized resulting in trace amount of glucuronide, N-acetyl metabolite and Tigecycline epimer.
Elimination Renal elimination is 59% with half-life of 27-42 hours.

Drug interactions

Oral contraceptives: Tigecycline may decrease effects of oral contraceptives.
Warfarin: Tigecycline may increase concentration of warfarin, increase bleeding time.
Digoxin: Tigecycline can cause an increase in the absorption of Digoxin resulting in an increased serum concentration and potentially a worsening of adverse effects.

Side effects

Common (more than 10%) Diarrhea; Nausea; Vomiting; loss of appetite, mouth sores, black hairy tongue, sore throat; rectal discomfort; headache
Less common (1-10%) Abdominal pain; Anemia; Dizziness; Dyspnea; Fever; Headache; HTN; Hypotension; Infection; Insomnia; Pruritus; Rash.
Rare but serious (less than 1%) Acute pancreatitis; Eosinophilia; Hepatic cholestasis; Hypofibrinogenemia; Increased international normalized ratio (INR); Jaundice; Prolonged activated partial thromboplastin time (aPTT); Prolonged prothrombin time (PT); Severe skin reactions; Stevens Johnson Syndrome; Symptomatic hypoglycemia in patients with or without diabetes Mellitus; Thrombocytopenia.

Patient educations

Report diarrhea, rash, mouth soreness, other new symptoms ; An antibiotic that works by stopping the growth of bacteria ;Works best when taken on an empty stomach 1 hour before or 2 hours after meals; Should be taken 2-3 hours before or after taking any products containing Magnesium, Aluminum, or Calcium.

Timolol

ATC Code: S01ED01 Ophthalmologicals (Beta blocking agents)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Ocular hypertension: insert 1 drop into affected eye twice daily.

Off-label uses

None.

Contraindications

Hypersensitivity to timolol; History of bronchial asthma or severe chronic obstructive pulmonary disease (COPD); Sinus bradycardia; Second and third degree heart block; Overt cardiac failure; Cardiogenic shock.

Cautions

Monotherapy for angle closure glaucoma.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Timolol 2.5mg/1ml 0.25% eye drop
  Tilol (PIONEER IRAQ).
- Timolol 5mg/1ml 0.5% eye drop
  Tilol (PIONEER IRAQ).

Pharmacokinetic parameters

Absorption Minimal systemic absorption detected.
Distribution Vd=1.3-1.7L/kg, 10%protein bound.
Metabolism Timolol is metabolized in the liver by the cytochrome P450 2D6 enzyme.
Elimination Timolol elimination half-life is 3 hours.

Drug interactions

Betxolol: Betxolol and Timolol, increased risk of adverse effects.

Side effects

Common (more than 10%) Burning or stinging.
Less common (1-10%) Blurred vision; Cataract; Conjunctivitis; Decreased visual acuity; Headache; Hypertension; Infection; Itching.
Rare but serious (less than 1%) Blepharitis; Blepharoptosis; Choroidal detachment following filtration surgery; Conjunctival injection; Corneal fluorescein staining; Cystoid macular edema; Decreased corneal sensitivity; Diplopia; Dry eyes; Epiphora; Eyelid erythema; Foreign body sensation; Keratitis; Ocular irritation; Ocular pain; Photophobia; Pseudopemphigoid; Ptosis; Retinal vascular disorder.

Patient educations

Do not stop taking timolol unless instructed to do so by your health care provider; Administer eye drops properly to minimize systemic absorption.

Tinidazole

ATC Code: J01XD02, G01AF04 Antibacterials for Systemic Use (Imidazole Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Avoid; breastfeeding discontinue 3 days after the last dose.

Indications and Dosage

- Intestinal amoebiasis: 2g daily for 3 days.
- Amebic hepatic abscess 2g daily for 3-5 days.
- Giardiasis: 2g as a single dose.
- Trichomoniasis: 2g as a single dose.
- Bacterial vaginosis: 2g once daily for 2 days; or 1 g taken once daily for 5 days.

Dosage forms and trade names available in Iraq

Tinidazole 500mg tablet
FASIGYN (Pfizer France).

Off-label uses

None.

Contraindications

Hypersensitivity to tinidazole.

Cautions

Blood dyscrasias.
Dose adjustment in renal failure: Half the usual dose at the end of hemodialysis.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%, food may delay absorption.
Distribution Vd=50L, 12%protein bound.
Metabolism Hepatic metabolism mainly via CYP3A4.
Elimination Renal elimination is 20-25% with half-life of 14 hours.

Drug interactions

Sodium Picosulfate: Tinidazole may diminish the therapeutic effect of sodium picosulfate, consider using an alternative product for bowel cleansing prior to a colonoscopy in patients who have recently used or are concurrently using tinidazole.

Side effects

Common (more than 10%) None.
Less common (1-10%) Anorexia; Constipation; Dizziness; Dysgeusia; Dyspepsia; Headache; Nausea; Vomiting; Weakness.
Rare but serious (less than 1%) Ataxia; Candida overgrowth; Convulsions and transient peripheral neuropathy; Darkened urine; Diarrhea; Numbness and paresthesia; Tongue discoloration; Transient leukopenia.

Patient educations

Take tinidazole exactly as prescribed, complete the full course of the therapy and do not use tinidazole to treat any other infections; If you miss a dose, take the next dose as soon as you remember; do not take more than the prescribed dose each day; Take tinidazole with food to help decrease gastrointestinal side effects; Be aware that your urine may become dark; Do not drink alcohol while taking this drug and for three days following completion of the treatment; serious adverse effects could occur.

Tiotropium

ATC Code: R03BB04 Drugs for Obstructive Airway Diseases (Anticholinergics)

Pregnancy category:
FDA A B **C** D X N
TGA A **B1** B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• COPD: For adults, Inhalation contents of 1 capsule (18mcg) once daily by using manufacturer provided device or inhalation of 2 puffs (5mcg) once daily.

Off-label uses

None.

Contraindications

History of hypersensitivity to ipratropium or tiotropium; History of severe hypersensitivity to milk proteins (excipient in powder contained in capsule); Lactose allergy.

Cautions

Narrow angle glaucoma; Prostatic hypertrophy; Bladder neck obstruction; Myasthenia gravis.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Tiotropium 18mcg capsules for inhalation
SPIRIVA (Boehringer ingelheim Germany).

Pharmacokinetic parameters

Absorption After inhalation, well absorbed into the lung, less than 19.5% of dose is absorbed systemically.
Distribution Vd=32L/kg, 72% protein bound.
Metabolism Minimal hepatic metabolism.
Elimination Renal elimination is 14% with a half-life of 5-6 days.

Drug interactions

Diphenhydramine: Diphenhydramine and tiotropium both decrease cholinergic effects.
Tiotropium cannot be administered with Glucagon, Pramlintide and Revefenacin; In addition, it interacts with Tricyclic antidepressants and most of the antipsychotic drugs.

Side effects

Common (more than 10%) Blurred vision; Diarrhea; Dry mouth; Sinusitis; Upper respiratory tract infection.
Less common (1-10%) Allergic reaction; Angina pectoris; Cataract; Chest pain; Constipation; Depression; Dyspepsia; Dysphonia; Edema; Epistaxis; Gastroesophageal reflux; Herpes zoster; Hypercholesterolemia; Hyperglycemia; Leg pain; Moniliasis; Myalgia; Paresthesia; Rash; Rhinitis; Skeletal pain; Stomatitis; Urinary tract infection; Vomiting.
Rare (less than 1%) Angioedema; Fibrillation; Supraventricular tachycardia; Urinary retention.

Patient educations

Increase fluid intake (decreases lung secretion viscosity); Do not use more than 1 capsule for inhalation in a 24h period; Rinsing mouth with water immediately after inhalation may prevent mouth/throat dryness, thrush; Avoid excessive use of caffeine derivatives (chocolate, coffee, tea, cola, cocoa); Report eye pain, blurred vision.

Note

The dose of tiotropium is either through hard capsule (Spiriva Handihalar®) or solution (Spiriva Respimat®).

Tizanidine

ATC Code: M03BX02 Muscle Relaxants (Other Centrally Acting Agents).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Unknown caution is advised.

Dosage forms and trade names available in Iraq

- Tizanidine 2mg tablet
- Tizanidine 4mg tablet

Indications and Dosage

Tizanidine is indicated for the management of spasticity. The dose is individualized according to the patient's response, starting at 2 mg and can be increased by 2-4 mg as needed, up to a maximum of 36 mg daily.

Off-label uses

The management of fibromyalgia and migraine headaches.

Contraindications

Hypersensitivity to Tizanidine; In patients with severe hepatic impairment.

Cautions

Hypotension; hallucinations; sedation.
It should be used with caution in elderly patients and those with renal impairment.
Dose adjustment in renal failure: Adjustment is necessary based on the patient's creatinine clearance.
Dose adjustment in hepatic failure: Contraindicated in severe hepatic impairment; use caution and monitor closely in mild to moderate impairment.

Pharmacokinetic parameters

Absorption Bioavailability is approximately 34-40%.
Distribution Volume of distribution is 2.4 L/kg, 30% protein bound.
Metabolism Metabolized by CYP1A2.
Elimination Primarily excreted in urine (60%) with a half-life of 2.5 hours.

Drug interaction

CYP1A2 inhibitors (e.g., fluvoxamine, ciprofloxacin): May increase tizanidine levels, leading to increased adverse effects.
Antihypertensive drugs: Co-administration with tizanidine may enhance the hypotensive effect.

Side effects

Common (more than 10%): Dry mouth; somnolence; asthenia (weakness).
Less common (1-10%): Dizziness; urinary frequency; hypotension.
Rare but serious (less than 1%): Hepatotoxicity; hallucinations; severe allergic reactions.

Patient education

• This medication can cause drowsiness; avoid driving or operating heavy machinery until you know how it affects you.
• Stand up slowly from a sitting or lying position to reduce the risk of dizziness and lightheadedness.

Tobramycin

ATC Code: S01AA12 Ophthalmologicals (Antibiotics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

- Tobramycin 3mg/ml 0.3% eye drop
- Tobramycin 3mg/1g 0.3% eye ointment

Indications and Dosage

• Superficial eye infections including blepharitis, conjunctivitis, keratitis, and corneal ulcers: 1–2 drops in affected eye every 4 hours (2 drops per hours for severe infections). Apply eye ointment to conjunctiva every 8–12 hours (every 3–4 hours for severe infections).

Off-label uses

None.

Contraindications

Hypersensitivity to tobramycin.

Cautions

Auditory or vestibular impairment; Conditions that depress neuromuscular transmission; Parkinson's disease; Myasthenia gravis; Hypocalcemia.

Dose adjustment in renal failure: CrCl 10-20ml per minute increase interval to every 48 hours; CrCl less than 10ml per minute increase interval to every 72 hours.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Tobramycin absorbed into aqueous humor, absorption greatest when cornea is abraded.

Distribution Vd=0.2-0.3L/kg, 30%protein bound.

Metabolism Not metabolized.

Elimination Renal elimination is 90-95% with half-life of 3 hours.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%) Voice alteration.

Less common (1-10%) Epistaxis; Laryngitis; Myalgia; Tinnitus.

Rare but serious (less than 1%) Aphonia; Bronchospasm; Decreased appetite; Dysgeusia; Hearing loss; Malaise; Oropharyngeal pain; Pruritus; Rash; Sputum discolored; Urticaria.

Patient educations

Report any hearing, visual, balance, urinary problems, even after therapy is completed; Report persistent tearing, redness and irritation.

Tocilizumab

ATC Code: L04AC07 Immunosuppressants (Interleukin Inhibitors).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Caution is advised.

Dosage forms and trade names available in Iraq

Tocilizumab 20mg/ml (10 ml vial)
Actemra (F.Hoffman - La Roche Switzerland).

Indications and Dosage

• Rheumatoid arthritis: 4 mg/kg i.v. every 4 weeks initially; may increase to 8 mg/kg every 4 weeks based on clinical response not to exceed 800 mg/dose every 4 weeks.
• Giant cell arteritis: 6 mg/kg i.v. every 4 weeks in combination with tapering course of glucocorticoids.

Off-label uses

Treatment of severe COVID-19.

Contraindications

Hypersensitivity to tocilizumab.

Cautions

• It's been associated with serious infections, gastrointestinal perforations; Hypersensitivity reactions.
• Monitor patients closely for these events.

Dose adjustment in renal failure: No guidelines provided, caution is advised

Dose adjustment in hepatic failure: Use with caution in patients with hepatic impairment; if AST or ALT is more than 1.5 times the upper limit of normal, consider dose interruptions or discontinuation.

Pharmacokinetic parameters

The specific parameters for tocilizumab are not well documented.

Drug interaction

Live vaccines: Avoid use with tocilizumab, due to the potential for increased risk of infection.

CYP450 substrates (e.g., warfarin, oral contraceptives): Tocilizumab can affect the expression of CYP450 enzymes, potentially altering the levels/effects of these drugs.

Side effects

Common (more than 10%): Upper respiratory tract infections; nasopharyngitis; headache; hypertension and increased alanine aminotransferase levels.

Less common (1-10%): Urinary tract infections; abdominal pain; rash and weight gain.

Rare but serious (less than 1%): Serious infections; tuberculosis; gastrointestinal perforation; hepatotoxicity and severe hypersensitivity reactions.

Patient education

Advise patients on potential liver damage and to seek medical attention if they experience symptoms such as yellowing of the skin or eyes, dark urine, or abdominal pain.

Tofacitinib

ATC Code: L04AA29 Immunosuppressants (Selective Immunosuppressants).

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C **D** X N

Lactation: Caution is advised.

Indications and Dosage

• Treatment of moderate to severe rheumatoid arhritis, psoriatic arthritis:5 mg twice daily.
• Ulcerative colitis: Initial dose 10 mg twice daily for 8 weeks, followed by 5 mg twice daily.

Off-label uses

None.

Contraindications

Hypersensitivity reaction to tofacitinib; Severe hepatic impairment.

Cautions

Serious infections; malignancies and thrombosis.
Dose adjustment in renal failure: For moderate to severe renal impairment or end-stage renal disease, reduce the dose to 5 mg once daily.
Dose adjustment in hepatic failure: For moderate hepatic impairment, reduce the dose to 5 mg once daily. It's contraindicated in severe hepatic impairment.

Dosage forms and trade names available in Iraq

Tofacitinib Citrate 11mg tablet
Xeljanz XR (Pfizer USA).

Pharmacokinetic parameters

Absorption Bioavailability is approximately 74%.
Distribution Volume of distribution is approximately 87 L. It is 40% bound to plasma proteins.
Metabolism Primarily metabolized by CYP3A4 and to a lesser extent by CYP2C19.
Elimination 70% of the dose is excreted in feces, with a half-life of approximately 3 hours.

Drug interaction

Potent CYP3A4 inhibitors (like ketoconazole): Co-administration may increase tofacitinib levels, monitor closely for adverse reactions.
Potent CYP3A4 inducers (like rifampin): Co-administration may decrease tofacitinib levels, which may decrease its efficacy.

Side effects

Common (more than 10%): Upper respiratory tract infections; headache; diarrhea.
Less common (1-10%): Hypertension; bronchitis; nasopharyngitis.
Rare but serious (less than 1%): Serious infections; malignancies; thrombosis; interstitial lung disease.

Patient education

Seek immediate medical attention if you have signs of infection (fever, chills, cough, shortness of breath).

Tolnaftate

ATC Code: D01AE18 Antifungals for Dermatological Use (Other Antifungals for Topical Use)

Pregnancy category:

FDA A B **C** D X N

TGA A B1 B2 B3 C D X **N**

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Tinea pedis, tinea cruris, tinea corporis: Apply lotion into affected skin bid for 2-4 weeks.

Off-label uses

None.

Contraindications

Hypersensitivity to tolnaftate; Nail and scalp infections.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Tolnaftate absorption through intact skin is minimal.

Distribution Undetermined.

Metabolism Tolnaftate metabolism not known following local application.

Elimination Tolnaftate excretion not known following local application.

Dosage forms and trade names available in Iraq

Tolnaftate 1g/100g 1% lotion

Drug interactions

There are no known significant interactions.

Side effects

Irritation; Contact dermatitis; Pruritus; Stinging.

Patient educations

Instruct patient to apply medication as directed for full course of therapy, even if feeling better; Emphasize the importance of avoiding the eyes; Caution patient that tolnaftate may stain fabric, A skin, or hair, fabrics stained from lotion can usually be cleaned by handwashing with soap and warm water; Patients with athlete's foot should be taught to wear well-fitting, ventilated shoes, to wash affected areas thoroughly, and to change shoes and socks at least once a day; Advise patient to report increased skin irritation or lack of response to therapy to health care professional; Inform health care professional if patient has diabetes mellitus before using.

Note

Don't apply this medication in the eye, nose, mouth or vagina.

Tolperisone

ATC Code: M03BX04 Muscle Relaxants (Other Centrally Acting Agents)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: No data available.

Indications and Dosage

• Muscle spasms, spasticity: 150mg tid.

Off-label uses

None.

Contraindications

Hypersensitivity to Tolperisone; Myasthenia gravis.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=20%.

Distribution Vd=5.1±1L/kg.

Metabolism Extensively metabolized by liver and kidney.

Elimination Tolperisone elimination half-life is 1.5 hours.

Dosage forms and trade names available in Iraq

Tolperisone 150mg tablet
MYDOCALM (Labatec Switzerland).

Drug interactions

There are no known significant interactions.

Side effects

Abdominal discomfort; Headache; Hypotension; Muscular weakness; Nausea; Vomiting.

Patient educations

Tolperisone should be taken with food.

General
medicines

Solid Dosage Form

Dubai Pharmaceutical Industries

DUBAI

DUFEED
Pseudoephedrine HCL 60 mg
Triprolidine HCL 2.5 mg

DUFEED
Pseudoephedrine HCL 60 mg
Triprolidine HCL 2.5 mg

Dexaphar
Dexamethasone 0.5mg

Dulabid S
Isopropamide (as Iodide) 5 mg
Trifluoperazine (as HCl) 1 mg

Dumet tablet
Methyldopa 250 mg

Dumet tablet
Methyldopa 250 mg

DUSTOP Tablet
Diphenoxylate Hcl 2.5 mg
Atropine sulphate 0.025 mg

DUSTOP Tablet
Diphenoxylate Hcl 2.5 mg
Atropine sulphate 0.025 mg

Folic Acid Tablet
Folic Acid 400 mcg

Folic Acid Tablet
Folic Acid 400 mcg

Prednisolone
Prednisolone 5mg

Duspirin
Acetylsalicylic acid 100 mg

Alledramine Tablets
.Diphenhydramine HCl 25 mg

Paracetamol
Paracetamol 500mg

FLO NOT
Paracetamol, CNorpheniramine

Vomit End
Ondansetron (As HCL Dihydrate) 8mg

Codegesic
Paracetamol 325mg
Caffeine anhydrous 50mg
Codeine phosphate 10mg

Tolterodine

ATC Code: G04BD07 Urologicals (Drugs for Urinary Frequency and Incontinence)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 **B3** C D X N

Lactation: Avoid.

Indications and Dosage

• Overactive bladder: 1mg–2mg bid.

Off-label uses

None.

Contraindications

Hypersensitivity to tolterodine; Gastric retention; Uncontrolled narrow angle glaucoma; Urinary retention.

Cautions

Congenital prolonged QT; Electrolyte imbalance; Bradycardia; Cardiac disease; Benign prostatic hypertrophy; Intestinal atony; Pyloric stenosis; Narrow angle glaucoma; Alzheimer's disease; Autonomic neuropathy; Hiatus hernia.

Dose adjustment in renal failure: In sever renal failure use of tolterodine is not recommended.

Dose adjustment in hepatic failure: In sever hepatic failure use of tolterodine is not recommended.

Dosage forms and trade names available in Iraq

Tolterodine 2 mg tablet
Detrusitol (Pfizer Italy).

Pharmacokinetic parameters

Absorption F=77%.
Distribution Vd=113±26.7L, 96.3%protein bound.
Metabolism Extensively metabolized by the liver primarily by CYP2D6.
Elimination Renal elimination is 7% with half-life of 1.9–3.7 hours.

Drug interactions

Carbamazepine: Carbamazepine will decrease the level or effect of tolterodine by affecting hepatic enzyme CYP3A4 metabolism.

Enzalutamide: Enzalutamide will decrease the level or effect of tolterodine by affecting hepatic enzyme CYP3A4 metabolism.

Fluoxetine: Fluoxetine will increase the level or effect of tolterodine by affecting hepatic enzyme CYP2D6 metabolism.

Side effects

Common (more than 10%) Dry mouth.
Less common (1-10%) Blurred vision; Constipation; Dizziness; Drowsiness; Dyspepsia; Headache; Xerophthalmia.
Rare but serious (less than 1%) None.

Patient educations

May cause blurred vision, dry eyes, mouth, constipation; Report any confusion, altered mental status; Avoid tasks that require alertness, motor skills until response to drug is established.

Topiramate

ATC Code: N03AX11 Antiepileptics (Other Antiepileptics)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid; Monitor the infant for diarrhea, drowsiness, irritability.

Indications and Dosage

• **Partial or tonic-clonic seizure:** 25mg bid for 1 week, (max 200mg bid).
• **Migraine prophylaxis:** Initially, 25mg once daily for 1 week may titrate to 50mg bid.

Off-label uses

Cluster headache prophylaxis.

Contraindications

Hypersensitivity to topiramate; Recent alcohol use within 6 hr prior to or after topiramate.

Cautions

Patients who are at high risk for suicide; Respiratory impairment, Congenital metabolism dysfunction; Strenuous exercise; Exposure to high environmental temperature; Elderly patients.
Dose adjustment in renal failure: CrCl less than 70ml/min: reduce dose by 50%.
Dose adjustment in hepatic failure: Use cautiously.

Dosage forms and trade names available in Iraq

- Topiramate 100mg tablet
  Topamax (Janssen cilag Switzerland).
- Topiramate 50mg tablet
  Topamax (Janssen cilag Switzerland).
- Topiramate 25mg tablet
  Topamax (Janssen cilag Switzerland).

Pharmacokinetic parameters

Absorption F=80%, food has no effect on absorption.
Distribution Vd=0.6-0.8L/kg, 15-41% protein bound.
Metabolism Minor hepatic metabolism.
Elimination Renal elimination is 70% with a half-life of 21 hr.

Drug interactions

Lacosamide: Topiramate may enhance the adverse effect of Lacosamide, specifically the risk for bradycardia, ventricular tachyarrhythmias, or a prolonged PR interval may be increased.

Side effects

Common (more than 10%): Abnormal vision; Anorexia; Ataxia; Confusion; Decrease in serum bicarbonate; Decreased memory; Dizziness; Fatigue; Injury; Nausea; Nervousness; Paresthesia; Psychomotor slowing; Speech disorder.
Less common (1-10%): Abdominal pain; Abnormal gait; Apathy; Asthenia; Bradycardia; Diplopia; Dry mouth; Edema; Hypertension; Menorrhagia; Mood problems; Pallor; Pharyngitis; Skin disorder; Syncope; Taste change; Tremor; Weight loss.
Rare (less than 1%): Angina; Erythema; Hepatic failure; Hyperthermia; Hypokalemia; Neuropathy; Toxic epidermal necrolysis.

Patient educations

Avoid tasks that require alertness, motor skills until response to drug is established (may cause dizziness, drowsiness, impaired concentration); Drowsiness usually diminishes with continued therapy; Avoid use of alcohol; Do not abruptly discontinue drug (may precipitate seizures); Report suicidal ideation, depression, unusual behavior; Use caution with activities that may increase core temperature (exposure to extreme heat, dehydration).

Torasemide

ATC Code: C03CA04 Diuretics (Sulfonamides, Plain)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 B3 C D X **N**

Lactation: Avoid.

Dosage forms and trade names available in Iraq

- Torasemide 5mg tablet
  Toras - Denk (Denk pharma Germany).
- Torasemide 10mg tablet
  Toras - Denk (Denk pharma Germany).

Indications and Dosage

- Congestive heart failure: 10mg-20mg once daily.
- Chronic renal failure: 20mg once daily.
- Hepatic cirrhosis: 5mg-10mg once daily.
- Hypertension: 2.5mg-5mg daily.

Off-label uses

None.

Contraindications

Hypersensitivity to torasemide; Anuria; Hepatic coma; Hypotension; Cardiac arrhythmias.

Cautions

Hyperuricemia; Gout; Diabetes mellitus.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=80%.
Distribution Vd=0.2L/kg, 99%protein bound.
Metabolism Torasemide is extensively metabolized in the liver.
Elimination Renal elimination is 20-30% with half-life of 3.5 hours.

Drug interactions

Amphotericin B: Torasemide increased risk of severe hypokalemia with amphotericin B.
Aminoglycosides: Torasemide increased potential for ototoxicity and nephrotoxicity with aminoglycosides.
Digoxin: Torasemide increased risk of toxicity with digoxin.

Side effects

Common (more than 10%) Dizziness or Confusional states; hypotension.
Less common (1-10%) Headache; Excessive thirst; Muscle cramps or weakness; Upset stomach or vomiting; hypokalemia; cerebral hypoperfusion; thromboembolic complications.
Rare but serious (less than 1%) Dehydration and severe loss of Electrolytes; Severe allergic reactions (rash, itching, swelling, severe dizziness, trouble breathing); Hearing changes or loss (usually reversible); Severe abdominal or stomach pain, possibly with nausea and vomiting

Patient educations

- Always take this medicine exactly as your doctor has told you. Contact your doctor if you experience side effects like dizziness, weakness, or confusion.
- While on this medication, regular blood tests may be required to monitor your kidney function and electrolyte levels. Make sure to keep all your medical appointments.

Tramadol

ATC Code: N02AX02 Analgesics (Other Opioids)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Management of moderate to severe pain, chronic pain, headache, osteoarthritis: 50mg prn, (max 200mg daily).

Off-label uses

None.

Contraindications

Hypersensitivity to tramadol; Acute alcohol intoxication; Severe acute bronchial asthma; Hypercapnia; Significant respiratory depression.

Cautions

CNS depression; Anoxia, Hepatic cirrhosis; Seizures; Acute abdominal conditions; Opioid dependent patients; Head injury; Myxedema; Hypothyroidism; Hypoadrenalism; Avoid use in patients who are suicidal or addiction prone; Emotionally disturbed; Depression; Heavy alcohol users; Elderly patients.

Dose adjustment in renal failure: CrCl less than 30ml/min: increase dosing interval.

Dose adjustment in hepatic failure: In cirrhosis decreased dosage to 50mg.

Dosage forms and trade names available in Iraq

Tramadol 100mg/2ml ampoule

Pharmacokinetic parameters

Absorption F=75%, food has no effect on absorption.

Distribution Vd=3L, 20% protein bound.

Metabolism Hepatic metabolism more than 90%.

Elimination Renal elimination is 30% with a half-life of 6 hours.

Drug interactions

Morphine: Coadministration tramadol and morphine may increase CNS depression.

Paroxetine: Coadministration tramadol and paroxetine may increase risk of seizures, risk of serotonin syndrome.

Side effects

Common (more than 10%) Dizziness; Vertigo; Nausea; Constipation; Headache; Drowsiness.

Less common (1-10%) Vomiting; Pruritus; Nervousness; Anxiety; Agitation; Tremor; Euphoria; Mood swings; Hallucinations; Diaphoresis; Dyspepsia; Dry mouth; Diarrhea.

Rare but serious (less than 1%) Malaise; Vasodilation; Anorexia; Flatulence; Rash; Blurred vision; Urinary retention; Menopausal symptoms.

Patient educations

Tramadol may cause dependence; Avoid alcohol; Tramadol may cause drowsiness, dizziness, blurred vision, avoid tasks requiring alertness, motor skills until response to drug is established; Report severe constipation, difficulty breathing, excessive sedation, seizures, muscle weakness, tremors, chest pain, palpitations.

Tranexamic Acid

ATC Code: B02AA02 Antihemorrhagics (Amino acids)

Pregnancy category:
FDA A **B** C D X N
TGA A **B1** B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Cyclic heavy menstrual bleeding: 1000mg tid for a maximum of 5 days during monthly menstruation.
• Dental extraction in patients with hemophilia: By I.v. injection, 10mg/kg before surgery.

Off-label uses

None.

Contraindications

Hypersensitivity to tranexamic acid; DVT; Pulmonary embolism; Cerebral thrombosis; Retinal vein or artery occlusion; Thrombogenic cardiac or valvular disease; Hypercoagulopathy; Subarachnoid hemorrhage.

Cautions

Patients with enormous hematuria from upper urinary tract; History of thromboembolic diseases; Women with subarachnoid hemorrhage or irregular menstrual cycle.

Dose adjustment in renal failure: In sever renal failure use of tranexamic acid is contraindicated.
Dose adjustment in hepatic failure: In sever hepatic failure use of tranexamic acid is contraindicated.

Dosage forms and trade names available in Iraq

Tranexamic Acid 500mg/5ml ampule
Taxaneer (Pioneer Iraq).
Tranexamic Acid 500mg tablet
EXACYL (Sanofi Aventis France).

Pharmacokinetic parameters

Absorption F=30-50%, food has no effect on absorption.
Distribution Vd=0.18L/kg, 3%protein bound.
Metabolism Not metabolized.
Elimination Renal elimination is 95% with half-life of 2-11 hours.

Drug interactions

Dienogest/estradiol valerate: Coadministration of tranexamic acid and combination hormonal contraceptives increases thrombotic risk.

Side effects

Common (more than 10%) Abdominal pain; Back pain; Headache; Musculoskeletal pain; Nasal and sinus symptoms.
Less common (1-10%) Anemia; Arthralgia; Migraine; Muscle cramps.
Rare but serious (less than 1%) Diarrhea; Hypotension; Nausea; Visual abnormalities; Vomiting.

Patient educations

Stop smoke while taking tranexamic acid to avoid increases in thrombotic risk, especially if over 35 years of age; Have patient report any visual difficulties or signs of allergic reaction, such as difficulty breathing.

Trastuzumab

ATC Code: L01FD01 Antineoplastic Agents (HER2 (Human Epidermal Growth Factor Receptor 2) Inhibitors)

Pregnancy category:

FDA A B C D X **N**

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid; Breastfeeding discontinue 7 months after the last dose.

Dosage forms and trade names available in Iraq

Trastuzumab 150mg vial

Trazimera (Pfizer Europe Belgium).

trastuzumab 420mg per vial

Trazimera (Pfizer Europe Belgium).

Trastuzumab 440mg vial

Herceptin (Hoffmann – La Roche Switzerland).

trastuzumab 600mg/5 ml vial

Herceptin (F. Hoffman – La Roche Switzerland).

Indications and Dosage

• Breast cancer: Initially, 4mg/kg as 90 min infusion, then 2mg/kg weekly as 30 min infusion for 12 weeks followed 1 week later (when concurrent chemotherapy completed) by 6mg/kg infusion over 30–90 min every 3 weeks for total therapy duration of 52 weeks.

• Gastric cancer: By i.v. infusion, 8mg/kg initially over 90 min, then 6mg/kg over 30–90 min every 3 weeks until disease progression.

Off-label uses

None.

Contraindications

Hypersensitivity to trastuzumab; Preexisting cardiac disease.

Cautions

Preexisting cardiac disease or dysfunction; Preexisting pulmonary disease or extensive pulmonary tumor involvement.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=0.04L/kg.

Metabolism Trastuzumab is metabolized intracellularly into smaller peptides and amino acids.

Elimination Trastuzumab elimination half-life is 12 days.

Drug interactions

There are no known significant interactions.

Side effects

Common (more than 10%): Abdominal pain; Asthenia; Back pain; Chills; Cough; Diarrhea; Dyspnea; Fever; Headache; Infection; Nausea; Pain; Vomiting,

Less common (1-10%): Anorexia; Arthralgia; Bone pain; Depression; Dizziness; Edema; Flu-like symptoms; Insomnia; Paresthesia; Pharyngitis; Rhinitis; Sinusitis; Tachycardia.

Rare but serious (less than 1%): Allergic reaction; Anemia; Herpes simplex; Leukopenia; Neuropathy.

Patient educations

Do not have immunizations without physician's approval (lowers resistance); Avoid contact with those who have recently taken oral polio vaccine; Avoid crowds, those with infection.

Tretinoin

ATC Code: D10AD01 Anti-Acne Preparations (Retinoids for Topical Use in Acne)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D **X** N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Acne: Apply once daily at bedtime or in the evening.

Off-label uses

Some skin cancers.

Contraindications

Hypersensitivity to tretinoin.

Cautions

Those with considerable sun exposure in their occupations.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Tretinoin 0.5mg/1g (0.05%) cream
- Tretinoin 0.25mg/1g 0.025% gel
  Optimal (Pharma International Jordan).
- Tretinoin 0.25mg/g 0.025% cream

Pharmacokinetic parameters

Absorption F=1-31%.

Distribution Vd=Undetermined, 95%protein bound.

Metabolism Metabolized in the liver by CYP450 enzymes to form 4-oxo-trans-retinoic acid.

Elimination Renal elimination is 63% with half-life of 0.5-2 hours.

Drug interactions

Doxycycline: Doxycycline and tretinoin both increases toxicity of the other by unspecified interaction mechanism, both tretinoin and tetracyclines can cause increased intracranial pressure.

Side effects

Temporary change in pigmentation; Photosensitivity; Peeling; Dry skin; Stinging; Erythema; Pruritus.

Patient educations

Avoid exposure to sunlight, tanning beds; Use sunscreens, protective clothing; Protect affected areas from wind, cold; If skin is already sunburned, do not use drug until fully healed; Keep tretinoin away from eyes, mouth, angles of nose, mucous membranes; Do not use medicated, drying, abrasive soaps; wash face no more than 2–3 times per day with gentle soap; Avoid use of preparations containing alcohol, menthol, spice, lime (e.g., shaving lotions, astringents, perfume); Mild redness, peeling are expected; decrease frequency or discontinue medication if excessive reaction occurs; Non medicated cosmetics may be used; however, cosmetics must be removed before tretinoin application; Improvement noted during first 24 weeks of therapy.

Triamcinolone

ATC Code: D07AB09 Corticosteroids, Dermatological Preparations (Corticosteroids, Moderately Potent (Group II))

Pregnancy category:

FDA A B **C** D X N

TGA **A** B1 B2 B3 C D X N

Lactation: Compatible with breastfeeding.

Indications and Dosage

• Oral inflammatory or ulcerative lesions: Apply orabase as thin film enough to cover the lesion at night may increase to bid or tid if lesions are severe.

Off-label uses

None.

Contraindications

Hypersensitivity to triamcinolone.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Not absorbed.

Distribution Not absorbed.

Metabolism Not absorbed.

Elimination Not absorbed.

Drug interactions

There are no known significant interactions.

Side effects

Hypothalamic-pituitary-adrenal axis suppression.

Patient educations

A Patient education is not currently available for this monograph.

Dosage forms and trade names available in Iraq

Triamcinolone acetonid in orabase 0.1%

Trifluoperazine

ATC Code: N05AB06 Psycholeptics (Phenothiazines with Piperazine Structure)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Schizophrenia and psychosis: 2-5 mg twice daily by mouth with or without food.
• Non-psychotic anxiety: 1mg-2mg twice daily, (max 6 mg daily), not to exceed 12 weeks.

Off-label uses

None.

Contraindications

Hypersensitivity to trifluoperazine; Severe hypotension; Severe CNS depression; uncontrolled seizure; brain damage; Severe cardiovascular disease; Blood disorders; hepatic failure; Parkinson.

Dosage forms and trade names available in Iraq

- Triflouperazine 1mg tab
  IRALZIN (SDI Iraq).
  Triflouperazine 2mg tab
- **IRALZINE** (SDI Iraq).
  Triflouperazine 5mg tab
- **IRALZINE** (SDI Iraq).

Cautions

Arrhythmia; Angina pectoris; Hypovolemia; Diabetes; Decreased gastrointestinal motility; Paralytic ileus; Urinary retention; Benign prostatic hyperplasia; Xerostomia, Narrow angle glaucoma; Myasthenia gravis; brain degenerative disease;Cerebrovascular disease; Seizures; Previous brain damage; Alcoholism; Dehydration; Strenuous exercise

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Use of trifluoperazine in hepatic failure is contraindicated.

Pharmacokinetic parameters

Absorption Readily absorbed from the gastrointestinal tract.

Distribution Undetermined.

Metabolism Undergoes the first pass metabolism in the gut wall.

Elimination Majority of the drug is metabolized in liver. Its half-life is multiphasic that it is about 5 hrs during the first 12 hours after ingestion and then become about 12-13 hours.

Drug interactions

Indapamide: Trifluoperazine and indapamide both increase QTc interval.

Side effects

Common (more than 10%) Drowsiness; Dizziness; Dry mouth; Blurred vision; Constipation; Agitation; Akathisia; Anorexia; Anticholinergic effects; Anxiety; Blood dyscrasia; Cerebral edema; Depression; Weight gain.

Less common (1-10%) Restlessness; Muscle Stiffness; Tremors; Tardive dyskinesia; Difficulty Urinating; Changes in menstrual periods; ECG changes; Erectile dysfunction; Euphoria; Galactorrhea.

Rare but serious (less than 1%) Severe constipation; abdominal pain-Persistent nausea; vomiting; Cholestatic jaundice; Neuroleptic malignant syndrome; Agranulocytosis Seizures.

Patient educations

It is preferred to give it after a meal to avoid gastric upset; the patients should be asked not to indulge in activities that need mental alertness like driving. Furthermore, caution should be exercised while giving it to patients.

Trimetazidine

ATC code: C01EB15 Cardiac Therapy (Trimetazidine)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: No data available.

Indications and Dosage

• Stable angina: 35mg twice daily.

Off-label uses

None.

Contraindications

Hypersensitivity to trimetazidine; Parkinson's disease; Tremors; Restless leg syndrome and other movement related disorders.

Cautions

Not indicated for initial treatment of unstable angina, myocardial infarction nor in the pre-hospital phase or during the first days of hospitalization.

Dose adjustment in renal failure: CrCl 30-60ml per minute, use 35mg once daily.; CrCl less than 30ml per minute, use of trimetazidine is contraindicated.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Trimetazidine dihydrochloride 35mg Tablet
  VASTAREL MR (Les Laboratories Servier France).

Pharmacokinetic parameters

Absorption Rapidly and completely absorbed from the gastrointestinal tract.
Distribution Vd=4.8L/kg, 15%protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 79-84% with half-life of 7.8 hours.

Drug interactions

There are no known significant interactions.

Side effects

Abdominal pain; Arterial hypotension; Asthenia; Diarrhea; Dyspepsia; Instability; Nausea; Orthostatic hypotension; Parkinsonian symptoms; Pruritus; Rash; Restless leg syndrome; Tremors; Urticaria; Vomiting.

Patient educations

Trimetazidine may cause dizziness and drowsiness, if affected, do not drive or operate machinery.

Triptorelin

ATC Code: L02AE04 Endocrine Therapy (Gonadotropin Releasing Hormone Analogues)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage

• Prostate cancer: By i.m. injection, 3.75mg once every 4 weeks.

• Female infertility: By subcutaneous injection, 0.1mg daily starting from the second day of the menstrual cycle for 10-12 days. in conjunction with gonadotrophins.

Off-label uses

None.

Contraindications

Hypersensitivity to Triptorelin.

Cautions

Pituitary adenoma; Weight related amenorrhea until weight corrected; Polycystic ovary disease; metabolic bone disease; Contraceptive measures to be taken to protect against unwanted ovulation in females.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

Triptorelin acetate 0.1mg/1ml Pre-Filled Syringe **Decapeptyl** (Ferring Germany).

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=30-33L, triptorelin does not bind to plasma proteins.

Metabolism Not metabolized.

Elimination Triptorelin elimination half-life is 6 minutes to 3 hours.

Drug interactions

Fluoxetine: Triptorelin increases toxicity of fluoxetine by QTc interval, increases risk of torsades de pointes.

Side effects

Common (more than 10%) Headache; Hot flushes; Injection site pain; Injection site redness; Nasopharyngitis; Skeletal pain.

Less common (1-10%) Cough; Diarrhea; Fatigue; Generalized pain; Headache; Hot flushes; Hypertension; Impotence; Injection site pain; Injection site pruritus; Injection site swelling; Insomnia; Pruritus; Spinal cord compression; Upper respiratory infection; Upper respiratory tract infections; Vaginal bleeding; Vomiting.

Rare but serious (less than 1%) Convulsions; Interstitial lung disease; Pituitary apoplexy; Thromboembolic events including pulmonary emboli, CVA, MI, DVT, TIA, and thrombophlebitis.

Patient educations

Do not miss monthly injections; May experience increased skeletal pain, blood in urine, urinary retention initially (subsides within 1 week); Hot flashes may occur; Report tachycardia, persistent nausea or vomiting, numbness of arms and legs, difficulty breathing, infection at injection site.

Tropicamide

ATC Code: S01FA06 Ophthalmologicals (Anticholinergics)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 **B2** B3 C D X N

Lactation: Tropicamide might interfere with breastfeeding.

Dosage forms and trade names available in Iraq

Tropicamide 10mg/1ml 1% eye drop
Miotrop (Cooper Greece).

Indications and Dosage

• Production of cycloplegia: Instill 1-2 drops repeated after 5 min an additional drop may be admin after 20-30 min for prolonged effect.
• Production of mydriasis: Instill 1 drop 15-20 min before examination.

Off-label uses

None.

Contraindications

Hypersensitivity to tropicamide; Angle closure glaucoma; Narrow anterior chamber angle.

Cautions

Patient with inflamed eyes; Increased intraocular pressure.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Undetermined.
Distribution Undetermined.
Metabolism Undetermined.
Elimination Tropicamide elimination half-life is 30 minutes.

Drug interactions

There are no known significant interactions.

Side effects

Blurred vision; Dry mouth; Headache; Increased IOP; Parasympathetic stimulation; Photophobia with or without corneal staining; Tachycardia; Transient stinging.

Patient educations

Remove contact lenses before application and wait for at least 15 minutes before reinsertion. Tropicamide may cause drowsiness, blurred vision and sensitivity to light, if affected, do not drive or operate machinery.Note placing pressure over the tear duct by the corner of the eye for at least 1 minute and removing excess solution with an absorbent tissue substantially reduces the amount of drug that reaches breast milk after using eye drops.

Trospium

ATC Code: G04BD09 Urologicals (Drugs for Urinary Frequency and Incontinence)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: No data available.

Indications and Dosage

Overactive bladder: 20mg bid, it works by relaxing the bladder muscles to prevent urgent, frequent, or uncontrolled urination.

Off-label uses

None.

Contraindications

Hypersensitivity to trospium; Gastric retention; Uncontrolled narrow angle glaucoma; Urinary retention.

Cautions

Bladder outflow obstruction; Pyloric stenosis; Intestinal atony; Ulcerative colitis; Autonomic neuropathy; Angle closure glaucoma; Hiatus hernia associated with reflux esophagitis; CHF; Coronary artery disease; Hyperthyroidism; Alzheimer's disease.

Dose adjustment in renal failure: CrCl less than 30ml per minute, use 20mg once daily at bedtime.

Dose adjustment in hepatic failure: In sever hepatic failure, use with caution.

Dosage forms and trade names available in Iraq

- Trospium Chloride 20mg tab
  Spasmolyt (MEDA Pharma Germany).

Pharmacokinetic parameters

Absorption F=9.6%, food has no effect on absorption.
Distribution Vd=395±140L, 50-85%protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 60% with half-life of 20 hours.

Drug interactions

Digoxin: Digoxin and trospium chloride, both increases levels of the other by decreasing renal clearance.
Metformin: Metformin may decrease the serum concentration of trospium.
Topiramate: Trospium may enhance the adverse effect of trospium.

Side effects

Common (more than 10%) Dry mouth.
Less common (1-10%) Abdominal distention; Abdominal pain; Constipation; Dry eyes; Dyspepsia; Fatigue; Flatulence; Headache; Nasal dryness; Nasopharyngitis; Rash; Tachycardia; Urinary retention; Urinary tract infection.
Rare but serious (less than 1%) None.

Patient educations

Report nausea, vomiting, diaphoresis, increased salivary secretions, palpitations, severe abdominal pain; Swallow tablets whole; Give 1 hour before meals.

Ursodeoxycholic Acid

ATC Code: A05AA02 Bile and Liver Therapy (Bile Acids and Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Ursodeoxycholic Acid 300mg tablet
URSOCHOLIN (PIONEER Iraq).

Indications and Dosage

• **Dissolution of cholesterol rich gallstones:** 8mg-12mg/kg once daily at bedtime or in 2 divided doses continued for 3-4 months after radiological disappearance of gallstones, duration of treatment up to 2 years.

• Prophylaxis of gallstones in patients undergoing rapid weight loss: 300mg bid.

• **Primary biliary cirrhosis:** 10mg-16mg/kg daily in 2-4 divided doses.

Off-label uses

Cholestatic liver conditions including sclerosing cholangitis, graft-vs-host disease, cholestasis of pregnancy and the liver disease of cystic fibrosis.

Contraindications

Hypersensitivity to ursodeoxycholic acid; Acute inflammation of gallbladder or biliary tract; Occlusion of biliary tract; Frequent episodes of biliary colic; Radio-opaque calcified gallstones; Inflammatory bowel disease; Extrahepatic and intrahepatic cholestasis; Ileal resection and stoma; Regional ileitis; Active duodenal and gastric ulcer.

Cautions

Nonvisualizing gallbladders; Variceal bleeding; Hepatic encephalopathy; Ascites; Urgent liver transplant.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure:contraindicated in acute, chronic or severe hepatic disease.

Pharmacokinetic parameters

Absorption Absorbed from the gastrointestinal tract.
Distribution Vd=Undetermined, 70% protein bound.
Metabolism Undergoes extensive enterohepatic recycling.
Elimination Renal elimination is 1% with half-life of 4-6 days.

Drug interactions

Clofibrate: Clofibrate possibly reduced efficacy of ursodeoxycholic acid.

Side effects

Arthralgia; Arthritis; Cholecystitis; Cough; Diarrhea; Headache; Musculoskeletal pain; Myalgia; Nausea; Peripheral oedema Pharyngitis; Pruritus; Rhinitis; Sinusitis; Viral infection; Vomiting;

Patient educations

Tell patient to take ursodeoxycholic acid with meals; Urge patient to take aluminum-containing antacids at least 1 hour before or 4 hours after ursodeoxycholic acid to support absorption; Urge patient to notify prescriber immediately if evidence of acute cholecystitis develops; Advise diabetic patient to monitor blood glucose levels during therapy because ursodeoxycholic acid may alter blood glucose control.

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Aspin
Acetylsalicylic acid 81 mg
Reduce risk of heart attack and stroke.

Aspin
Acetylsalicylic acid 100 mg
Reduce risk of heart attack and stroke.

Glimee
Glimepiride 2mg
is used with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes

Glimee
Glimepiride 4mg
is used with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes

DIOVASAM
Valsartan 80mg
High blood pressure and heart failure and Post-Myocardial Infarction

DIOVASAM
Valsartan 160mg
High blood pressure and heart failure and Post-Myocardial Infarction

ATORVASAM
Atorvastatin 20mg
Used along with a proper diet to help lower "bad" cholesterol and fats (such as LDL, triglycerides) and raise "good" cholesterol (HDL) in the blood.

ATORVASAM
Atorvastatin 40mg
Used along with a proper diet to help lower "bad" cholesterol and fats (such as LDL, triglycerides) and raise "good" cholesterol (HDL) in the blood.

CRESTOSAM
Rosuvastatin 10mg
It's used for hypercholesterolemia, hyperlipidemia, mixed dyslipidemia, primary dysbetalipoproteinemia, hypertriglyceridemia, and prevention of cardiovascular disease

CRESTOSAM
Rosuvastatin 20mg
It's used for hypercholesterolemia, hyperlipidemia, mixed dyslipidemia, primary dysbetalipoproteinemia, hypertriglyceridemia, and prevention of cardiovascular disease

Carvidisam
Carvedilol
High blood pressure and heart failure

Ustekinumab

ATC Code: L04AC05 Immunosuppressants (Interleukin Inhibitors).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: It's not yet known, caution is advised.

Indications and Dosage

• Moderate to severe plaque psoriasis: Initial dose of 45 mg or 90 mg (depending on weight) subcutaneously, followed by a dose 4 weeks later, then every 12 weeks thereafter.

• Active psoriatic arthritis: 45 mg subcutaneously, with doses 4 weeks apart, then every 12 weeks thereafter. Can be used alone or in combination with methotrexate.

Off-label uses

Ankylosing spondylitis.

Contraindications

Severe hypersensitivity to Ustekinumab or to any of the excipients, active serious infection, concomitant live vaccines.

Dosage forms and trade names available in Iraq

Ustekinumab 130mg vial
Stelara (Janssen-Cilag Belgium).

Ustekinumab 45mg 0.5ml Prefilled syringe.
Stelara (Janssen cilag Belgium).

Ustekinumab 90mg 1ml Prefilled syringe.
Stelara (Janssen cilag Belgium).

Cautions

Increased risk of infections; screen for tuberculosis before initiating, Possible increased risk of malignancies. Use caution in patients genetically deficient in IL-12/IL-23, , psoriatic arthritis, and Crohn's disease;
Dose adjustment in renal failure: Not studied enough, but it is not typically needed.
Dose adjustment in hepatic failure: Not studied enough, but it is not typically needed.

Pharmacokinetic parameters

Absorption After subcutaneous injection, it is slowly absorbed with a median time to reach maximum serum concentration of 13.5-14 days.
Distribution, Metabolism, Elimination Being a monoclonal antibody, it is expected to be degraded into small peptides and amino acids via catabolic pathways in the same manner as endogenous IgG. It has a half-life of approximately 3 weeks.

Drug interaction

adenovirus types 4 and 7 live, oral, influenza virus vaccine quadrivalent, adjuvanted, influenza virus vaccine quadrivalent, intranasal, influenza virus vaccine quadrivalent, recombinant, influenza virus vaccine trivalent, adjuvanted, influenza virus vaccine trivalent, recombinant, measles (rubeola) vaccine, measles mumps and rubella vaccine, live, rotavirus oral vaccine, live, rubella vaccine, smallpox (vaccinia) vaccine, live, varicella virus vaccine live, yellow fever vaccine, zoster vaccine live.

Side effects

Common (more than 10%): Upper respiratory infection, Headache
Less Common (1-10%): Fatigue, Back pain
Rare but serious (less than 1%): Serious infections (such as tuberculosis), Malignancies.

Patient Education

• Inform your healthcare provider of any signs of infection, such as fever; cough, or flu-like symptoms.
• Report any history of tuberculosis exposure before starting treatment.
• Do not get live vaccines while on this treatment.

Valsartan

ATC Code: C09CA03 Agents Acting on The Renin-Angiotensin System (Angiotensin II Receptor Blockers (ARBs), Plain)

Pregnancy category:

FDA A B C **D** X N

TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Indications and Dosage

- Heart failure: 40mg bid.
- Hypertension: 80mg-160mg daily.
- Myocardial infarction: 20mg bid, (max 320mg daily).

Off-label uses

Left ventricular hypertrophy; Diabetic nephropathy.

Contraindications

Hypersensitivity to valsartan.

Cautions

Renal artery stenosis; Aortic stenosis; Mitral stenosis; Elderly Patients.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Dosage forms and trade names available in Iraq

- Valsartan 160mg tab
  DIOSTAR (Pharma International Jordan).
- Valsartan 80mg tab
  DIOSTAR (Pharma International Jordan).

Pharmacokinetic parameters

Absorption F=25%, food has no effect on absorption.

Distribution Vd=017L, 95% protein bound.

Metabolism Minimal liver metabolism.

Elimination Renal elimination is 7-13% and bile elimination is 89% with a half-life 6-9 hr.

Drug interactions

Captopril: Captopril and valsartan increases toxicity of the other by pharmacodynamic synergism, avoid or use alternate drug, dual blockade of renin angiotensin system increases risks of hypotension, hyperkalemia, and renal impairment.

Atenolol: Valsartan and atenolol both increase serum potassium; Risk of fetal compromise if given during pregnancy.

Side effects

Common (more than 10%) Arthralgia; Back pain; Diarrhea; Fatigue; Hyperkalemia; Hypotension; Increased **BUN; Postural dizziness.**

Less common (1-10%) Blurred vision; Headache; Nausea; Neutropenia; Renal impairment; Syncope; Upper abdominal pain; Vertigo.

Rare but serious (less than 1%) Cough; Increased blood creatinine; Rash.

Patient educations

Females of childbearing potential must use effective contraception during treatment; Report any sign of infection (sore throat, fever); Do not stop taking medication; Report swelling of extremities, chest pain, palpitations; decreased urine output, amber colored urine, fatigue, yellowing of the skin or eyes.

Vancomycin

ATC Code: J01XA01 Antibacterials for Systemic Use (Glycopeptide Antibacterials)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: No data available.

Indications and Dosage

• Treatment of infections caused by staphylococcal, streptococcal species bacteria: 15mg–20mg/kg/dose every 8–12 hr.

Off-label uses

Treatment of infections caused by gram positive organisms in patients with serious allergies to beta-lactam antibiotics; Treatment of beta-lactam resistant gram positive infections; Surgical prophylaxis; Treatment of prosthetic joint infection; Treatment of brain abscess.

Dosage forms and trade names available in Iraq

Vancomycin 500mg vial
Vancomycin 1g vial
VANCONEER (Pioneer Iraq).

Contraindications

Hypersensitivity to vancomycin.

Cautions

Elderly patients; Dehydration.

Dose adjustment in renal failure: Mild-to-severe: Initial dose should be no less than 15 mg/kg. Functionally a nephritic patients: Initial dose of 15 mg/kg of body weight to achieve prompt therapeutic serum concentration; start at 1.9 mg/kg/24 hr after the initial dose of 15 mg/kg.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=60%.

Distribution Vd=0.4-1L/kg, 50% protein bound.

Metabolism Not metabolized.

Elimination Renal elimination is 75% with half-life of 4-6 hours.

Drug interactions

Amikacin: Amikacin and vancomycin both increase nephrotoxicity and ototoxicity.

Methotrexate: Vancomycin decreases levels of methotrexate by inhibition of gastrointestinal absorption.

• Co-administration of other medications, along with vancomycin, may increase the risk of adverse effects and toxicity.

Side effects

Acute generalized exanthematous pustulosis; Acute kidney injury; Agranulocytosis; Cardiac arrest; Chest pain; Chills; Dizziness; Dyspnea; Elevated blood urea nitrogen; Elevated serum creatinine; Eosinophilia; Fever; Hearing loss; Hypotension; Injection site irritation; Interstitial nephritis; Leukopenia; Muscle pain; Neutropenia; Pancytopenia; Phlebitis; Pseudomembranous colitis; Red man syndrome; Shock; Stevens-Johnson syndrome; Thrombocytopenia; Tinnitus; Toxic epidermal necrolysis; Vasculitis; Vertigo; Wheezing.

Patient educations

Continue therapy for full length of treatment; Doses should be evenly spaced; Report ringing in ears, hearing loss, changes in urinary frequency or consistency.

Vardenafil

ATC Code: G04BE09 Urologicals (Drugs Used in Erectile Dysfunction)

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: Vardenafil is not indicated for use in female patients.

Dosage forms and trade names available in Iraq

- Vardenafil 10mg tab
  Horse Man (Pioneer Iraq).
- Vardenafil 20mg tab
  Horse Man (Pioneer Iraq).

Indications and Dosage

• Erectile dysfunction: 10mg-20mg 60 min prior to anticipated sexual activity, (max frequency is once daily).

Off-label uses

None.

Contraindications

Hypersensitivity to vardenafil.

Cautions

Cardiovascular disease; Retinitis pigmentosa; Sickle cell disease; Leukemia; Multiple myeloma; Polycythemia; Priapism.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Avoid.

Pharmacokinetic parameters

Absorption F=15%, food has minimal effect on absorption.

Distribution Vd=209L, 95% protein bound.

Metabolism Hepatic metabolism 90-95%.

Elimination Renal elimination is 2-6% with half-life of 4-6 hours.

Drug interactions

Isosorbide: Coadministration isosorbide and vardenafil have additive vasodilation, potentially fatal hypotension.

Side effects

Common (more than 10%) Flushing; Headache.

Less common (1-10%) Back pain; Dizziness; Dyspepsia; Flu-like syndrome; Increased creatine phosphokinase; Nausea; Rhinitis; Sinusitis.

Rare (less than 1%) Angina; Insomnia; Myocardial infarction; Postural hypotension; Priapism; Pruritus; Rash.

Patient educations

For best results, tell patient to take drug 1 hour before anticipated sexual activity; Tell patient not to take vardenafil if he takes an organic nitrate, continuously or intermittently, or within 4 hours of taking an alpha blocker because profound hypotension and death could result; Caution patient not to take vardenafil more than once daily or to exceed 20mg daily for oral tablet; To avoid possible penile damage and permanent loss of erectile function, urge patient to notify prescriber at once if erection is painful or lasts longer than 4 hours.

Velaglucerase Alfa

ATC Code: A16AB10 Alimentary Tract and Metabolism (Enzymes).

Pregnancy category:
FDA A **B** C D X N
TGA A B1 **B2** B3 C D X N

Lactation: Caution is advised.

Indications and Dosage
Treatment of type 1 Gaucher's disease: 60 Units/kg body weight administered every other week as a 60-minute intravenous infusion.

Off-label uses
None.

Contraindications
Hypersensitivity to velaglucerase alfa or to any of the excipients.

Cautions
Infusion reactions may occur; pre-treatment with antihistamines is recommended; Consideration should be given to testing for IgG antibodies if there is evidence of a lack of clinical response.
Dose adjustment in renal failure: None.
Dose adjustment in hepatic failure: Use with caution.

Dosage forms and trade names available in Iraq

Velaglucerase Alfa 400Units vial
Vpriv 400 Units (Shire Pharmaceuticals Ireland)

Pharmacokinetic parameters
Absorption (F=100%).
Distribution There is no specific volume of distribution (Vd).
Metabolism Is metabolized by proteolytic enzymes.
Elimination Its half-life is approximately 3 to 5 days.

Drug interactions
No specific interactions with velaglucerase alfa are known.

Side effects
Common (more than 10%): Dizziness; Headache; Nausea.
Less Common (1-10%): Fatigue; Fever.
Rare but serious (less than 1%): Hypersensitivity reactions, including anaphylaxis.

Patient Education
Inform your healthcare provider of any side effects that occur during or after the infusion; Do not miss scheduled infusions as this may affect the effectiveness of the therapy.

Venlafaxine

ATC Code: N06AX16 Psychoanaleptics (Other Antidepressants)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 **B2** B3 C D X N

Lactation: Avoid.

Indications and Dosage
• Generalized anxiety disorder, depression, panic disorder, social anxiety disorder: 75mg-150mg daily, (max 225mg daily).

Off-label uses
Premenstrual dysphoric disorder; Treatment of attention deficit hyperactivity disorder (ADHD); Obsessive compulsive disorder; Hot flashes; diabetic neuropathy; Post-traumatic stress disorder.

Contraindications
Hypersensitivity to venlafaxine.

Cautions
Seizure disorder; Patients at high risk for suicide; Recent myocardial infarction; Mania; Narrow angle glaucoma; Heart failure; Hyperthyroidism; Abnormal platelet function; Elderly patients.

Dosage forms and trade names available in Iraq

- Venlafaxine 150mg prolonged release tab **VELEXEL** (Exeltis Spain).
- Venlafaxine 75mg prolonged release tab **VELEXEL** (Exeltis Spain).

Dose adjustment in renal failure: In mild to moderate renal failure reduce dosage by 25%.
Dose adjustment in hepatic failure: In moderate hepatic failure reduce dosage by 50%.

Pharmacokinetic parameters
Absorption F=12.6%, food has no effect on absorption.
Distribution Vd=7.5L, 27-30% protein bound.
Metabolism Hepatic metabolism 87%.
Elimination Renal elimination is 87% with a half-life of 5 hours.

Drug interactions
Enoxaparin: Venlafaxine may enhance the anticoagulant effect of enoxaparin, discontinue venlafaxine prior to initiating enoxaparin whenever possible, if concomitant administration is unavoidable, monitor closely for signs and symptoms of bleeding.

Side effects
Common (more than 10%) Anorexia; Anorgasmia; Asthenia; Diaphoresis; Dizziness; Dry mouth; Ejaculation disorder; Headache; Insomnia; Nausea; Nervousness; Somnolence.
Less common (1-10%) Abnormal vision; Dyspepsia; Flatulence; Hypertension; Impotence; Mydriasis; Paresthesia; Pruritus; Tremor; Twitching; Vasodilation; Vomiting; Weight gain; Weight loss; Yawning.
Rare (less than 1%) Agranulocytosis; Anemia; Aneurism; Angioedema; Anuria; Bacteremia; Myasthenia; Suicide ideation/attempt; Syncope.

Patient educations
Advise patient to avoid alcohol during venlafaxine therapy; Advise patient not to stop taking venlafaxine abruptly; Urge caregivers to monitor patient closely for suicidal tendencies, especially when therapy starts or dosage changes; Alert patient that fertility impairment may occur while taking venlafaxine; Caution patient to avoid aspirin and NSAIDs, if possible, while taking venlafaxine.

Verapamil

ATC Code: C08DA01 Calcium Channel Blockers (Phenylalkylamine Derivatives)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 **C** D X N

Lactation: Compatible with breastfeeding.

Dosage forms and trade names available in Iraq

Verapamil hydrochloride 240 mg tablet
Isoptin SR (Abbott Germany).

Verapamil hydrochloride 5mg/2ml ampoule
Isoptin (Abbott Germany).

Indications and Dosage

• Hypertension: 80mg tid.

• Angina: 80mg-120mg tid (max. 480mg daily).

• Atrial arrhythmia or paroxysmal supraventricular tachycardia prophylaxis: 240mg-320mg daily in 3-4 divided doses.

• Supraventricular arrhythmia, Atrial fibrillation or flutter: By i.v. injection, 2.5mg-5mg over 2 min, 5mg-10mg dose may be repeated after 15-30 min.

Off-label uses

Ventricular tachycardia; Migraine headache prophylaxis; Neurogenic bladder; Premature labor.

Contraindications

Hypersensitivity to verapamil; Atrial fibrillation or flutter; Severe left ventricular dysfunction; Cardiogenic shock; Second or third degree heart block; Hypotension; Sick sinus syndrome.

Cautions

Myasthenia gravis; Elderly patients; Hypertrophic cardiomyopathy; Avoid use in heart failure.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Reduce dose by 20-50%.

Pharmacokinetic parameters

Absorption F=13-65%, food has no effect on absorption.

Distribution Vd=3.89L/kg, 86-94% protein bound.

Metabolism Hepatic metabolism 70%. By enzyme CYP3A4

Elimination Renal elimination is 70% and 9-16% in feces, with a half-life of 4-12 hr.

Drug interactions

Simvastatin: Verapamil will increase the level or effect of simvastatin by affecting hepatic/intestinal enzyme CYP3A4 metabolism; Avoid or use alternate drug. Do not exceed simvastatin 10mg daily when given concurrently. Potential for increased risk of myopathy and rhabdomyolysis.

Ergotamine: increase the level of ergotamine by affecting on CYP3A4 metabolism.

Erythromycin: VERAPAMIL increase the level of Erythromycin by affecting on CYP3A4 metabolism.

Side effects

Common (more than 10%) Headache, Gingival hyperplasia.

Less common (1-10%) Constipation, Dizziness, Hypotension, Dyspepsia, Nausea, Edema, Rash, Increased liver enzymes, Sleep disturbance, Dyspnea.

Patient educations

Direct patient to check pulse before taking verapamil and to notify prescriber if it's below 50 beats/min; Encourage patient to increase dietary fiber intake to help prevent constipation.

Vildagliptin

ATC Code: A10BH02 Drugs Used in Diabetes (Dipeptidyl Peptidase 4 (DPP4-) Inhibitors)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Indications and Dosage
• Diabetes mellitus (Type 2): 50mg twice daily.

Off-label uses
None.

Contraindications
Hypersensitivity to vildagliptin.

Cautions
Cardiac failure; Type 1 diabetes; Acute pancreatitis; Diabetic ketoacidosis.
Dose adjustment in renal failure: In severe hepatic failure reduce dosage to 50mg once daily.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters
Absorption F=85%, food decrease absorption.
Distribution Vd=71L, 9.3%protein bound.
Metabolism Hepatic metabolism.
Elimination Renal elimination is 85% with half-life of 2 hours.

Dosage forms and trade names available in Iraq

Vildagliptin 50mg tablet
Viltin (Pharma International Jordan).

Drug interactions
Acetazolamide: The therapeutic efficacy of vildagliptin can be increased when used in combination with acetazolamide.
Loperamide: The risk or severity of hypoglycemia can be increased when loperamide is combined with vildagliptin.
Methylprednisolone: The risk or severity of hyperglycemia can be increased when methylprednisolone is combined with vildagliptin.
Olanzapine: The therapeutic efficacy of vildagliptin can be decreased when used in combination with olanzapine.
Selegiline: Selegiline may increase the hypoglycemic activities of vildagliptin.
Verapamil: The risk or severity of hypoglycemia can be increased when verapamil is combined with vildagliptin.

Side effects
Arthralgia; Asthenia; Constipation; Dizziness; Exfoliative and bullous; Skin reactions; Headache; Hepatic dysfunction; Hypoglycemia; Nasopharyngitis; Nausea; Pancreatitis; Peripheral edema; Tremor; Upper respiratory tract infection.

Patient educations
Take vildagliptin with or without food; Diabetes requires lifelong control; Diet and exercise are principal parts of treatment; do not skip or delay meals; Test blood glucose regularly; Monitor daily calorie intake.

Vincristine

ATC Code: L01CA02 Antineoplastic Agents (Vinca Alkaloids and Analogues)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Vincristine Sulfate 1mg/1ml injection
VINCRISTINE SULFATE (Pfizer Australia).

Indications and Dosage
• Acute leukemia, advanced non-Hodgkin's lymphoma, disseminated Hodgkin's disease, neuroblastoma, rhabdomyosarcoma, Wilms's tumor: By i.v. injection, 0.4mg-1.4mg/m^2 once a week.

Off-label uses
Treatment of multiple myeloma; Chronic lymphocytic leukemia; Brain tumors; Small cell lung cancer; Ovarian germ cell tumors, Ewing's sarcoma, Gestational trophoblastic tumors; Retinoblastoma.

Contraindications
Hypersensitivity to vincristine; Demyelinating form of Charcot - Marie-Tooth syndrome. Intrathecal administration.

Cautions
patients receiving radiation therapy through ports (including liver); Neurotoxicity; Neuromuscular disease; Hepatobiliary dysfunction; Elderly.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Bilirubin greater than 3mg/dL, use 50% of normal dose.

Pharmacokinetic parameters
Absorption F=100%.
Distribution Vd=8.4L/kg, 44%protein bound.
Metabolism Metabolized by the liver.
Elimination Vincristine elimination half-life is 10.5–37.5 hours.

Drug interactions
Enzalutamide: Enzalutamide will decrease the level or effect of vincristine by affecting hepatic and intestinal enzyme CYP3A4 metabolism.

Side effects
Common (more than 10%) leukopenia, ocular palsy, laryngeal nerve paralysis, loss of deep tendon reflex, ataxia, motor and sensory neuropathy, vocal cord paralysis, hypotension, hypertension, oropharyngeal pian, paralytic ileus, diarrhea, jaw pain, urine retention, injection site reaction.
Less common (1-10%) Acute uric acid nephropathy; Amenorrhea; Aspermia; Constipation; Gait changes; Hypertension; Hypotension; Jaw pain; Leukopenia; Loss of deep-tendon reflexes; Myelosuppression; Nausea; Paralytic ileus; Paresthesia; Peripheral neuropathy; Sensory loss; Vomiting.
Rare but serious (less than 1%) cellulitis, allergic reaction, anaphylaxis, flushing and oedema, syndrome of inappropriate antidiuretic hormone secretion, optic nerve atrophy and blindness, vestibular and auditory lesions, rash..

Patient educations
Immediately report any pain and burning at injection site during administration; Hair loss is reversible, but new hair growth may have different color and texture.

Vinorelbine

ATC Code: L01CA04 Antineoplastic Agents (Vinca Alkaloids and Analogues)

Pregnancy category:
FDA A B C **D** X N
TGA A B1 B2 B3 C **D** X N

Lactation: Discontinue breast-feeding.

Dosage forms and trade names available in Iraq

Vinorelbine 50mg/5ml vial

Indications and Dosage

• Advanced non–small cell lung cancer monotherapy: By i.v. injection, 30mg/m^2 administered every 7 days over 6-10 min.

• Advanced non–small cell lung cancer combination therapy with cisplatin: 25mg–30mg/m^2 every week.

Off-label uses

Treatment of metastatic breast cancer; Cervical carcinoma; Ovarian carcinoma; Malignant pleural mesothelioma; Soft tissue sarcoma; Small cell lung cancer.

Contraindications

Hypersensitivity to vinorelbine; Granulocyte count before treatment of less than 1000 cells/mm^3.

Cautions

Compromised marrow reserve due to prior chemotherapy or radiation therapy; Hepatic impairment; Neurotoxicity; Neuropathy; Pulmonary impairment.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Bilirubin 2.1-3mg/dL, use 50% of normal dose; Bilirubin greater than 3mg/dL, use 25% of normal dose.

Pharmacokinetic parameters

Absorption F=100%.

Distribution Vd=25.4-40.1L/kg, 80-90%protein bound.

Metabolism Mostly metabolized by the liver.

Elimination Renal elimination is 11% with half-life of 28-44 hours.

Drug interactions

COVID-19 Vaccine: Immunosuppressant effect of vinorelbine may diminish the therapeutic effect of COVID-19 Vaccine.

Side effects

Common (more than 10%) Alopecia; Anemia; Anorexia; Asthenia; Constipation; Elevated AST; Fatigue; Granulocytopenia; Leukopenia; Nausea; Peripheral neuropathy; Stomatitis; Vomiting.

Less common (1-10%) Chest pain; Dyspnea; Hemorrhagic cystitis; Rash.

Rare but serious (less than 1%) Bowel obstruction; Hepatic toxicity; Pulmonary toxicity; Respiratory failure.

Patient educations

Immediately report redness, swelling, pain at injection site; Avoid crowds, those with infection; Do not have immunizations without physician's approval; Promptly report fever, signs of infection, unusual bleeding from any site, difficulty breathing; Avoid pregnancy; Hair loss is reversible, but new hair growth may have different color, texture.

Vitamin A

ATC Code: A11CA01 Vitamins (Vitamin A, Plain)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Use is considered acceptable.

Dosage forms and trade names available in Iraq

Vitamin A Palmitate 50mg equivalent to vit.A 50000IU Soft gelatin Capsule
A-Viton (Kahira Pharmaceuticals Cairo)

Indications and Dosage
Prevention and treatment of Vitamin A deficiency, which could lead to conditions such as night blindness, xerophthalmia, and keratomalacia: The Recommended Dietary Allowance (RDA) is 900 mcg (3000 IU) for men and 700 mcg (2333 IU) for women.

Off-label uses
Psoriasis.

Contraindications
Hypersensitivity to vitamin A or any component of the formulation; Hypervitaminosis A.

Cautions
Chronic high doses of vitamin A can lead to toxicity; Pregnant women due to the potential risk of causing birth defects. High-dose vitamin A therapy is contraindicated in women who are or may become pregnant; Patients with liver disease, high alcohol intake, or severe malnutrition may be at higher risk for vitamin A toxicity.
Dose Adjustment in Renal Failure: None.
Dose Adjustment in Hepatic Failure: Excessive intake can lead to vitamin A toxicity, especially in those with decreased liver function, so caution is needed.

Pharmacokinetic Parameters
Absorption Vitamin A is fat-soluble and is absorbed in the intestines along with dietary fat.
Distribution Vitamin A is stored mainly in the liver. Specific volume of distribution (Vd) values are not readily available.
Metabolism Vitamin A is metabolized in the liver.
Elimination Vitamin A excreted in the urine and feces with half-life range from days to months depending on body stores and dietary intake.

Drug Interactions
Orlistat: Orlistat may decrease the absorption of Vitamin A, potentially reducing its effectiveness.
Retinoids (including isotretinoin): Combined use may increase risk of hypervitaminosis A, potentially causing toxicity symptoms.

Side Effects
Common (more than 10%): Dry skin; Dry mucous membranes (e.g., dry eyes, dry mouth).
Less Common (1-10%): Hair loss; Mild headache.
Rare but Serious (less than 1%): Hypervitaminosis A (symptoms include dizziness, nausea, skin peeling); Liver damage; bone loss; birth defects.

Patient Education
Do not exceed the recommended dosage, high doses can lead to toxicity; Report any new or worsening symptoms such as prolonged headache, skin changes or yellowing of eyes/skin.

Vitamin C (Ascorbic Acid)

ATC Code: A11GA01 Vitamins (Ascorbic Acid (Vitamin C), Plain)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Vitamin C is excreted in breast milk; no adjustments needed.

Dosage forms and trade names available in Iraq

- Ascorbic acid (vitamin C) 500mg chewable tablets **vitamin C** (Wadi Al-Rafidain Iraq), **Vitamin C Kindi** (Al-Kindi Iraq).
- Ascorbic acid (vitamin C) 250mg chewable tablets **Vitamin C kindi** (Al-Kindi Iraq).
- Vitamin C 1000mg effervescent tablet
- Ascorbic acid 500 mg Sachet

Indications and Dosage

Prevent or treat vitamin C deficiency, a condition that can lead to scurvy: The Recommended Dietary Allowance (RDA) is 75-90 mg per day for adults, but a typical supplemental dose can be up to 500-1000 mg per day. 300 to 1000 mg daily in divided doses for at least one week, followed by 100 to 500 mg daily for at least another month.

Off-label uses

Enhancing iron absorption; Reducing the duration and symptoms of the common cold; Helping in the prevention of complex regional pain syndrome (CRPS) after surgical procedures.

Contraindications

Hypersensitivity to ascorbic acid or any component of the formulation; History of kidney stones or kidney disease.

Cautions

Patients with (G6PD) deficiency, as high doses of vit C can cause hemolysis in these individuals; High doses of vit C can cause diarrhea and GIT disturbances; also with Long-term use it can increase the risk of cataracts; History of iron overload diseases.

Dose Adjustment in Renal Failure: avoid high doses of vit C because it might increase the risk of calcium oxalate kidney stones.

Dose Adjustment in Hepatic Failure: None.

Pharmacokinetic Parameters

Absorption F=70-90%; at doses above 1g the bioavailability drops significantly due to absorption saturation.

Distribution it is distributed throughout the body with higher concentrations in glandular tissues and white blood cells.Protein binding 25% & Vd is not Available

Metabolism A small portion is metabolized in the body. The majority is excreted unchanged in the urine.

Elimination The kidney is chiefly responsible for the excretion of vitamin C with half-life 16 to 20 hours.

Drug Interactions

Iron Supplements: Vit C can enhance the absorption of iron, especially from non-meat sources. This could be harmful in patients with hemochromatosis & thalassemia.

Aluminum-Containing Antacids: Concurrent use can increase the body's absorption of aluminum from these antacids, which can be harmful for individuals with kidney problems.

Side Effects

Common (more than 10%): Abdominal cramps; Diarrhea; Nausea.

Less Common (1-10%): Flushing or redness of the skin; Headache.

Rare but Serious (less than 1%): Hemolysis in individuals with G6PD deficiency.

Vitamin E

ATC Code: A11HA03 Vitamins (Other Plain Vitamin Preparations)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Vitamin E is excreted in breast milk; no adjustments is needed for nursing mothers.

Dosage forms and trade names available in Iraq

Vitamin E 400mg soft gelatin capsule

Indications and Dosage

• Antioxidant supplement: 15 mg PO qDay; not to exceed 1000 mg/day.

• Treat or prevent vitamin E deficiency (this deficiency is rare, but can occur in people with certain genetic disorders): The dose may vary, but generally, 400-800 IU per day. 400mg of Vitamin E equates to approximately 600 IU.

Off-label uses

Management of fibrocystic breast disease; Helping reduce the incidence of intraventricular hemorrhage in premature infants; Management of tardive dyskinesia.

Contraindications

Hypersensitivity to vitamin E or any component of the formulation.

Cautions

Heart condition or diabetes; In people with a specific genetic mutation (in the BCO1 gene), long-term vitamin E supplementation may increase the risk of prostate cancer.

Dose Adjustment in Renal Failure: None

Dose Adjustment in Hepatic Failure: In cases of hepatic impairment, since the liver plays a significant role in the metabolism of vitamin E, careful monitoring may be necessary.

Pharmacokinetic Parameters

Absorption F= 20-70%

Distribution distributed to all tissues, but the highest concentrations are found in adipose tissue and muscle.

Metabolism primarily metabolized in the liver by cytochrome P450 enzymes.

Elimination Renal excretion with half-life 13-18 hr.(single dose), 48-60 hr. with (continued dosing).

Drug Interactions

Anticoagulants (Warfarin): Vitamin E can enhance the anticoagulant effects, potentially increasing the risk of bleeding. Close monitoring of coagulation parameters is recommended.

Chemotherapy or Radiotherapy: Concurrent use might interfere with the therapeutic effectiveness of these cancer treatments.

Side Effects

Common (more than 10%): Diarrhea; Fatigue; Headache; Skin rash.

Less Common (1-10%): Abdominal cramps; Blurred vision; Nausea.

Rare but Serious (less than 1%): Hemorrhagic stroke; Increased risk of certain types of cancers (in some studies with high dose, long-term use); Serious allergic reactions.

Patient Education

Take vitamin E with a meal to enhance absorption; Report any unusual bruising, bleeding, or signs of an allergic reaction (such as difficulty breathing, or swelling of the face, lips, tongue or throat).

Voriconazole

ATC Code: J02AC03 Antimycotics for Systemic Use (Triazole and Tetrazole Derivatives)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N
Lactation: Avoid.

Dosage forms and trade names available in Iraq

Vericonazole 200mg vial
VFEND (Pfizer USA).

Vericonazole 200mg Tablet
Veron (Pharma International Jordan).

Indications and Dosage
• Invasive aspergillosis: 100mg-200mg bid.
• Candidemia, other deep tissue candida infections: 100mg-200mg bid.
• Esophageal candidiasis: 200mg bid for 14 days.

Off-label uses
Empiric treatment of fungal meningitis or osteoarticular infections; Coccidioidomycosis in HIV patients; fungal endophthalmitis; Infection prophylaxis of graft-vs-host disease or patients with allogeneic hematopoietic stem cell transplant.

Contraindications
Hypersensitivity to voriconazole.

Cautions
Acute pancreatitis; Hypokalemia; Hypomagnesemia; Hypocalcemia; Voriconazole may prolong QT interval.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: In mild to moderate hepatic failure, reduce maintenance dose by 50%; In severe hepatic failure, use only if benefits outweigh risks, monitor closely for toxicity.

Pharmacokinetic parameters
Absorption F=96%.
Distribution Vd=4.6L/kg, 58%protein bound.
Metabolism Highly metabolized by the hepatic P450 enzymes CYP2C19, CYP2C9, CYP3A4.
Elimination Renal elimination is 2% with half-life of 6-9 hours.

Drug interactions
Clopidogrel: Voriconazole decreases effects of clopidogrel by affecting hepatic enzyme CYP2C19 metabolism, clopidogrel efficacy may be reduced by drugs that inhibit CYP2C19. Inhibition of platelet aggregation by clopidogrel is entirely due to an active metabolite. Clopidogrel is metabolized to this active metabolite in part by CYP2C19.

Side effects
Common (more than 10%) Visual changes (photophobia, color changes, increased or decreased visual acuity, or blurred vision occur in 21%)
Less common (1-10%) Abdominal pain; Alkaline phosphatase increased; Chills; Cholestatic jaundice; Diarrhea; Fever; Hallucinations; Headache; Hypertension; Hypokalemia; Hypomagnesemia; Hypotension; Nausea; Peripheral edema; Photosensitizing skin reactions; Pruritus; Rash; Tachycardia; Thrombocytopenia; Vasodilation; Vomiting; Xerostomia.
Rare but serious (less than 1%) None.

Patient educations
Take at least 1 hour before or 1 hour after a meal; Avoid driving at night; Report visual changes (blurred vision, photophobia, yellowing of skin and eyes); Avoid performing hazardous tasks if changes in vision occur; Avoid direct sunlight.

Vortioxetine

ATC Code: N06AX26 Psychoanaleptics (Other Antidepressants)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Indications and Dosage
• Major depressive disorder: Initially, 10mg once daily, may increase to 20mg as tolerated, maintenance 5mg–20mg once daily.

Off-label uses
None.

Contraindications
Hypersensitivity to vortioxetine.

Cautions
Suicide related events; Bipolar disorder; Mania or hypomania; Seizure disorders; Unstable epilepsy; Bleeding disorders; Cirrhosis; Narrow angle glaucoma; Elderly.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: In sever hepatic failure use of vortioxetine is not recommended.

Dosage forms and trade names available in Iraq

- Vortioxetine 5mg tab
  Brintellix (H. lundbeck Denmark).
- Vortioxetine 10 mg tab
  Brintellix (H. lundbeck Denmark).
- Vortioxetine 15 mg tab
  Brintellix (H. lundbeck Denmark).

Pharmacokinetic parameters
Absorption F=75%, food has no effect on absorption.
Distribution Vd=2600L, 98%protein bound.
Metabolism Extensively metabolized in the liver by CYP450 isoenzymes, mainly CYP2D6.
Elimination Renal elimination is 59% with half-life of 66 hours.

Drug interactions
Clomipramine: Clomipramine increases toxicity of vortioxetine by serotonin levels.
Dexmedetomidine: Dexmedetomidine increases levels of vortioxetine by affecting hepatic enzyme CYP2D6 metabolism decrease vortioxetine dose by 50% when coadministered with strong CYP2D6 inhibitors.

Side effects
Common (more than 10%) Nausea.
Less common (1-10%) Flatulence; Pruritus; Abnormal dreams; Constipation; Vomiting; Dry mouth; Dizziness; Diarrhea.
Rare but serious (less than 1%) Acute pancreatitis; Aggression, agitation, anger, hostility, irritability; Angle closure glaucoma; Difficulties in sexual desire, sexual performance, and sexual satisfaction; Rash; Seizure; Weight gain.

Patient educations
Avoid Dry mouth may be relieved with sugarless gum, sips of water. Avoid tasks that require alertness, motor skills until response to drug is established (may cause dizziness, drowsiness); Take with food if nausea occurs; Immediately report thoughts of suicide, self-destructive behavior, or violence; Sexual dysfunction such as inability to reach orgasm, difficulty maintaining an erection, or lack of sexual drive may occur; Do not suddenly stop treatment, dose must be gradually reduced over time.

Xylometazoline

ATC Code: R01AA07 Nasal Preparations (Sympathomimetics, Plain)

Pregnancy category:
FDA A B **C** D X N
TGA A B1 B2 B3 C D X **N**

Lactation: No data available.

Indications and Dosage

• Nasal congestion: Apply 1 spray in each nostril tid for max 5 days.

Off-label uses

None.

Contraindications

Hypersensitivity to xylometazoline; Heart disease.

Cautions

Hypertension; Diabetes mellitus; Hyperthyroidism; Prostatic hyperplasia; Urinary obstruction; Elderly.
Dose adjustment in renal failure: Not required.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption Systemic absorption may occur following nasal application of xylometazoline.
Distribution Undetermined.
Metabolism Undetermined
Elimination Undetermined.

Dosage forms and trade names available in Iraq

- Xylometazoline Hydrochloride 0.05% nasal drop
- Xylometazoline Hydrochloride 0.1% nasal drop
- Xylometazoline Hydrochloride 0.1% nasal spray
  Otrivin (GSK Switzerland).
- Xylometazoline Hydrochloride 0.05% nasal spray
  Otrivin (GSK Switzerland).

Drug interactions

Amitriptyline: Amitriptyline increase effects of sympathomimetic, by blocking reuptake of NE, or blocking uptake of indirect sympathomimetic into the adrenergic neuron.
Cabergoline: Cabergoline, increases effects of xylometazoline by pharmacodynamic synergism, additive vasospasm and risk of hypertension.
Clomipramine: Clomipramine increase effects of xylometazoline, by blocking reuptake of NE, or blocking uptake of indirect sympathomimetics into the adrenergic neuron.
Maprotiline: Maprotiline increase effects of xylometazoline, by blocking reuptake of NE, or blocking uptake of indirect sympathomimetics into the adrenergic neuron.
Selegiline: Selegiline increases effects of xylometazoline by pharmacodynamic synergism, risk of acute hypertensive episode.

Side effects

Anxiety; Burning; Dizzy; Dryness; Overuse may cause rebound congestion; Stinging; Tremor.

Patient educations

Avoid excessive or prolonged use.

Zinc Oxide

ATC Code: D02AB Emollients and Protectives (Zinc Products)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Discontinue breast-feeding.

Indications and Dosage

• Mild skin irritations and abrasions (such as chapped skin, diaper rash): Apply as needed.

Off-label uses

None.

Contraindications

Hypersensitivity to zinc oxide.

Cautions

None.

Dose adjustment in renal failure: Not required.

Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption No significant percutaneous absorption from topically applied zinc oxide.

Distribution Undetermined.

Metabolism Undetermined.

Elimination Undetermined.

Drug interactions

There are no known significant interactions.

Side effects

Dry skin.

Patient educations

A Patient education is not currently available for this monograph.

Dosage forms and trade names available in Iraq

Zinc oxide 150mg/1g (15%) Ointment

ZINC OXIDE (SDI Iraq), **Zinc oxide** (Dubai co. Iraq), **ZINCODAIN** (Wadi Al-Rafidain Iraq).

Zinc Sulfate

ATC Code: A12CB01 Mineral Supplements (Zinc).

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Excreted in breast milk. But Considered safe when used within RDA.

Dosage forms and trade names available in Iraq

Zinc Sulfate Monohydrate 125mg (45mg zinc) tab
Zincodad (Wadi Al Rafidain Company Iraq).

Indications and Dosage

- Prevention and treatment of zinc deficiency: 30-150 mg of elemental zinc per day, depending on the severity of the deficiency.
- Treatment of Wilson's disease: Up to 150 mg of elemental zinc per day, divided into three doses.

Off-label uses

Adjunct treatment for wound healing; Management of common cold symptoms. It's sometimes taken to treat a zinc deficiency or to promote wellness.

Contraindications

Hypersensitivity to zinc sulfate; Acute kidney injury and chronic kidney disease, as it might cause metal accumulation.

Cautions

Prolonged use of high doses of oral zinc is associated with copper deficiency, which can result in anemia and neurologic disease.

Dose Adjustment in Renal Failure: It is recommended to use zinc sulfate with caution in patients with renal impairment or failure.

Dose Adjustment in Hepatic Failure: None

Pharmacokinetic Parameters

Absorption F=60%, absorption can vary and is influenced by several factors, including dietary content.

Distribution Vd and protein binding of zinc specifically is not available.

Metabolism Zinc does not undergo metabolism in the way that medications typically do. Instead, it functions mainly as a cofactor for various enzymes.

Elimination Zinc excretion is fecal, with lesser amounts lost in urine and sweat. with half-life of 12 to 16 months.

Drug Interactions

Quinolone or Tetracycline Antibiotics: Zinc can bind to these antibiotics in the stomach and decrease their effectiveness. It's recommended to take zinc supplements at least 2 hours before or 4-6 hours after taking these medications.

Side effects

Common (more than 10%): Abdominal pain (with high doses); Nausea; Vomiting.

Less common (1-10%): Diarrhea; Metallic taste in the mouth.

Rare but serious (less than 1%): Zinc toxicity with excessive intake.

Patient Educations

Take zinc supplements with food; High-dose, long-term zinc supplementation can lead to copper deficiency. Report any symptoms like fatigue, difficulty walking, or numbness;

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ANTIBIOTICS
URINARY ALKALINIZER
SAMARRA DRUG INDUSTRY PRODUCTION

CIPROSAM
Ciprofloxacin 500mg

It's used to treat chest infections, skin infections, sexually transmitted infections (STIs), conjunctivitis, eye infections and ear infections

CIPROSAM
Ciprofloxacin 750mg

It's used to treat chest infections, skin infections, sexually transmitted infections (STIs), conjunctivitis, eye infections and ear infections

AZITHROSAM
Azithromycin 500mg

Chest infection, sinusitis and some skin infection.

AZITHROSAM
Azithromycin 250mg

Chest infection, sinusitis and some skin infection.

Samaxime
Cefixime 200mg

It's used to treat certain infections caused by bacteria such as bronchitis, gonorrhea and infections of the ears, throat, tonsils, and urinary tract.

Samaxime
Cefixime 400mg

It's used to treat certain infections caused by bacteria such as bronchitis, gonorrhea and infections of the ears, throat, tonsils, and urinary tract.

CEFDINISAM
Cefdinir 300mg

It's used to treat certain infections caused by bacteria such as bronchitis; pneumonia ; and infections of the skin, ears, sinuses, throat, and tonsils

Levosam
Levofloxacin 500mg

It's used to treat infections of the UTI,prostatitis, skin, lungs, ears, airways, bones, and joints caused by susceptible bacteria

UROKAL
Sodium citrate , Citric Acid, Tartaric Acid, Sodium Bicarbonate

Urinary Alkalinizer, Urinary stones and Heartburn

Zoledronic Acid

ATC Code: M05BA08 Drugs for Treatment of Bone Diseases (Bisphosphonates)

Pregnancy category:
FDA A B C D X N
TGA A B1 B2 B3 C D X N

Lactation: Avoid.

Dosage forms and trade names available in Iraq

Zoledronic acid 4mg/5ml vial
Zoledronic acid-hameln (Siegfried hamlen GERMANY).

Indications and Dosage

• Hypercalcemia: By i.v. infusion, 4mg given over 15 min, may repeated after 7 days.
• Multiple myeloma: By i.v. infusion, 4mg given over 15 min, may repeated after 7 days.

Off-label uses

Prevention of bone loss associated with aromatase inhibitor therapy in postmenopausal women with breast cancer or androgen deprivation therapy in men with prostate cancer; Post-renal transplant bone loss.

Contraindications

Hypersensitivity to zoledronic acid.

Cautions

Hypoparathyroidism; Malabsorption syndrome; Elderly; History of aspirin sensitive asthma.
Dose adjustment in renal failure: CrCl 30-60ml per minute reduce dose to 3mg; CrCl less than 30ml per minute, use of zoledronic acid is not recommended.
Dose adjustment in hepatic failure: Not required.

Pharmacokinetic parameters

Absorption F=100%.
Distribution Undetermined.
Metabolism Not metabolized.
Elimination Renal elimination is 23-53% with half-life of 167 hours.

Drug interactions

Calcium carbonate: Calcium carbonate decreases levels of zoledronic acid by inhibition of GI absorption; Separate by 30 minutes.

Side effects

Common (more than 10%) Anemia; Bone pain; Constipation; Diarrhea; Dyspnea; Fever; Headache; Hypokalemia; Hypomagnesemia; Hypophosphatemia; Hypotension; Rash; Vomiting.
Less common (1-10%) None.
Rare but serious (less than 1%) None.

Patient educations

Monitor serum renal function, CBC; Assess vertebral bone mass (document stabilization, improvement). Monitor serum calcium, phosphate, creatinine levels; Assess for fever; Monitor food intake, daily pattern of bowel activity, stool consistency; Check serum BUN, creatinine in patients with renal impairment.

Zolpidem

ATC Code: N05CF02 Psycholeptics (Benzodiazepine Related Drugs).

Pregnancy category:
FDA A **B** C D X N
TGA A B1 B2 **B3** C D X N

Lactation: Not recommended, as zolpidem is excreted in breast milk.

Dosage forms and trade names available in Iraq

- Zolpidem Tartrate 10mg tablet
  Stilnox (Sanofi Aventis France).

Indications and Dosage:

Treatment of insomnia 10 mg once per day immediately before bedtime, the total dose should not exceed 10 mg per day.

Off-label uses

•Treatment of certain brain disorders; Assisting with withdrawal from substances like alcohol and benzodiazepines; As a premedication for anesthesia.

Contraindications

Hypersensitivity; History of complex sleep behaviors after taking Zolpidem, such as sleep-walking, sleep-driving, and engaging in other activities while not fully awake.

Cautions

History of drug or alcohol abuse; Zolpidem is not intended for long-term use; History of depression, mental illness or suicidal thoughts.

Dose Adjustment in Renal Failure: None

Dose Adjustment in Hepatic Failure: Zolpidem is metabolized in the liver and can accumulate in the body if liver function is compromised.

Pharmacokinetic Parameters

Absorption F=70% due to first-pass metabolism, rapidly absorbed from the GIT.
Distribution Vd=0.54 L/kg. 92-93% protein-bound.
Metabolism metabolized in the liver, primarily by CYP3A4 (cytochrome P450 3A4).
Elimination 56% of an administered dose is excreted in urine and 34% in feces. with half-life 2.5-3 hours.

Drug Interactions

Alcohol or CNS Depressants: Combining Zolpidem with alcohol or other CNS depressants can enhance the sedative effects, potentially causing dangerous respiratory depression, extreme drowsiness, or loss of consciousness

Strong CYP3A4 Inhibitors: Drugs like ketoconazole, itraconazole, and ritonavir inhibit CYP3A4 and may increase the plasma concentrations of Zolpidem, intensifying its sedative effects and potentially leading to severe respiratory depression or excessive sedation.

Side effect

Common (more than 10%): Dizziness; Headache; Drowsiness.
Less common (1-10%): Dry mouth; Nausea; Diarrhea; Hallucinations; Agitation.
Rare but serious (less than 1%): Complex sleep behaviors (e.g., sleepwalking, sleep driving).

Patient Educations

Take Zolpidem immediately before going to bed and only when you can dedicate 7 to 8 hours to sleep to prevent memory problems or injuries; Do not drink alcohol or use other sedatives while taking Zolpidem; it may cause severe drowsiness or slowed breathing; Report any unusual sleep-related behavior to your doctor, such as sleepwalking or doing other activities while asleep.

APPENDIX 1

MECHANISM OF ACTION

APPENDIX 1 | MECHANISM OF ACTION

Abemaciclib: A cyclin-dependent kinase inhibitor, Abemaciclib primarily targets CDK4 and CDK6 enzymes. This action prevents cell cycle progression, effectively impeding the growth of cancer cells.

Abiraterone: As an androgen biosynthesis inhibitor, Abiraterone blocks the enzyme cytochrome P17. This results in reduced androgen production in both the testes and adrenal glands, leading to decreased tumor growth in prostate cancer.

Aceclofenac: A member of the NSAID family, Aceclofenac inhibits COX enzymes, which are instrumental in prostaglandin synthesis. Its anti-inflammatory effects come from this action, providing pain relief and reduced swelling.

Acetaminophen (Paracetamol): Acetaminophen primarily acts in the brain, where it inhibits an enzyme variant of COX. As a result, it reduces the production of pain- and fever-inducing prostaglandins without producing much anti-inflammatory effect.

Acetylsalicylic Acid (Aspirin): Aspirin works by irreversibly inhibiting COX enzymes. This leads to reduced prostaglandin and thromboxane production, providing anti-inflammatory, analgesic, and anti-thrombotic effects.

Aciclovir (Acyclovir): An antiviral agent, Aciclovir gets incorporated into viral DNA upon phosphorylation. It then inhibits viral DNA polymerase, effectively arresting viral DNA synthesis and replication.

Adalimumab: This monoclonal antibody specifically targets and binds to TNF-alpha. By neutralizing the activity of this cytokine, Adalimumab reduces inflammatory responses seen in various autoimmune conditions.

Adapalene: Classified as a retinoid, Adapalene works on the skin by normalizing the differentiation of follicular epithelial cells. This action prevents comedone formation and also has anti-inflammatory effects.

Adenosine: A naturally occurring nucleoside, Adenosine increases intracellular cyclic AMP. This action slows conduction time through the AV node, making it useful in certain tachyarrhythmias.

Adrenaline (Epinephrine): A powerful endogenous catecholamine, Adrenaline stimulates both alpha and beta-adrenergic receptors. This results in vasoconstriction, bronchodilation, and an overall increase in cardiac output and metabolism.

Aescin: Derived from horse chestnut seeds, Aescin has anti-inflammatory and venotonic properties. It reduces vascular permeability, thereby diminishing edema and swelling often associated with chronic venous insufficiency.

Aflibercept: A fusion protein designed to bind VEGF-A, VEGF-B, and PlGF. By binding these growth factors, Aflibercept inhibits their interaction with receptors, thus inhibiting angiogenesis, which is key in diseases like age-related macular degeneration.

Agalsidase Beta: A recombinant enzyme that replaces the deficient alpha-galactosidase A enzyme in patients with Fabry disease. It breaks down accumulated globotriaosylceramide, alleviating the disease's symptoms.

Albendazole: An antiparasitic drug, Albendazole impedes the uptake of glucose by helminths, depleting their energy stores. It also inhibits tubulin polymerization, leading to degenerative alterations in the worm's integument and intestines.

Albumin: Mainly used for its colloid osmotic properties, Albumin increases plasma volume by drawing fluid from the interstitial space. It can also bind and transport various endogenous substances and drugs in the bloodstream.

Alectinib: Decreases rate of bone resorption and may directly block dissolution of hydroxyapatite crystals of bone; inhibits osteoclast activity.

Alendronic Acid: A bisphosphonate that binds to hydroxyapatite in bone. It inhibits osteoclast activity, leading to reduced bone resorption and turnover, thereby treating conditions like osteoporosis.

Alfacalcidol: A prodrug of calcitriol (active Vitamin D3). It undergoes hepatic conversion to calcitriol, aiding in calcium absorption from the gut and regulating bone mineralization.

Alfuzosin: An alpha-1 adrenergic receptor antagonist. It relaxes the smooth muscles in the prostate and bladder neck, easing the urinary flow in conditions like benign prostatic hyperplasia.

Alglucosidase (assuming you meant Alglucosidase Alfa): A recombinant form of the human enzyme acid alpha-glucosidase. It breaks down lysosomal glycogen in Pompe disease patients, addressing the enzyme deficiency.

Allopurinol: A xanthine oxidase inhibitor. It reduces the synthesis of uric acid, decreasing its levels in the bloodstream and urine, which is beneficial for gout and certain types of kidney stones.

Alprazolam: A benzodiazepine that enhances the effect of GABA, a neurotransmitter that inhibits activity in the brain, producing sedative and anxiolytic effects.

Alprostadil: A prostaglandin E1 analogue that causes vasodilation and inhibits platelet aggregation, used for erectile dysfunction and patent ductus arteriosus in neonates.

Ambrisentan: Blocks type A endothelin receptor. theirfore it Blocks effects of endothelin on vascular smooth muscle, produces vasodilation.

Amikacin: An aminoglycoside antibiotic that inhibits bacterial protein synthesis by binding to the 30S ribosomal subunit.

Aminophylline: A bronchodilator, it inhibits phosphodiesterase, leading to increased levels of cAMP and better bronchial muscle relaxation.

Amiodarone: An antiarrhythmic drug that affects sodium, potassium, and calcium channels, as well as having non-competitive alpha- and beta-adrenergic antagonist properties.

Amisulpride: An atypical antipsychotic which acts by antagonizing dopamine D2 and D3 receptors.

Amitriptyline: A tricyclic antidepressant that inhibits the reuptake of serotonin and norepinephrine, enhancing their effects.

Amlodipine: A calcium channel blocker that relaxes blood vessels by preventing calcium from entering the smooth muscle cells of the arteries.

Amoxicillin: A beta-lactam antibiotic that inhibits bacterial cell wall synthesis.

Amphotericin B: An antifungal that binds to ergosterol in fungal cell membranes, creating pores that disrupt normal function.

APPENDIX 1 | MECHANISM OF ACTION

Ampicillin: A beta-lactam antibiotic that inhibits bacterial cell wall synthesis.

Anastrozole: An aromatase inhibitor that reduces the synthesis of estrogen, used mainly for breast cancer in post-menopausal women.

Anti-D Immunoglobulin: Used to prevent RhD isoimmunization in pregnancy; it binds to and removes fetal RhD positive red cells from the maternal circulation.

Antitetanus Immunoglobulin: Provides passive immunity by neutralizing circulating tetanus toxin.

Apixaban: A direct factor Xa inhibitor that prevents thrombin formation and thrombus development.

Aprepitant: An NK1 receptor antagonist that inhibits substance P, reducing nausea and vomiting, especially during chemotherapy.

Aripiprazole: An atypical antipsychotic that acts as a partial agonist at dopamine D2 and serotonin 5-HT1A receptors and an antagonist at 5-HT2A receptors.

Arsenic Trioxide: Induces apoptosis and affects the promyelocytic leukemia (PML) oncogene, used in acute promyelocytic leukemia (APL).

Asparaginase: Converts asparagine to aspartic acid and ammonia, depriving leukemia cells of asparagine which is essential for their growth.

Atenolol: A beta-1 selective adrenergic antagonist that reduces heart rate and blood pressure by blocking the effects of adrenaline on the heart and blood vessels.

Atezolizumab: Atezolizumab is a monoclonal antibody that inhibits programmed death-ligand 1 (PD-L1). By blocking PD-L1, it prevents the interaction with PD-1 receptors on T-cells, restoring their ability to detect and attack cancer cells. This enhances the immune response against tumors.

Atomoxetine: A selective norepinephrine reuptake inhibitor (NRI) used for attention-deficit/hyperactivity disorder (ADHD).

Atorvastatin: A statin that inhibits HMG-CoA reductase, the rate-limiting enzyme in cholesterol synthesis, thus lowering LDL cholesterol.

Atosiban: An oxytocin receptor antagonist used to delay premature labor by inhibiting uterine contractions.

Atracurium Besilate: A non-depolarizing neuromuscular blocker that competes with acetylcholine for receptor sites on the motor end-plate, leading to muscle relaxation.

Atropine: A muscarinic antagonist that blocks acetylcholine at parasympathetic sites in smooth muscle, secretory glands, and the CNS.

Azacitidine: Hypomethylating Agent that works by inhibiting DNA methylation. It incorporates into RNA and DNA, disrupting normal methylation processes, which can lead to the reactivation of tumor suppressor genes and the induction of cancer cell apoptosis (cell death).

Azathioprine: An immunosuppressant that is metabolized to 6-mercaptopurine, which inhibits DNA and RNA synthesis.

Azelaic Acid: Has antimicrobial and anti-inflammatory properties, and reduces keratin production, used mainly for acne.

Azelastine: A selective histamine H1 antagonist used to treat allergic symptoms.

Azilsartan: An angiotensin II receptor, type AT1, antagonist that blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II, inhibiting the binding of angiotensin II to the AT1 receptors.

Azithromycin: A macrolide antibiotic that inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit.

Baclofen: A GABA-B receptor agonist that depresses monosynaptic and polysynaptic reflex transmission at the spinal level, used as a muscle relaxant.

Barium sulfate: Barium sulfate is a radiopaque contrast agent used primarily in medical imaging, particularly in X-ray and CT scans. When ingested or administered as an enema, it coats the lining of the gastrointestinal tract, making it visible on X-rays.

BCG (Bacillus Calmette-Guérin): A live attenuated strain of Mycobacterium bovis used as a vaccine against tuberculosis and for bladder cancer treatment.

Beclomethasone: A corticosteroid with anti-inflammatory and vasoconstrictive properties, used mainly for asthma and allergic rhinitis.

Bemiparin: A low molecular weight heparin that potentiates the inhibition of factor Xa and thrombin by antithrombin.

Bendamustine: An alkylating agent that forms DNA crosslinks, leading to cell cycle arrest and apoptosis.

Benralizumab: A monoclonal antibody that targets the IL-5α receptor, reducing eosinophilic inflammation in asthma.

Benzoyl Peroxide: Has antibacterial actions and decreases keratin production, used topically for acne treatment.

Benzydamine: A non-steroidal anti-inflammatory drug (NSAID) with local analgesic and anti-inflammatory properties, mainly used for sore throat.

Benzyl Benzoate: Acts as an acaricide and scabicide, killing lice and the mites responsible for scabies through asphyxiation.

Beractant: A pulmonary surfactant that lowers surface tension in the alveoli, preventing atelectasis and assisting in lung function in premature infants with respiratory distress syndrome.

Besifloxacin: A fluoroquinolone antibiotic that inhibits bacterial DNA gyrase and topoisomerase IV, leading to bacterial DNA fragmentation.

Betahistine: An analog of histamine that acts mainly on histamine H1-receptors, used to treat Meniere's disease and its associated vertigo.

Betamethasone: A corticosteroid that reduces inflammation by inhibiting multiple inflammatory cytokines and promoting anti-inflammatory mediators.

Beta-sitosterol: Beta-sitosterol is a plant sterol (phytosterol) that is structurally similar to cholesterol. It works by inhibiting cholesterol absorption in the intestines and may also have anti-inflammatory and immune-modulating effects.

Betaxolol: A selective beta-1 adrenergic receptor blocker, decreasing heart rate and blood pressure.

Bevacizumab: A monoclonal antibody that inhibits vascular endothelial growth factor (VEGF), reducing angiogenesis and tumor growth.

Bicalutamide: A non-steroidal anti-androgen that inhibits the action of testosterone at androgen receptors, used for prostate cancer.

Bilastine: An antihistamine that selectively antagonizes H1-receptors, reducing allergic symptoms.

Bisacodyl: A stimulant laxative that increases electrolyte and fluid secretion into the intestine and stimulates colonic motility.

Bismuth subsalicylate: An antinauseant and antiulcer agent that absorbs water and toxins in the large intestine and forms a protective coating in the intestinal mucosa. Also possesses antisecretory and antimicrobial effects.

Bisoprolol: A selective beta-1 adrenergic receptor antagonist, reducing heart rate and blood pressure.

Bortezomib: A proteasome inhibitor that causes the accumulation of unfolded proteins in cancer cells, leading to apoptosis.

Bosentan: An endothelin receptor antagonist that dilates blood vessels, used for pulmonary arterial hypertension.

Bosutinib: A tyrosine kinase inhibitor that blocks the activity of the BCR-ABL kinase and other kinases, used for chronic myeloid leukemia.

Brimonidine: An alpha-2 adrenergic agonist that decreases aqueous humor production and increases uveoscleral outflow, reducing intraocular pressure.

Bromfenac: A non-steroidal anti-inflammatory drug (NSAID) that inhibits prostaglandin synthesis, leading to reduced inflammation and pain.

Bromhexine: A mucolytic agent that breaks down mucus, helping in respiratory conditions where mucus is a problem.

Bromocriptine: A dopamine D2 receptor agonist that inhibits prolactin secretion and is used for Parkinson's disease, hyperprolactinemia, and acromegaly.

Budesonide: A corticosteroid that reduces inflammation by suppressing immune reactions.

Bumetanide: A loop diuretic that inhibits sodium-potassium-chloride cotransporters in the thick ascending limb of the loop of Henle.

Bupivacaine: A local anesthetic that inhibits sodium ion channels, preventing nerve impulses.

Cabergoline: A dopamine agonist that inhibits prolactin secretion.

Calcium Carbonate: An antacid that neutralizes stomach acid.

Calcium Chloride: Provides calcium ions for cellular activities and coagulation.

Candesartan: An angiotensin II receptor blocker (ARB) that dilates blood vessels and reduces blood pressure.

Capecitabine: A prodrug of 5-fluorouracil; inhibits thymidylate synthase, affecting DNA synthesis in cancer cells.

Captopril: An angiotensin-converting enzyme (ACE) inhibitor that reduces blood pressure.

Carbamazepine: Antiepileptic that stabilizes inactive sodium channels, reducing neural firing.

Carbetocin: An oxytocin analog that stimulates uterine contractions.

Carbimazole: Inhibits thyroid hormone synthesis.

Carboplatin: An alkylating agent that cross-links DNA, inhibiting DNA replication in cancer cells.

Carboxymethyl Cellulose: Used as a lubricant in artificial tears and in oral forms as a bulking agent.

Cariprazine: A dopamine D3/D2 receptor partial agonist used for schizophrenia.

Carteolol: A non-selective beta-blocker that reduces intraocular pressure.

Carvedilol: A non-selective beta and alpha-1 adrenergic antagonist that lowers blood pressure.

Caspofungin: An echinocandin antifungal that inhibits fungal cell wall synthesis.

Cefaclor: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Cefadroxil: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Cefdinir: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Cefepime: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Cefixime: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Cefotaxime: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Cefpodoxime: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Ceftazidime: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Ceftriaxone: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Cefuroxime: Cephalosporin antibiotic that inhibit bacterial cell wall synthesis.

Celecoxib: A selective COX-2 inhibitor NSAID reducing inflammation without affecting gastric mucosa.

Cephalexin: A first-generation cephalosporin that inhibits bacterial cell wall synthesis.

Cetirizine: A second-generation piperazine that competes with histamine for H1-receptor sites on effector cells in the GI tract, blood vessels, and respiratory tract.

Cetrimide: An antiseptic that disrupts cell membranes of microbes.

Cetuximab: A monoclonal antibody that targets the epidermal growth factor receptor (EGFR), inhibiting cell growth and inducing apoptosis.

Chloramphenicol: An antibiotic that inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit.

Chlordiazepoxide: Benzodiazepine that potentiates GABA, inducing sedation and reducing anxiety.

Chlorhexidine: Antiseptic that disrupts microbial cell membranes, causing cell death.

Chlorpheniramine: H1 antihistamine that blocks histamine receptors, reducing allergy symptoms.

Chorionic Gonadotrophin: Stimulates ovulation and testosterone production by acting like LH.

Ciclosporin: Immunosuppressant that inhibits calcineurin, reducing T-cell activity.

Cinacalcet: Increases sensitivity of calcium-sensing receptor, reducing PTH secretion.

Cinnarizine: Calcium channel blocker and H1 antihistamine; reduces vertigo and tinnitus.

Ciprofloxacin: Fluoroquinolone antibiotic that inhibits bacterial DNA gyrase.

Cisplatin: Chemotherapeutic that cross-links DNA, inhibiting DNA synthesis and function.

Citicoline: May enhance phospholipid synthesis and neuroprotection in the brain.

Citrulline: Converted to arginine in kidneys; precursor for nitric oxide synthesis.

Cladribine: Antimetabolite that disrupts DNA synthesis and induces apoptosis in lymphocytes.

Clarithromycin: Macrolide antibiotic that inhibits bacterial protein synthesis.

Clindamycin: Antibiotic that binds to bacterial ribosomes, inhibiting protein synthesis.

Clobetasol: Potent corticosteroid that suppresses inflammation and immune responses.

Clomiphene: Induces ovulation by antagonizing estrogen receptors in the hypothalamus.

Clonazepam: Benzodiazepine that enhances GABA activity, producing sedative effects.

Clopidogrel: Inhibits platelet aggregation by blocking P2Y12 adenosine diphosphate receptors.

Clotrimazole: Antifungal that disrupts fungal cell membranes.

Colchicine: Alters microtubule polymerization, reducing inflammation in gout.

Cotrimoxazole (trimethoprim-sulfamethoxazole): Combination antibiotic that inhibits folic acid synthesis in bacteria.

Crizotinib: Tyrosine kinase inhibitor targeting ALK and ROS1, halting tumor growth.

Cromoglicate: also known as sodium cromoglycate, is a mast cell stabilizer. It works by inhibiting the release of histamine and other inflammatory mediators from mast cells.

Crotamiton: Scabicide that likely kills mites and soothes itching.

Cyanocobalamin (Vitamin B12): Essential for DNA synthesis and neurologic function.

Cyclopentolate: Muscarinic antagonist that dilates pupils (mydriasis) and paralyzes eye focus.

Cyclophosphamide: Alkylating agent that cross-links DNA, suppressing immune responses and tumor growth.

Cyproheptadine: H1 antihistamine with antiserotonergic properties.

Cytarabine: Antimetabolite that inhibits DNA synthesis, used in leukemia treatment.

Dabigatran: Direct thrombin inhibitor that prevents clot formation.

Dacarbazine: Alkylates DNA, RNA; inhibits RNA, DNA synthesis; also responsible for breakage, cross-linking DNA strands; activity is not cell cycle phase specific.

Dacomitinib: Dacomitinib is a targeted cancer therapy that works as an irreversible inhibitor of the epidermal growth factor receptor (EGFR) tyrosine kinase. By binding to the EGFR, dacomitinib blocks the signaling pathways that promote cancer cell growth and survival, leading to the inhibition of tumor proliferation.

Danazol: Synthetic steroid that suppresses gonadotropin production, treating endometriosis.

Dapagliflozin: SGLT2 inhibitor that prevents glucose reabsorption in the kidneys, leading to increased urinary glucose excretion.

Dapoxetine: Selective serotonin reuptake inhibitor (SSRI) that increases synaptic serotonin, delaying ejaculation reflex.

Daptomycin: Antibiotic that disrupts bacterial cell membrane function, causing rapid cell death.

Daratumumab: Monoclonal antibody targeting CD38 on myeloma cells, inducing cell death via multiple mechanisms.

Darbepoetin Alfa: Erythropoiesis-stimulating agent (ESA) that stimulates red blood cell production by mimicking erythropoietin.

Dacarbazine: Alkylating agent that adds alkyl groups to DNA, inhibiting replication and transcription.

Decitabine: Hypomethylating agent that incorporates into DNA and inhibits DNA methyltransferase, promoting gene re-expression.

Deferasirox: Iron-chelating agent that binds free iron, facilitating its excretion in feces.

Deferiprone: Iron chelator that binds free iron, facilitating its urinary excretion.

Deferoxamine: Iron-chelating agent that binds excess iron, facilitating urinary and fecal excretion.

Deflazacort: Corticosteroid that suppresses inflammatory and immune responses.

Denosumab: Monoclonal antibody that inhibits RANKL, reducing bone resorption and increasing bone density.

Dequalinium: Antiseptic that damages bacterial cell membranes, leading to cell death.

Desflurane: Inhalational anesthetic that potentiates GABA_A receptor, inducing anesthesia.

Desloratadine: H1 antihistamine that blocks histamine receptors, alleviating allergy symptoms.

Desmopressin: Synthetic vasopressin analog that increases water reabsorption in kidneys and raises factor VIII levels.

Desogestrel: Progestin that suppresses ovulation and thickens cervical mucus, preventing pregnancy.

Dexamethasone: Corticosteroid that modulates gene transcription, suppressing inflammation and immune responses.

Dexmedetomidine: Alpha-2 adrenergic agonist providing sedation, analgesia, and anxiolysis without respiratory depression.

Dexpanthenol: Provitamin of B5 that aids in skin and mucous membrane healing.

Dextromethorphan: NMDA receptor antagonist that suppresses cough reflex centrally in the medulla.

Dextrose: simple sugar used as energy source and in medical treatment to correct hypoglycemia.

Diazepam: Benzodiazepine that potentiates GABA neurotransmission, inducing sedation, muscle relaxation, and anxiolysis.

Diclofenac: NSAID that inhibits COX enzymes, reducing prostaglandin synthesis and inflammation.

Dienogest: Progestin with antiandrogenic properties, suppressing endometriosis and preventing ovulation.

Digoxin: Cardiac glycoside that inhibits Na+/K+ ATPase, increasing intracellular calcium and enhancing cardiac contractility.

Diloxanide: Amebicide that acts against trophozoites in the intestines, treating asymptomatic Entamoeba histolytica infection.

Diltiazem: Calcium channel blocker that relaxes vascular smooth muscle and slows cardiac conduction.

Dimethindene: H1 antihistamine that reduces allergy symptoms by blocking histamine receptors.

Dinoprostone: Prostaglandin analog that induces cervical ripening and uterine contractions for labor induction.

Diosmin: Venotropic drug that improves venous tone and lymphatic drainage, used in chronic venous disease.

Diphenhydramine: H1 antihistamine that blocks histamine receptors, reducing allergy symptoms and inducing sedation.

Dipyridamole: Inhibits platelet aggregation by increasing cAMP levels, also dilates coronary arteries.

Dobutamine: Beta-1 adrenergic agonist that increases cardiac contractility without greatly increasing heart rate.

Docetaxel: Taxane that stabilizes microtubules, inhibiting cell division and promoting apoptosis.

Domperidone: D2 receptor antagonist that enhances gastric motility and suppresses nausea and vomiting.

Donepezil: AChE inhibitor that boosts acetylcholine in the brain, enhancing cognitive function in Alzheimer's disease.

Dopamine: Neurotransmitter that stimulates dopaminergic receptors; in medications, improves hemodynamics in shock states.

Dorzolamide: Carbonic anhydrase inhibitor that reduces aqueous humor production, lowering intraocular pressure in glaucoma.

Doxazosin: Alpha-1 adrenergic blocker that relaxes smooth muscle in the prostate and bladder neck and dilates blood vessels.

Doxorubicin: Anthracycline that intercalates DNA and inhibits topoisomerase II, disrupting DNA and RNA synthesis.

Doxycycline: Tetracycline antibiotic that inhibits bacterial protein synthesis by binding the 30S ribosomal subunit.

Dulaglutide: GLP-1 receptor agonist that stimulates insulin secretion and suppresses glucagon, improving glycemic control.

Duloxetine: SNRI that increases synaptic concentrations of serotonin and norepinephrine, managing depression and neuropathic pain.

Dutasteride: 5-alpha reductase inhibitor that blocks the conversion of testosterone to DHT, treating benign prostatic hyperplasia.

Dydrogesterone: Progestin that mimics the action of natural progesterone, managing menstrual disorders and endometriosis.

Econazole: Imidazole antifungal that disrupts fungal cell membrane, causing increased permeability and cell death.

Emicizumab: Bispecific antibody bridging activated factor IX and factor X, restoring hemostasis in hemophilia A with inhibitors.

APPENDIX 1 | MECHANISM OF ACTION

Empagliflozin: SGLT2 inhibitor that blocks glucose reabsorption in the kidney, promoting urinary glucose excretion.

Enalapril: ACE inhibitor that reduces angiotensin II and aldosterone, dilating vessels and reducing blood pressure.

Enoxaparin: Low molecular weight heparin that inhibits factor Xa, preventing thrombus formation.

Entecavir: Nucleoside analog that inhibits hepatitis B viral DNA polymerase, suppressing HBV replication.

Enzalutamide: Androgen receptor inhibitor that blocks testosterone signaling, inhibiting prostate cancer growth.

Epirubicin: Anthracycline that intercalates DNA and disrupts topoisomerase II, hindering DNA and RNA synthesis.

Epoetin Alfa: Recombinant human erythropoietin stimulating red blood cell production, managing anemia.

Eptacog Alfa: Recombinant factor VIIa, aids clot formation in hemophilia A or B with inhibitors.

Ergocalciferol (Vitamin D): Converted to active vitamin D, promoting calcium absorption in the gut.

Erlotinib: Tyrosine kinase inhibitor targeting EGFR, halting proliferation in certain cancers.

Ertugliflozin: SGLT2 inhibitor that promotes urinary glucose excretion by inhibiting renal glucose reabsorption.

Erythromycin: Macrolide antibiotic binding the 50S ribosomal subunit, inhibiting bacterial protein synthesis.

Escitalopram: SSRI that increases synaptic serotonin levels, managing depression and anxiety.

Esomeprazole: Proton pump inhibitor (PPI) that reduces stomach acid production by inhibiting H+/K+ ATPase.

Estradiol: Estrogen hormone replacement that regulates female reproductive processes and treats hormone deficiencies.

Etanercept: TNF-alpha inhibitor that reduces inflammation in diseases like rheumatoid arthritis.

Etonogestrel: Progestin that prevents ovulation, modifies cervical mucus, and thins endometrial lining.

Etoposide: Topoisomerase II inhibitor that prevents DNA re-ligation, causing DNA damage and cell death.

Etoricoxib: Selective COX-2 inhibitor that reduces prostaglandin synthesis, alleviating inflammation and pain.

Evening primrose oil: a mixture of fatty acids, and may function like essential oils and act as precursors of prostaglandins that help regulate metabolic functions.

Everolimus: mTOR inhibitor that regulates cell growth and proliferation, used in cancers and transplant rejection.

Ezetimibe: Inhibits cholesterol absorption at the intestinal brush border, reducing total cholesterol.

Factor IX: a protein that plays a crucial role in the blood coagulation process. It is one of the essential clotting factors involved in the cascade that leads to the formation of a blood clot, and is particularly important in the activation of Factor X, which is a critical step in the coagulation pathway.

Factor VIII: Essential clotting factor that interacts with factor IXa to form tenase complex, correcting hemophilia A deficiency.

Factor XIII: a clotting factor that plays a key role in the final stage of the blood coagulation process. Once a blood clot is formed, Factor XIII stabilizes it by cross-linking fibrin strands, which strengthens and solidifies the clot, preventing it from breaking down prematurely.

Famotidine: H2 receptor antagonist that inhibits gastric acid secretion in the stomach.

Febuxostat: A non-purine, selective inhibitor of xanthine oxidase. Therefore, it Decreases serum uric acid.

Fenofibrate: PPARα agonist that increases HDL and decreases triglycerides.

Fentanyl: Potent opioid agonist that binds to μ-opioid receptors producing analgesia.

Fexofenadine: Non-sedating antihistamine that blocks histamine H1 receptors.

Fibrinogen: Plasma protein converted into fibrin in clotting cascade, used in bleeding disorders.

Filgrastim: Recombinant G-CSF that stimulates neutrophil production.

Finasteride: 5α-reductase inhibitor, blocks testosterone to DHT conversion.

Fingolimod: Sphingosine-1-phosphate receptor modulator, sequesters lymphocytes in lymph nodes.

Fluorometholone: Corticosteroid that reduces inflammation.

Flavoxate: Antimuscarinic agent, relaxes smooth muscle in urinary tract.

Flucinolone Acetonide: Corticosteroid, anti-inflammatory and immunosuppressive.

Fluconazole: Triazole antifungal, inhibits fungal cytochrome P450.

Fludarabine: Purine analog, inhibits DNA synthesis leading to cytotoxicity.

Fluorometholone: Topical corticosteroid, reduces eye inflammation.

Fluorouracil (5-FU): Pyrimidine analog, inhibits DNA synthesis.

Fluoxetine: SSRI that increases extracellular levels of serotonin in the brain.

Fluphenazine: Typical antipsychotic, blocks dopamine D2 receptors.

Flurbiprofen: Non-steroidal anti-inflammatory drug (NSAID), inhibits COX enzymes.

Fluticasone Propionate: Corticosteroid, anti-inflammatory used for asthma and allergic rhinitis.

Folic Acid: Essential B vitamin, required for DNA synthesis and repair.

Follitropin Alpha: Recombinant FSH, stimulates ovarian follicular growth.

Fondaparinux Sodium: Factor Xa inhibitor, prevents thrombus formation.

Fosfomycin: Antibacterial that inhibits cell wall synthesis.

Fulvestrant: Estrogen receptor antagonist, used in hormone-receptor-positive metastatic breast cancer.

Furosemide: Loop diuretic, inhibits Na-K-2Cl symporter in thick ascending loop.

Fusidic Acid: Fusidic acid is an antibiotic, it works by inhibiting bacterial protein synthesis, effectively stopping the growth and multiplication of bacteria.

Gabapentin: GABA analog, modulates calcium channels reducing neuropathic pain.

Gadobutrol: MRI contrast agent, enhances visualization in MRI scans.

Gadoteric acid: Gadoteric acid is a gadolinium-based contrast agent (GBCA) used in magnetic resonance imaging (MRI) to enhance the visibility of internal body structures.

Galsulfase: Enzyme replacement therapy for Mucopolysaccharidosis VI.

Ganciclovir: Guanosine analog, inhibits DNA polymerase in cytomegalovirus (CMV).

Ganirelix: GnRH antagonist that inhibits the release of LH and FSH from the pituitary gland, preventing ovulation.

Gatifloxacin: broad-spectrum fluoroquinolone antibiotic, It works by inhibiting bacterial DNA gyrase and topoisomerase IV, enzymes critical for DNA replication, transcription, repair, and recombination, leading to the death of the bacterial cells.

Glucagon: A glucose-elevating agent that promotes hepatic glycogenolysis, gluconeogenesis. Stimulates production of cyclic adenosine monophosphate (cAMP), which results in increased plasma glucose concentration, smooth muscle relaxation, and an inotropic myocardial effect.

Glucose: Glucose is a simple sugar (monosaccharide) that is a primary source of energy for cells in the body. It is essential for various bodily functions, including metabolism and energy production.

Gefitinib: EGFR tyrosine kinase inhibitor, prevents cancer cell growth by blocking EGFR-mediated signal transduction.

Gelatin Polysuccinate: Plasma volume expander; increases blood volume by exerting osmotic pressure.

Gemcitabine: Nucleoside analog, inhibits DNA synthesis and promotes apoptosis of cancer cells.

Gemifloxacin: Fluoroquinolone antibiotic, inhibits bacterial DNA gyrase and topoisomerase IV.

Gentamicin: Aminoglycoside antibiotic, inhibits protein synthesis in susceptible bacteria.

Glibenclamide (Glyburide): Sulfonylurea that stimulates insulin secretion from pancreatic beta cells.

Gliclazide: Sulfonylurea; enhances insulin secretion and increases insulin action.

Glimepiride: Sulfonylurea that increases pancreatic insulin secretion.

Glipizide: Sulfonylurea; promotes insulin secretion from pancreatic beta-cells.

Glycerin: Osmotic agent, draws water into the intestines to promote bowel movement.

Glyceryl trinitrate: Glyceryl trinitrate acts as a nitrate, which dilates blood vessels, particularly veins. It also dilates coronary arteries, improving blood flow to the heart muscle.

Glycine: Inhibitory neurotransmitter in CNS; also acts as a co-agonist with glutamate.

Golimumab: Monoclonal antibody specific for human tumor necrosis factor (TNF); elevated levels of TNF are found in patients with rheumatoid arthritis.

Goserelin Acetate: A gonadotropin-releasing hormone analogue and antineoplastic agent that stimulates the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) from the anterior pituitary gland. In males, increases testosterone concentrations initially, and then suppresses secretion of LH and FSH, resulting in decreased testosterone levels.

Granisetron: 5-HT3 receptor antagonist, prevents nausea and vomiting by blocking serotonin receptors.

Haloperidol: Dopamine D2 receptor antagonist, used as an antipsychotic.

Heparin: Anticoagulant; enhances antithrombin III, inhibiting thrombin and Factor Xa.

Hexetidine: Antiseptic; reduces bacterial cell membrane permeability causing cell death.

Hexol: Antiseptic, germicidal and fungicidal agent.

Homatropine: Muscarinic acetylcholine receptor antagonist, induces pupil dilation and cycloplegia.

Human Chorionic Gonadotropin (hCG): is a hormone produced during pregnancy by the placenta. It plays several important roles in maintaining pregnancy and supporting fetal development.

Human Normal Immunoglobulin: Contains antibodies; provides passive immunity.

Human Tetanus Immunoglobulin: HTIG contains antibodies (immunoglobulins) specific to the tetanospasmin toxin produced by Clostridium tetani. These antibodies neutralize the toxin and provide immediate, short-term protection against the disease.

Human Plasma Coagulation Factor XIII: Stabilizes fibrin clots by cross-linking fibrin.

Human Von Willebrand Factor: Binds to platelets and collagen, promoting platelet adhesion at injury sites.

Hydralazine: Vasodilator; relaxes arterial smooth muscle, reducing blood pressure.

Hydrochlorothiazide: Thiazide diuretic; inhibits sodium reabsorption in distal convoluted tubule.

Hydrocortisone: Corticosteroid; anti-inflammatory and immunosuppressive actions.

Hydroquinone: Reduces melanin synthesis by inhibiting tyrosinase, used for hyperpigmentation.

Hydroxide Polymaltose Complex: Iron complex for treating iron-deficiency anemia.

Hydroxocobalamin: Vitamin B12 form, essential for DNA synthesis and neurological function.

Hydroxycarbamide: it inhibits ribonucleotide reductase, an enzyme crucial for DNA synthesis and repair. This results in reduced production of deoxyribonucleotides and ultimately inhibits the proliferation of cancer cells. Also, it increases fetal hemoglobin (HbF) levels, which reduces the sickling of red blood cells and decreases the frequency of painful crises.

Hydroxy Propyl Methyl Cellulose (Hypromellose): Lubricates the eye, used as artificial tears.

Hydroxycarbamide: Inhibits ribonucleotide reductase, decreasing DNA synthesis.

Hydroxychloroquine Sulfate: Modulates immune response; also inhibits lysosomal acidification.

Hydroxyl Carbamide: Inhibits DNA synthesis by blocking ribonucleotide reductase.

Hydroxyprogesterone: Progestin; supports pregnancy by enhancing endometrial receptivity.

Hydroxyurea: Inhibits ribonucleotide reductase; decreases DNA synthesis.

Hyoscine (Scopolamine): Muscarinic antagonist, prevents motion sickness and reduces secretions.

Hypromellose: a semi-synthetic polymer derived from cellulose. acts as a lubricant by forming a protective layer on the surface of the eye, reducing friction and providing moisture.

Ibandronic Acid: Bisphosphonate; inhibits osteoclast-mediated bone resorption.

Ibrutinib: Bruton's tyrosine kinase inhibitor; hampers B-cell proliferation and survival.

Ibuprofen: NSAID; inhibits COX enzymes, reducing prostaglandin synthesis.

Idursulfase: Enzyme replacement therapy for Hunter syndrome, breaks down glycosaminoglycans.

Ifosfamide: Alkylating agent; cross-links DNA, preventing cancer cell replication.

Imatinib: Tyrosine kinase inhibitor; blocks BCR-ABL and other kinases, inhibiting cancer growth.

Imiglucerase: An enzyme replacement therapy that breaks down glucocerebroside, compensating for the deficiency seen in Gaucher's disease.

Imiquimod: Immune response modifier, stimulates the body's innate immune system, primarily by enhancing the activity of Toll-like receptor 7.

Indapamide: A thiazide-like diuretic that inhibits sodium reabsorption in the distal convoluted tubules, leading to increased urinary excretion of sodium and water.

Indomethacin: Non-steroidal anti-inflammatory drug (NSAID) that inhibits cyclooxygenase (COX), reducing the synthesis of prostaglandins and inflammation.

Infliximab: Monoclonal antibody that targets and neutralizes tumor necrosis factor-alpha (TNFα), a pro-inflammatory cytokine.

Influenza Vaccine: Stimulates an immune response against viral antigens, conferring protection against specific influenza strains.

Interferon: A biological response modifier that inhibits viral replication in virus-infected cells, suppresses cell proliferation, increases phagocytic action of macrophage, and augments specific lymphocytic cell toxicity.

Iohexol: Nonionic, water-soluble contrast medium used in radiography; helps visualize vascular structures on imaging.

Ipratropium: Muscarinic receptor antagonist that relaxes bronchial smooth muscles by blocking acetylcholine.

Irbesartan: Angiotensin II receptor blocker (ARB) that relaxes blood vessels and reduces blood pressure.

Irinotecan: Topoisomerase I inhibitor that prevents DNA unwinding, leading to cancer cell death.

Iron: Essential for hemoglobin synthesis in red blood cells and vital for oxygen transportation.

Isoflurane: Inhalational anesthetic that depresses central nervous system activity, inducing anesthesia.

Isoniazid: Antitubercular agent that inhibits mycolic acid synthesis in Mycobacterium tuberculosis.

Isosorbide: Organic nitrate that dilates blood vessels, increasing blood flow and decreasing myocardial oxygen demand.

Isotretinoin: Reduces sebum production and inflammation; affects cell differentiation and reduces acne formation.

Ispaghula Husk: Bulk-forming laxative; absorbs water in the intestines, softening stool and increasing its bulk.

Itraconazole: Antifungal that inhibits ergosterol synthesis, disrupting fungal cell membrane.

Ivabradine: Selectively inhibits the I(f) current in the sinoatrial node, reducing heart rate.

Ivermectin: Increases permeability of cell membranes to chloride ions in parasitic worms, leading to paralysis.

Ivy leaves dry extract: derived from the ***Hedera helix*** plant (common ivy), The saponins in ivy leaves stimulate the production of mucus and help expel it from the airways, also the extract breaks down and thins mucus, making it easier to clear from the respiratory tract.

Ketamine: NMDA receptor antagonist that induces a trance-like state while providing pain relief, sedation, and memory loss.

Ketoconazole: Inhibits fungal ergosterol synthesis, disrupting the fungal cell membrane.

Ketoprofen: An NSAID that produces analgesic and antiinflammatory effects by inhibiting prostaglandin synthesis.

Ketorolac: NSAID that inhibits prostaglandin synthesis by blocking COX enzymes, providing analgesic and anti-inflammatory effects.

Ketotifen: H1 antihistamine and mast cell stabilizer, reducing allergic reactions.

L-Arginine Monohydrochloride: Amino acid supplement; arginine is a precursor for nitric oxide, promoting vasodilation.

Lacosamide: Enhances slow inactivation of voltage-gated sodium channels, stabilizing neuronal membranes.

Lactulose: Synthetic sugar that draws water into the intestines and is broken down to organic acids, softening stools.

Lamotrigine: Antiepileptic that stabilizes neuronal membranes by inhibiting sodium and calcium channels.

Lanreotide: Octapeptide somatostatin analog that inhibits insulin-like growth factor-1 (IGF-1) and growth hormone.

Lansoprazole: Proton pump inhibitor (PPI) that reduces stomach acid production by blocking the H+/K+ ATPase system.

Laronidase: Enzyme replacement for mucopolysaccharidosis I; breaks down glycosaminoglycans.

Latanoprost: Prostaglandin analog that increases aqueous humor outflow, reducing intraocular pressure.

Lauromacrogol 400: Sclerosing agent; damages endothelium of varicose veins, leading to vein shrinkage and closure.

Lenalidomide: Immunomodulatory drug; inhibits angiogenesis and promotes immune responses against tumor cells.

Lercanidipine: Calcium Channel Blocker that selectively inhibits L-type calcium channels in vascular smooth muscle cells.

Letrozole: Aromatase inhibitor; blocks the conversion of androgens to estrogens, reducing estrogen levels.

Levamisole: Immunomodulator and anthelmintic; paralyzes worm muscles and also modulates human immune responses.

Levetiracetam: Antiepileptic; modulates neurotransmitter release via binding to synaptic vesicle protein.

Levocetirizine: H1 histamine receptor antagonist; reduces allergic symptoms by inhibiting histamine effects.

Levofloxacin: Fluoroquinolone antibiotic; inhibits bacterial DNA gyrase and topoisomerase IV, hindering bacterial DNA replication.

Levothyroxine: Synthetic thyroid hormone; replaces or supplements natural thyroid hormones, regulating metabolism.

Lidocaine: Local anesthetic; blocks sodium channels, inhibiting nerve impulse conduction and pain sensation.

APPENDIX 1 | MECHANISM OF ACTION

Linagliptin: DPP-4 inhibitor; increases insulin secretion and lowers glucagon secretion, reducing blood glucose.

Linezolid: Oxazolidinone antibiotic; inhibits bacterial protein synthesis by binding to ribosomal RNA.

Liraglutide: GLP-1 agonist; stimulates insulin secretion, inhibits glucagon release, and delays gastric emptying.

Lisinopril: ACE inhibitor; prevents the conversion of angiotensin I to angiotensin II, reducing blood pressure.

Loperamide: Opioid agonist; slows intestinal motility by acting on opiate receptors in the gut wall.

Loratidine: H1 histamine receptor antagonist; inhibits action of histamine, reducing allergy symptoms.

Lorazepam: Benzodiazepine; enhances the effect of GABA, leading to CNS depression and anxiolysis.

Losartan: Angiotensin II receptor antagonist; blocks effects of angiotensin II, causing vasodilation.

Loteprednol Etabonate: Corticosteroid; reduces inflammation by inhibiting multiple inflammatory cytokines.

Lyophilized Fish Roe: Nutritional supplement; rich in omega-3 fatty acids and proteins. Not a drug.

Macrogol: Osmotic laxative; increases water content in the intestines, promoting bowel movements.

Magnesium carbonate: a chemical compound that serves various roles, such as it Neutralizes excess stomach acid by reacting with hydrochloric acid (HCl) to form magnesium chloride and carbon dioxide. Also Draws water into the intestines, which helps to soften stool and stimulate bowel movements.

Magnesium Sulfate: Electrolyte; acts as an anticonvulsant in eclampsia and replenishes magnesium deficiencies.

Mannitol: Osmotic diuretic; increases water and electrolyte excretion by increasing osmolarity of glomerular filtrate.

Mebendazole: Anthelmintic; disrupts microtubule structures, starving and killing susceptible worms.

Mebeverine: Antispasmodic; acts directly on smooth muscle in the gut, reducing muscle spasm.

Mecobalamin: Active form of Vitamin B12; essential for nerve function and red blood cell formation.

Medroxyprogesterone acetate: Conjugated estrogens that increase synthesis of DNA, RNA and various proteins in responsive tissues; reduces release of gonadotropin-releasing hormone, reducing follicle-stimulating hormone (FSH) and leuteinizing hormone (LH).

Mefenamic Acid: NSAID; inhibits cyclooxygenase, reducing the production of prostaglandins.

Meloxicam: NSAID; reduces inflammation by inhibiting prostaglandin synthesis via COX-2 inhibition.

Melphalan: Alkylating agent; damages DNA, disrupting cell replication and causing cell death.

Memantine: NMDA receptor antagonist; modulates glutamate activity, protecting neurons in Alzheimer's disease.

Menotrophin: Combination of FSH and LH; stimulates ovarian follicular growth in infertile women.

Mercaptopurine: Antimetabolite; interferes with nucleotide synthesis, inhibiting DNA replication in cancer cells.

Meropenem: A broad-spectrum carbapenem antibiotic. It binds to penicillin-binding proteins, inhibiting bacterial cell wall synthesis, causing cell lysis and death.

Mesalazine: Anti-inflammatory agent used for ulcerative colitis. It acts locally in the gut, modulating inflammatory responses and decreasing the production of pro-inflammatory mediators.

Mesna: A detoxifying agent, it binds to the metabolites of certain chemotherapy drugs, preventing hemorrhagic cystitis by neutralizing harmful metabolites in the urine.

Metformin: An antidiabetic drug that decreases hepatic glucose production, improves peripheral glucose uptake and utilization, and does not stimulate insulin secretion.

Methotrexate: An antimetabolite. It inhibits dihydrofolate reductase, blocking DNA synthesis, repair, and cellular replication, mainly in rapidly dividing cells.

Methyldopa: Antihypertensive. It's metabolized to alpha-methyl norepinephrine, which lowers blood pressure by central alpha-adrenergic stimulation, reducing sympathetic outflow.

Methylergometrine: Uterine stimulant. It induces rhythmic uterine contractions and decreases bleeding by direct action on the smooth muscle of the uterus.

Methylphenidate: CNS stimulant. It increases dopamine and norepinephrine in the brain, enhancing attention and decreasing impulsivity in ADHD patients.

Methylprednisolone: Corticosteroid. It suppresses inflammation and immune responses by decreasing the activity and volume of the lymphatic system.

Metoclopramide: Prokinetic and antiemetic. It stimulates gastric motility and accelerates intestinal transit by antagonizing dopamine receptors in the brain.

Metoprolol: Beta-blocker. It decreases heart rate and blood pressure by blocking beta-adrenergic receptors in the heart and vasculature.

Metronidazole: An antibiotic and antiprotozoal. It disrupts DNA of sensitive organisms, leading to the death of bacterial and protozoal cells.

Micafungin: Antifungal. It inhibits the synthesis of fungal cell walls by blocking β-1,3 D-glucan, leading to fungal cell death.

Miconazole: Antifungal. It interferes with fungal cell membrane permeability by inhibiting ergosterol synthesis.

Midazolam: Benzodiazepine. Enhances the activity of GABA, inducing sedation, anxiolysis, amnesia, and muscle relaxation.

Miglustat: Used for Gaucher's disease. It inhibits the synthesis of glucosylceramide, reducing harmful accumulations in cells.

Minocycline: Antibiotic. It inhibits protein synthesis in susceptible bacteria by binding to the 30S ribosomal subunit.

Minoxidil: Vasodilator. Opens potassium channels, causing hyperpolarization of cell membranes, and resulting in relaxation of vascular smooth muscle. Minoxidil, when used for hair loss, stimulates hair follicles, prolonging the growth phase of hair. It enhances blood flow to hair follicles and increases follicular size and hair shaft diameter. This leads to thicker, longer, and more visible hair.

Mirabegron: Treats overactive bladder. It relaxes the detrusor muscle by stimulating β3-adrenoceptors, increasing bladder capacity.

Mirtazapine: Antidepressant. Increases norepinephrine and serotonin by antagonizing central alpha-2 adrenergic inhibitory autoreceptors and heteroreceptors.

Misoprostol: Prostaglandin analog. Promotes gastric mucosal protection and induces uterine contractions by binding to prostaglandin receptors.

Mitoxantrone: Antineoplastic. Intercalates into DNA, causing crosslinks and strand breaks, and also inhibits topoisomerase II.

Mometasone: Corticosteroid. Modulates the immune response and inflammation by inhibiting the release of inflammatory mediators.

Montelukast: Leukotriene receptor antagonist. Reduces inflammatory symptoms of asthma by blocking leukotriene receptors in the bronchial wall.

Morphine: Opioid analgesic. Binds to mu-opioid receptors in the CNS, decreasing the perception of pain and increasing pain tolerance.

Moxifloxacin: Fluoroquinolone antibiotic. Inhibits bacterial DNA gyrase and topoisomerase IV, disrupting DNA replication and repair.

Mycophenolate Mofetil: Immunosuppressant. Inhibits purine synthesis, leading to reduced proliferation of T and B lymphocytes.

Naloxone: Opioid antagonist. Rapidly binds to opioid receptors, displacing opioids and reversing their effects.

Nandrolone: Anabolic steroid. Enhances protein synthesis, nitrogen retention, and muscle growth by binding to androgen receptors.

Naproxen: NSAID. Inhibits cyclooxygenase, reducing the synthesis of prostaglandins and inflammation.

Nebivolol: Beta-blocker. Reduces blood pressure by blocking β1-adrenergic receptors and inducing nitric oxide-mediated vasodilation.

Nefopam: Non-opioid analgesic. Its exact mechanism isn't fully understood, but it might involve the inhibition of reuptake of serotonin, norepinephrine, and dopamine.

Neostigmine: Anticholinesterase. Increases acetylcholine by inhibiting its breakdown, improving muscle strength in

myasthenia gravis.

Nepafenac: NSAID eye drop. Reduces inflammation after eye surgery by inhibiting prostaglandin synthesis.

Nifedipine: Calcium channel blocker. Inhibits the influx of calcium ions into vascular smooth muscle and cardiac muscle, leading to arterial dilation and reduced blood pressure.

Nilotinib: Tyrosine kinase inhibitor. Targets and binds to the BCR-ABL protein, halting its activity, thereby treating chronic myeloid leukemia.

Nintedanib: Tyrosine kinase inhibitor. Targets growth factor receptors, inhibiting fibroblast proliferation, migration, and differentiation in pulmonary fibrosis.

Nitrofurantoin: Antibiotic. Damages bacterial DNA, primarily targeting urinary tract pathogens by inhibiting various bacterial enzymes.

Norepinephrine: Neurotransmitter and vasoconstrictor. Stimulates α and β-adrenergic receptors, resulting in increased heart rate and blood pressure.

Norethisterone: Progestin. Mimics progesterone, regulating menstrual cycle, inhibiting ovulation, and used in various hormonal therapies.

Norfloxacin: Fluoroquinolone antibiotic. Inhibits bacterial DNA gyrase and topoisomerase IV, preventing bacterial DNA replication.

Nusinersen Sodium: Antisense oligonucleotide. Modifies splicing of the SMN2 gene, increasing production of the functional SMN protein in spinal muscular atrophy.

Nystatin: Antifungal. Binds to fungal cell membrane sterols, creating a permeable pore, leading to cell death.

Ocrelizumab: Monoclonal antibody. Targets CD20 on B cells, leading to B-cell lysis and reduced autoimmune responses in multiple sclerosis.

Octreotide: Somatostatin analog. Inhibits the release of growth hormone, insulin, and gastrin, useful for acromegaly and certain tumors.

Ofloxacin: Fluoroquinolone antibiotic. Inhibits bacterial DNA gyrase and topoisomerase IV, disrupting bacterial DNA function.

Olanzapine: Antipsychotic. Antagonizes various neurotransmitter receptors, particularly dopamine D2 and serotonin 5-HT2, reducing psychotic symptoms.

Olmesartan: Blocks the vasoconstrictor effects of angiotensin II by blocking the binding of angiotensin II to the AT 1 receptor in smooth muscle.

Olopatadine: Antihistamine. Inhibits histamine H1 receptor and stabilizes mast cells, reducing allergic reactions and inflammation.

Omeprazole: Proton pump inhibitor. Binds irreversibly to gastric proton pumps, reducing acid secretion in the stomach.

Ondansetron: Antiemetic. Blocks the action of serotonin at 5-HT3 receptors, reducing nausea and vomiting.

O-Phthaldialdehyde: High-level disinfectant. Reacts with proteins and nucleic acids, rendering microorganisms non-viable.

Orlistat: Lipase inhibitor. Blocks gastrointestinal lipases, reducing dietary fat absorption.

Orphenadrine: A skeletal muscle relaxant that is structurally related to diphenhydramine and is thought to indirectly affect skeletal muscle by central atropine-like effects.

Oseltamivir: Antiviral. Neuraminidase inhibitor, preventing the release of progeny influenza virus and thus limiting viral spread.

Otilonium: Antispasmodic. Blocks calcium uptake and has local anesthetic effects on the smooth muscle of the intestine.

Oxaliplatin: Chemotherapeutic agent. Forms DNA adducts, leading to DNA damage and cytotoxicity in cancer cells.

Oxybutynin: Anticholinergic. Relaxes bladder smooth muscle by blocking muscarinic receptors, treating overactive bladder symptoms.

Oxymetazoline: Alpha-adrenergic agonist. Constricts arterioles, reducing nasal congestion when used as a decongestant.

Oxytocin: Hormone. Stimulates uterine contractions and milk ejection by acting on uterine and mammary gland receptors.

Ozenoxacin: Quinolone antibiotic. Inhibits bacterial DNA replication enzymes, treating bacterial skin infections.

Paclitaxel: Antineoplastic agent. Stabilizes microtubules, inhibiting cell division and promoting apoptosis in cancer cells.

Palbociclib: CDK inhibitor. Inhibits CDK 4/6, blocking cell cycle progression and suppressing DNA synthesis in cancer cells.

Paliperidone: Antipsychotic. Antagonizes dopamine D2 and serotonin 5-HT2A receptors, mitigating symptoms of schizophrenia.

Palivizumab: Monoclonal antibody. Binds to respiratory syncytial virus (RSV), preventing its entry into cells and reducing severity of RSV infections.

Pancreatin: A pancreatic digestive enzyme combination (protease, lipase, amylase) that hydrolyzes fats to glycerol and fatty acids, converts proteins into peptides and amino acids, and converts starch into dextrins and maltose.

Pancuronium: Neuromuscular blocker. Competitively blocks nicotinic acetylcholine receptors, causing muscleparalysis.

Pantoprazole: Proton pump inhibitor. Irreversibly inhibits gastric proton pumps, reducing acid secretion.

Paroxetine: SSRI antidepressant. Inhibits the reuptake of serotonin, increasing its levels and enhancing its neurotransmission.

Pegfilgrastim: Granulocyte colony-stimulating factor. Stimulates neutrophil production, aiding recovery from neutropenia in chemotherapy patients.

Pelargonium Sidoides Extract: Herbal remedy. Displays antimicrobial and immunomodulatory properties, often used for bronchitis.

Pembrolizumab: Immune checkpoint inhibitor. Targets and binds to the PD-1 receptor, enhancing T-cell response against tumor cells.

Pemetrexed: Antimetabolite chemotherapy. Inhibits folate-dependent enzymes, disrupting DNA synthesis in cancer cells.

Penicillin: A penicillin that inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins of bacteria.

Perindopril: ACE inhibitor. Reduces angiotensin II levels, leading to arterial dilation and decreased blood pressure.

Pertuzumab: Monoclonal antibody. Binds HER2 receptor, preventing dimerization, thus inhibiting tumor growth in HER2-positive breast cancers.

Pethidine: Opioid analgesic. Binds μ-opioid receptors in CNS, decreasing perception of pain.

Phenobarbital: Barbiturate. Increases GABA activity in CNS, producing sedative, hypnotic, and antiseizure effects.

Phenylephrine: Alpha-1 adrenergic agonist. Induces vasoconstriction, increasing blood pressure and relieving nasal congestion.

Phenytoin: Anticonvulsant. Stabilizes neuronal membranes, reducing repetitive neuronal firing.

Phytomenadione: also known as vitamin K1, is a form of vitamin K, required for the synthesis of vitamin K-dependent clotting factors in the liver. It facilitates the carboxylation of certain proteins involved in blood clotting.

Pilocarpine: A cholinergic that increases exocrine gland secretions by stimulating cholinergic receptors.

Pimecrolimus: Calcineurin inhibitor. Reduces inflammation by inhibiting T-cell activation in atopic dermatitis.

Pioglitazone: Thiazolidinedione. Increases insulin sensitivity in muscle and adipose tissue, lowering blood glucose.

Piperacillin: is a broad-spectrum beta-lactam antibiotic, works by inhibiting bacterial cell wall synthesis.

Piracetam: Nootropic. Enhances membrane fluidity, potentially improving cognition, though exact MOA is unclear.

Piroxicam: NSAID. Inhibits COX enzymes, reducing prostaglandins and inflammation.

Pizotifen: Antihistamine and serotonin antagonist. Prevents vascular dilation, used for migraine prophylaxis.

Plerixafor: Hematopoietic agent. Blocks CXCR4, mobilizing stem cells from bone marrow into the bloodstream.

Potassium Chloride: Electrolyte supplement. Treats or prevents hypokalemia, maintaining neuromuscular function.

Povidone Iodine: Antiseptic. Releases iodine, killing bacteria, fungi, and viruses upon contact.

Pramipexole: Dopamine agonist. Binds dopamine D2/D3 receptors, treating Parkinson's symptoms and restless leg syndrome.

Prasugrel: Antiplatelet. Inhibits ADP receptors on platelets, reducing platelet aggregation.

Pravastatin: Statin. Inhibits HMG-CoA reductase, reducing cholesterol synthesis in the liver.

Prednicarbate: Topical corticosteroid. Reduces inflammation by suppressing immune responses in skin conditions.

Prednisolone: Corticosteroid. Modulates immune responses and inflammation, used in various inflammatory conditions.

Pregabalin: Neuropathic agent. Binds calcium channels in CNS, reducing neurotransmitter release and pain perception.

Prifinium Bromide: Antispasmodic. Relaxes smooth muscles in gastrointestinal tract, alleviating spasms.

Prochlorperazine: Antipsychotic/antiemetic. Blocks dopamine D2 receptors, reducing nausea and psychotic symptoms.

Procyclidine: Anticholinergic. Reduces acetylcholine activity, used in Parkinson's and drug-induced extrapyramidal symptoms.

Progesterone: Hormone. Prepares uterus for implantation, maintains pregnancy, and regulates menstrual cycle.

Propiverine: Anticholinergic. Relaxes bladder smooth muscle, treating overactive bladder symptoms.

Propofol: Anesthetic. Potentiates GABA_A receptor activity, inducing sedation and hypnosis.

Propolis Extract: Natural remedy. Offers antimicrobial, anti-inflammatory, and antioxidant properties.

Propranolol: Beta-blocker. Inhibits β1 and β2 receptors, reducing heart rate, blood pressure, and anxiety symptoms.

Propylthiouracil: Antithyroid agent. Inhibits thyroid hormone synthesis, treating hyperthyroidism.

Pyridoxine: Vitamin B6. Coenzyme in amino acid, glucose, and lipid metabolism.

Quetiapine: Antipsychotic. Antagonizes dopamine D2 and serotonin 5-HT2A receptors, reducing psychotic symptoms.

Rabeprazole: Proton pump inhibitor. Inhibits gastric acid secretion by binding to proton pumps.

Rabies antigen: It is a protein from the rabies virus that can be detected in tissues or fluids to diagnose rabies infection.

Racecadotril: Prodrug; its active metabolite inhibits enkephalinase, reducing diarrhea by decreasing intestinal secretions.

Ramipril: ACE inhibitor; reduces angiotensin II, leading to vasodilation and decreased blood pressure.

Ramucirumab: Monoclonal antibody; inhibits VEGFR-2, preventing angiogenesis in tumors.

Ranolazine: Antianginal; modifies sodium channel activity, decreasing myocardial oxygen demand.

Repaglinide: Increases insulin secretion from pancreatic β-cells by closing ATP-sensitive potassium channels.

Rho(D) Immune Globulin: used to prevent RhD isoimmunization; it binds to and removes fetal RhD positive red cells from the maternal circulation.

Ribavirin: A synthetic nucleoside that inhibits influenza virus RNA polymerase activity and interferes with expression of messenger RNA.

Rifampicin: Inhibits bacterial RNA polymerase, impeding bacterial transcription.

Rifaximin: Antibiotic; alters bacterial RNA synthesis, targeting gut bacteria in hepatic encephalopathy.

Risedronate: Bisphosphonate; inhibits osteoclast-mediated bone resorption.

Risperidone: Antipsychotic; antagonizes dopamine D2 and serotonin 5-HT2A receptors.

Rituximab: Monoclonal antibody; targets CD20 on B-cells, used in lymphomas and autoimmune diseases.

Rivaroxaban: Factor Xa inhibitor; reduces coagulation, preventing thrombosis.

Rocuronium: Non-depolarizing neuromuscular blocker; inhibits acetylcholine at the neuromuscular junction.

Romiplostim: Increases platelet production by mimicking thrombopoietin, helping in ITP.

Rosuvastatin: Statin; inhibits HMG-CoA reductase, reducing cholesterol synthesis.

Roxithromycin: Macrolide antibiotic; inhibits bacterial protein synthesis by targeting the ribosome.

Ruxolitinib: JAK inhibitor; reduces signaling in inflammatory and myeloproliferative disorders.

Saccharomyces boulardii: Probiotic yeast; promotes gut health and modulates local immune response.

Salbutamol: Beta-2 adrenergic agonist; bronchodilator used in asthma and COPD.

Saxagliptin: DPP-4 inhibitor; enhances incretin hormones, increasing insulin and decreasing glucagon release.

Semaglutide: GLP-1 receptor agonist; increases insulin, suppresses glucagon release, and slows gastric emptying.

Senna Calcium Salt: Laxative; stimulates intestinal peristalsis, aiding in constipation.

Sertaconazole Nitrate: Antifungal; inhibits ergosterol synthesis, disrupting fungal cell membranes.

Sertraline: SSRI; increases serotonin levels in the synaptic cleft, used in depression and anxiety.

Sevelamer: Phosphate binder; reduces serum phosphate levels in kidney disease patients.

Sevoflurane: Inhalational anesthetic; potentiates GABA receptors inducing anesthesia.

Sildenafil: PDE5 inhibitor; enhances nitric oxide signaling, inducing vasodilation, mainly in penile arteries.

Silver Sulfadiazine: Antimicrobial; used in burns to prevent infections.

Simethicone: Antifoaming agent; reduces gas bubbles in the gut.

Simvastatin: Statin; inhibits HMG-CoA reductase, reducing cholesterol synthesis.

Sirolimus: mTOR inhibitor; immunosuppressant, used in organ transplantation.

Sitagliptin: DPP-4 inhibitor; enhances incretin hormones, increasing insulin and decreasing glucagon release.

Sodium Bicarbonate: Alkalinizing agent; counteracts acidemia in various conditions.

Sodium Chloride: Essential electrolyte; maintains fluid balance, osmotic pressure, and pH in the body.

Sodium Fusidate (Fusidic Acid): Inhibits bacterial protein synthesis by targeting the ribosome.

Sodium Hyaluronate: Provides hydration and lubrication to tissues; used in osteoarthritis and dry eyes.

Sodium Picosulfate: Laxative; increases fluid secretion in the colon and stimulates colonic motility.

Sodium Valproate: Anticonvulsant; increases GABA in the brain, stabilizing neuronal membranes.

Solifenacin: Muscarinic receptor antagonist; relaxes the bladder muscle, treating overactive bladder.

Somatropin: Human growth hormone analog; stimulates growth and cell reproduction.

Sorafenib: Tyrosine kinase inhibitor; blocks tumor growth by inhibiting angiogenesis and promoting apoptosis.

Spectinomycin: Binds to bacterial ribosomes, interrupting protein synthesis.

Spiramycin: Macrolide antibiotic; inhibits bacterial protein synthesis.

Spironolactone: Aldosterone antagonist; diuretic, also used in hyperaldosteronism and hirsutism.

Sugammadex: Selectively binds and inactivates steroidal neuromuscular blocking agents.

Sumatriptan: 5-HT_1 receptor agonist; causes vasoconstriction in cranial arteries, treating migraines.

Sunitinib: Tyrosine kinase inhibitor; targets multiple receptors, hindering tumor growth and angiogenesis.

Tacrolimus: Calcineurin inhibitor; immunosuppressive, used post organ transplantation.

Tadalafil: PDE5 inhibitor; enhances nitric oxide signaling, causing vasodilation, especially in penile arteries.

Tafluprost: Prostaglandin analog; increases uveoscleral outflow, reducing intraocular pressure.

Tamsulosin: Alpha-1 adrenergic receptor antagonist; relaxes smooth muscle in the prostate and bladder neck.

Teicoplanin: Glycopeptide antibiotic; inhibits bacterial cell wall synthesis.

Telmisartan: Angiotensin II receptor antagonist; causes vasodilation and reduces blood pressure.

Temozolomide: Alkylating agent; causes DNA damage, used in brain tumors.

Tenofovir Disoproxil Fumarate: Nucleotide reverse transcriptase inhibitor; inhibits viral DNA synthesis in HIV and HBV.

Terbinafine: Inhibits fungal enzyme squalene epoxidase, disrupting ergosterol synthesis and fungal cell membrane.

Teriflunomide: Inhibits dihydroorotate dehydrogenase, reducing pyrimidine synthesis and T cell proliferation.

Tetracaine: Local anesthetic; blocks sodium channels, preventing nerve impulse conduction.

Tetracycline: Antibiotic; inhibits bacterial protein synthesis by binding to the ribosome.

Theophylline: Phosphodiesterase inhibitor; bronchodilator used in asthma and COPD.

Thiamine (Vitamin B1): Coenzyme in glucose metabolism; essential for nerve function.

Thioctic Acid (Alpha-lipoic acid): Antioxidant; regenerates other antioxidants and assists in glucose metabolism.

Thyrotropin Alfa: Recombinant TSH; used in testing for thyroid cancer recurrence.

Ticagrelor: P2Y12 receptor antagonist; inhibits platelet aggregation, reducing thrombotic events.

Tigecycline: A broad-spectrum antibiotic, it binds the bacterial 30S ribosomal subunit. This inhibits protein synthesis, preventing bacterial replication and growth. It's particularly effective against drug-resistant bacteria, including MRSA.

Timolol: A non-selective beta-adrenergic receptor blocker. It reduces intraocular pressure by decreasing aqueous humor secretion, making it effective in glaucoma treatment.

Tinidazole: An antiprotozoal, it damages DNA and prevents DNA synthesis in susceptible organisms, thereby inhibiting

their growth.

Tiotropium: A long-acting muscarinic antagonist. It blocks acetylcholine-mediated bronchoconstriction, leading to bronchodilation in chronic obstructive pulmonary disease (COPD) patients.

Tizanidine: An alpha-2 adrenergic agonist. It suppresses the release of excitatory amino acids and reduces muscle tone, offering relief from muscle spasticity.

Tobramycin: An aminoglycoside antibiotic. It binds to bacterial 30S ribosomal subunit, inhibiting protein synthesis and leading to bacterial cell death.

Tocilizumab: An interleukin-6 (IL-6) receptor antagonist. By blocking IL-6 signaling, it reduces inflammation, particularly in rheumatoid arthritis.

Tofacitinib: A Janus kinase (JAK) inhibitor. It modulates the immune system by blocking signaling pathways important in inflammation.

Tolnaftate: An antifungal. It disrupts the fungal cell membrane by inhibiting squalene epoxidase, stopping fungal growth.

Tolperisone: A muscle relaxant. It blocks sodium and calcium channels, reducing muscle spasm without depressing the central nervous system.

Tolterodine: A muscarinic receptor antagonist. It relaxes the bladder muscles, preventing urgent, uncontrolled contractions.

Topiramate: An antiepileptic. It stabilizes neuronal membranes, enhances GABA action, and inhibits glutamate receptors, reducing seizure activity.

Torasemide: A loop diuretic. It inhibits the Na-K-2Cl symporter in the thick ascending limb of the loop of Henle, leading to increased urine output.

Tramadol: An opioid analgesic. It binds to μ-opioid receptors and inhibits the reuptake of norepinephrine and serotonin, producing analgesia.

Tranexamic Acid: An antifibrinolytic. It blocks the conversion of plasminogen to plasmin, preventing clot breakdown and controlling bleeding.

Trastuzumab: A monoclonal antibody. It targets the HER2/neu receptor, inhibiting cancer cell growth in HER2-positive breast cancers.

Tretinoin: A vitamin A derivative. It promotes cell turnover and reduces keratinocyte cohesion, aiding in acne treatment and skin rejuvenation.

Triamcinolone: A corticosteroid. It suppresses inflammation, reduces immune responses, and alleviates allergic reactions.

Trifluoperazine: An antipsychotic. It blocks dopamine D2 receptors in the brain, reducing symptoms of schizophrenia.

Trimetazidine: An antianginal. It optimizes cellular energy production, improving cardiac function under ischemic conditions.

Triptorelin: A GnRH analog. It initially stimulates, then suppresses, the pituitary release of LH and FSH, impacting testosterone and estrogen levels.

Tropicamide: A muscarinic receptor antagonist. It causes pupil dilation (mydriasis) and paralysis of eye accommodation.

Trospium: An anticholinergic. It blocks muscarinic receptors, leading to relaxation of bladder smooth muscle.

Ursodeoxycholic Acid: A bile acid. It protects liver cells from bile acid-induced injury, used in gallstone dissolution and liver disorders.

Ustekinumab: A monoclonal antibody. It binds to the p40 subunit of IL-12 and IL-23, reducing inflammation in conditions like psoriasis.

Valsartan: An Angiotensin II receptor blocker (ARB). It blocks the vasoconstrictive and aldosterone-secreting effects of angiotensin II, reducing blood pressure.

Vancomycin: A glycopeptide antibiotic. It inhibits bacterial cell wall synthesis by binding to D-alanyl-D-alanine termini of cell wall precursors.

Vardenafil: A PDE5 inhibitor. It enhances nitric oxide-mediated vasodilation, improving erectile function.

Velaglucerase Alfa: A recombinant human beta-glucocerebrosidase. It replaces the deficient enzyme in Gaucher's disease, breaking down glucocerebroside.

Venlafaxine: A serotonin-norepinephrine reuptake inhibitor (SNRI). It increases the levels of serotonin and norepinephrine in the brain, elevating mood.

Verapamil: A calcium channel blocker. It inhibits calcium influx into vascular smooth muscle and myocardium, inducing vasodilation and reducing heart rate.

Voriconazole: An antifungal. It inhibits fungal cytochrome P450, preventing ergosterol synthesis, essential for fungal cell membranes.

Vildagliptin: A DPP-4 inhibitor. It increases incretin levels, which inhibit glucagon release and increase insulin release, lowering blood glucose.

Vincristine: An antineoplastic. It binds tubulin, inhibiting microtubule formation, causing cell cycle arrest and cancer cell death.

Vinorelbine: An antineoplastic. It interferes with microtubule assembly, inhibiting mitosis in cancer cells.

Vitamin A: Essential for vision, growth, cell differentiation, and immune function. It forms the light-absorbing molecule retinal essential for both low-light and color vision.

Vitamin C (Ascorbic Acid): An essential vitamin and antioxidant. It aids in collagen synthesis, facilitates iron ab-

sorption, and assists in hydroxylation reactions. Vitamin C also neutralizes free radicals, reducing oxidative stress and supporting immune function.

Vitamin E: A fat-soluble antioxidant. It protects cell membranes from damage by neutralizing free radicals, supports immune function, and prevents oxidative degradation of lipids.

Voriconazole: An antifungal agent. It inhibits fungal cytochrome P450, disrupting ergosterol synthesis, essential for fungal cell membrane integrity, leading to fungal cell death.

Vortioxetine: An antidepressant. It modulates neurotransmitter levels in the brain, acting as a serotonin modulator and stimulator, enhancing serotonergic, noradrenergic, dopaminergic, cholinergic, histaminergic, and glutamatergic neurotransmission.

Xylometazoline: A nasal decongestant. It activates alpha-adrenergic receptors in the nasal vasculature, causing vasoconstriction, reducing blood flow and edema in nasal passages.

Zinc Oxide: Used in dermatology. Provides a protective barrier, has mild astringent properties, and offers some antiseptic action. Also, it provides UV protection in sunscreens.

Zinc Sulfate: A source of zinc. It supports various enzymes, aids wound healing, supports growth, and plays a role in immune function, protein synthesis, and DNA synthesis.

Zoledronic Acid: A bisphosphonate. It binds to hydroxyapatite in bone, inhibiting osteoclast-mediated bone resorption, thereby increasing bone density and reducing fracture risk.

Zolpidem: A sedative-hypnotic. It enhances the effect of GABA, a neurotransmitter that inhibits brain activity, promoting sleep by slowing down brain activity.

APPENDIX 2

CHILDREN DOSES

ABEMACICLIB: 150 mg orally twice daily plus tamoxifen or an aromatase inhibitor.

ABIRATERONE: Safety and efficacy not established.

ACECLOFENAC: Not recommended for children.

ACETAMINOPHEN (Paracetamol): 10-15 mg/kg every 4-6 hours.

ACETYLSALICYLIC ACID (Aspirin): Not recommended due to Reye's syndrome risk, except in specific conditions: 10-15 mg/kg orally every 4 hours, up to 60-80 mg/kg/day.

ACICLOVIR: 20 mg/kg/dose for neonatal herpes.

ADALIMUMAB: Safety and efficacy not established.

ADAPALENE: Less than 12 years; Safety and efficacy not established.

ADENOSINE: Rapid i.v. ; Initial 0.1 mg/kg, maximum 6 mg; then 0.2 mg/kg, maximum 12 mg.

ADRENALINE (Epinephrine): Anaphylaxis; 0.01 mg/kg of 1:1,000 solution i.m.

AFLIBERCEPT: Ophthalmic use, 0.4 mg (0.01 mL) by intravitreal injection.

AGALSIDASE BETA: Specific to Fabry disease; Less than 2 years; Safety and efficacy not established; More than 2 years; 1 mg/kg i.v. every 2 weeks.

ALBENDAZOLE: 400 mg single dose.

ALBUMIN: Varies widely based on condition; 0.5-1 g/kg/dose i.v. infused over 1-3 hours.

Alectinib: Safety and efficacy have not been established in children.

ALENDRONIC ACID: Safety and efficacy not established.

ALFUZOSIN: Safety and efficacy not established.

ALGLUCOSIDASE: 20 mg/kg i.v. every 2 weeks; infuse over 4 hours.

ALLOPURINOL: 10-20 mg/kg/day.

ALPRAZOLAM: 0.25-0.5 mg orally every 6-8 hours; titrate to effect every 3-4 Days; not to exceed 4 mg/day.

ALPROSTADIL: Initial 0.05-0.1 mcg/kg/minute i.v.

Ambrisentan: Safety and efficacy have not been established to children.

AMIKACIN: 15-20 mg/kg/day i.v./i.m. divided every 8-12 hours.

AMINOPHYLLINE: Loading: 5-6 mg/kg i.v.; Maintenance: 1-2.5 mg/kg/hour i.v.

AMIODARONE: Load: 5 mg/kg i.v. or orally; then maintenance varies.

AMISULPRIDE: Safety and efficacy not established.

AMITRIPTYLINE: 1-2.5 mg/kg/day orally.

AMLODIPINE: 0.1-0.3 mg/kg/day.

AMOXICILLIN: 20-40 mg/kg/day divided every 8 hours.

AMPHOTERICIN B: 3-6 mg/kg I,v, every day.

AMPICILLIN: 25-50 mg/kg i.v./i.m. every 6-8 hours.

ANASTROZOLE: Not recommended for pediatrics.

APIXABAN: Safety and efficacy not established.

APREPITANT: Varies by weight, less than 30 kg; 125 mg on day 1, then 80 mg on days 2-3.

ARIPIPRAZOLE: Starting at 2 mg/day, adjust as needed.

ARSENIC TRIOXIDE: Safety and efficacy not established.

ASPARAGINASE: 25,000 IU/m^2 i.m./i.v. 3 times/week.

ATENOLOL: 0.5-1 mg/kg/day.

Atezolizumab: Safety and efficacy have not been established to children.

ATOMOXETINE: Initial doses of 0.5 mg/kg/day.

ATORVASTATIN: Starting dose is often 10mg daily.

ATOSIBAN: Used in obstetrics, not for pediatric use.

ATRACURIUM BESILATE: 0.3-0.5 mg/kg i.v.

ATROPINE: For bradycardia 0.02 mg/kg.

AZATHIOPRINE: 1-3 mg/kg/day.

AZELAIC ACID: Safety and efficacy not established.

Azacitidine: often administered at a starting dose of 75 mg/m^2 body surface area (BSA) given subcutaneously once daily for 7 days. Then This is usually repeated every 4 weeks.

AZELASTINE: Nasal spray, 0.1% or 0.15%; 1 spray per nostril every 12 hours.

Azilsartan: Safety and efficacy have not been established to children.

AZITHROMYCIN: 10 mg/kg on day 1, then 5 mg/kg days 2-5.

BACLOFEN: 0.5-1 mg/kg/day divided doses, titrate as needed.

Barium sulfate: PO For upper gastrointestinal (GI) studies

• Infants and Young Children: Generally, 60 to 180 mL may be used.

• Older Children: 180 to 360 mL may be used, depending on the procedure.

Rectal Administration: For lower GI studies (such as barium enema)

• Infants and Young Children: Approximately 60 to 120 mL of barium sulfate suspension may be used.

• Older Children: Approximately 120 to 240 mL may be used.

BCG: 0.2-0.3 mL percutaneous.

BECLOMETHASONE: Less than 4 years; Safety and efficacy not established. 4-11 years; 40 mcg inhaled twice daily.

BEMIPARIN: Not commonly used in pediatrics.

BENDAMUSTINE: Safety and efficacy not established.

BENZOYL PEROXIDE: Apply sparingly to affected areas every day after thoroughly washing skin; may gradually increase to twice daily/three time daily if needed.

BENZYL BENZOATE: For infants; Use mixed with three parts of water, just one time. For older children; Use mixed with an equal quantity of water, just one time.

BERACTANT: Premature neonates; Prophylaxis 100 mg phospholipids/kg (4 mL/kg) intratracheal within 15 minutes of birth; may administer 4 doses during the first 48 hours of life not more frequent than every 6 hours. Treatment if respiratory distress syndrome is confirmed by x-ray, administer 100 mg phospholipids/kg (4 mL/kg) intratracheal within 8 hours of birth; may administer 4 doses during the first 48 hours of life no more frequently than every 6 hours.

BESIFLOXACIN: Less than 1 year; Safety and efficacy not established. More than 1 year, 1 drop in affected eye(s) three times daily (4-12 hours apart) for7 days.

BETAHISTINE: 4-8 mg three times daily.

BETAMETHASONE: Children and adolescents 0.02-0.3 mg/kg/day i.m. divided every 8-12 hours. Topical less than 12 years; Not recommended. More than 12 years; Apply to the affected area every 12 hours.

Beta-sitosterol: If used in children, dosages would likely be lower and should be determined on a case-by-case basis.

BETAXOLOL: 0.25% suspension; 1 drop in affected eye every 12 hours.

BICALUTAMIDE: Safety and efficacy not established.

BILASTINE: 10 mg once daily for children 6-11 years.

BISACODYL: 5-10 mg daily.

Bismuth subsalicylate: Diarrhea, Gastric Distress: Children 9–12 yr. 1 tablet or 15 ml q30–60 min. Maximum: 8 doses in 24 hr. Children 6–8 yr. Two-thirds of a tablet or 10 ml q30–60 min. Maximum: 8 doses in 24 hr. Children 3–5 yr. One-third of a tablet or 5 ml q30–60 min. Maximum: 8 doses in 24 hr.

Chronic Infant Diarrhea: PO for Children 2–24 mo. 2.5 ml q4h.

BISOPROLOL: Safety and efficacy not established.

BORTEZOMIB: Safety and efficacy not established.

BOSENTAN: Starts 62.5mg twice daily for children more than 10 years.

BOSUTINIB: Safety and efficacy not established.

BRIMONIDINE: 1 drop in affected eye(s) twice daily.

BROMFENAC: Safety and efficacy not established.

BROMHEXINE: 2 mg three times daily for children 2-5 years old.

BROMOCRIPTINE: 1.25 mg daily for hyperprolactinemia.

BUDESONIDE: Safety and efficacy not established.

BUMETANIDE: 0.015-0.1 mg/kg/dose every 6-24 hours.

BUPIVACAINE: Maximum 2.5 mg/kg for local infiltration.

CABERGOLINE: Safety and efficacy not established.

CALCIUM CARBONATE: 50-150 mg elemental calcium/kg/day in divided dose.

CALCIUM CHLORIDE: Emergency hypocalcemia; 20 mg/kg/dose.

CANDESARTAN: Hypertension; 0.05-0.4 mg/kg/day.

CAPECITABINE: Safety and efficacy not established.

CAPTOPRIL: 0.1-0.5 mg/kg/dose every 8-12 hours.

CARBAMAZEPINE: 10-20 mg/kg/day in divided doses.

CARBETOCIN: Safety and efficacy not established.

CARBOPLATIN: Solid tumor, 300-600 mg/m² i.v. every 4 weeks; Sarcoma (bone/soft tissue)400 mg/m²/day for 2 days every 21 days; Brain tumor175 mg/m² every week for 4 weeks with a 2 weeks recovery period between courses; Bone

marrow transplant preparative regimen500 mg/m²/day for 3 days; Retinoblastoma 1-2 mL subconjunctival injection of 10 mg/mL solution per dose.

CARIPRAZINE: Safety and efficacy not established.

CARTEOLOL: Not recommended for pediatrics.

CARVEDILOL: 0.1-0.2 mg/kg/dose twice daily.

CASPOFUNGIN: 50 mg/m²/day (maximum 70 mg/day).

CEFACLOR: 20-40 mg/kg/day in divided doses.

CEFADROXIL: 30 mg/kg/day in divided doses.

CEFDINIR: 14 mg/kg/day in 1-2 doses.

CEFEPIME: 50 mg/kg/dose every 12 hours.

CEFIXIME: 8 mg/kg/day in a single dose.

CEFOTAXIME: 50-180 mg/kg/day in divided doses.

CEFPODOXIME: 10 mg/kg/day in divided doses.

CEFTAZIDIME: 30-50 mg/kg/dose every 8 hours.

CEFTRIAXONE: 50-75 mg/kg/dose once daily.

CEFUROXIME: 20-60 mg/kg/day in divided doses.

CELECOXIB: Less than 2 years; Safety and efficacy not established. More than 2 years 50-100 mg orally every 12 hours.

CEPHALEXIN: 25-50 mg/kg/day in divided doses.

CETIRIZINE: 2.5-10 mg/day based on age.

CETUXIMAB: Safety and efficacy not established.

CHLORDIAZEPOXIDE: Less than 6 years, safety and efficacy not established. More than 6 years, 5 mg orally twice daily/four times daily, may increase dose to 10 mg orally twice daily/three times daily if necessary.

.**CHLORHEXIDINE**: Safety and efficacy not established.

CHLORPHENIRAMINE: 0.35 mg/kg/day divided every 4-6 hours.

CICLOSPORIN: 2.5-6.5 mg/kg/day in 1-2 doses.

CINACALCET: Initial 0.2 mg/kg; adjust per serum PTH.

CINNARIZINE: 1-3 mg/kg/day in divided doses.

CIPROFLOXACIN: 10-20 mg/kg every 12 hours.

CISPLATIN: Osteogenic Sarcoma/Neuroblastoma (Off-label)90 mg/m² i.v. every 3weeks or 30 mg/m² i.v. every 3 weeks. Brain Tumors, Recurrent (Off-label) 60 mg/m² i.v. every day for 2 consecutive days every 3-4 weeks.

CLADRIBINE: Safety and efficacy not established.

CLARITHROMYCIN: 7.5-15 mg/kg every 12 hours.

CLINDAMYCIN: 10-40 mg/kg/day in divided doses.

CLOBETASOL: Topically less than 12 years, safety and efficacy not established. More than 12 years, apply thin layer to affected areas every 12hours not to exceed 50 g/week.

CLOMIPHENE: Not used in children.

CLONAZEPAM: 0.01-0.03 mg/kg/day.

CLOPIDOGREL: Load, 0.2 mg/kg; Maintenance, 1 mg/kg.

CLOTRIMAZOLE: Topically less than 12 years, safety and efficacy not established.

COLCHICINE: 0.6 mg for children more than 4 years.

COTRIMOXAZOL: 2-5 mg/kg trimethoprim component.

CRIZOTINIB: 280 mg/m² twice daily.

Cromoglicate: Children 2 to 5 years: Inhalation: 1-2 puffs (1 mg per puff) 4 times daily. Children 6 years and older: Inhalation: 2 puffs (1 mg per puff) 4 times daily.

CROTAMITON: Topical, wash thoroughly and scrub away loose scales, then dry, apply thin layer and massage drug onto skin of entire body from neck to toes, repeat in 24 hours bath 48 hours after final application to cleanse body may repeat treatment after 7-10 days if live mites present.

CYANOCOBALAMIN B12: 0.2 mcg/kg for 2 days, follow by 1000 mcg/day for 2-7 days follow by 100 mcg/day for 2-7 days then 100 mcg/week for 1 month; Maintenance 100 mcg i.m./s.c. monthly.

CYCLOPENTOLATE: 1 drop, repeat in 5-10 minutes if needed.

CYCLOPHOSPHAMIDE: Juvenile idiopathic arthritis10 mg/kg i.v. every 2 weeks; Nephrotic syndrome 2-3 mg/kg/day for up to 12 weeks when corticosteroids unsuccessful; Systemic lupus erythematosus 500-750 mg/m² i.v. monthly not to exceed 1 g/m².

CYPROHEPTADINE: 0.25-0.5 mg/kg/day.

CYTARABINE: Conventional as in adults; Liposomal not recommended.

DABIGATRAN: Less than 3 months, safety and efficacy not established. 3 months to 18 years, 30 mg-260 mg orally twice daily according to age and actual weight.

Dacarbazine: BSA-Based Dosing: 250 mg/m² IV every 3-4 weeks. Body Weight-Based Dosing: Approximately 2.5 mg/kg IV every 3-4 weeks.

Dacomitinib: Safety and efficacy have not been established in children.

DANAZOL: Safety and efficacy not established.

Dapagliflozin: Safety and efficacy not established.

DAPOXETINE: Not recommended for pediatrics.

DAPTOMYCIN: 7-12 mg/kg once daily.

DARATUMUMAB: Safety and efficacy not established.

DARBEPOETIN ALFA: 0.45 mcg/kg s.c. or i.v. every week.

DECARBAZINE: Hodgkin lymphoma with other antineoplastics, 150 mg/m² i.v. every day for 5 days, repeat every 4 weeks or 375mg/m² i.v. on day 1; repeat every 15 days. Neuroblastoma combination Therapy (Off-label) 800-900 mg/m² i.v. once on day 1; may repeat every 3-4weeks.

DECITABINE: Myelodysplastic syndromes, 3day regimen 15 mg/m² i.v. infusion over 3 hours repeated every 8 hours for 3 days; repeat every 6 weeks; repeat cycles every 6 weeks for a minimum of 4 cycles. 5-day regimen 20 mg/m² i.v. infusion over 1 hour every day for 5 days, repeat cycle every 4 weeks for a minimum of 4 cycles.

DEFERASIROX: 20-40 mg/kg once daily.

DEFERIPRONE: 25-100 mg/kg/day in divided doses.

DEFEROXAMINE: 15-50 mg/kg/day i.v./i.m./s.c.

DEFLAZACORT: 0.9 mg/kg/day.

DENOSUMAB: Giant cell tumor, less than13years or less than 45kg safety and efficacy not established. 13-17 years (more than 45kg) 120 mg s.c. every 4 weeks; give 2 additional 120 mg doses during the first month of therapy on days 8 and 15.

DESFLURANE: Administered as inhalation with dosage adjusted to effect.

DESLORATADINE: 1-5 mg daily.

DESMOPRESSIN: 2-4 mcg intranasally or 0.05-0.4 mg orally.

DESOGESTREL: Not recommended in pediatrics.

DEXAMETHASONE: 0.05-0.3 mg/kg/day in divided doses.

DEXMEDETOMIDINE: Initial 0.5-1 mcg/kg i.v. maintenance 0.2-0.7 mcg/kg/hour.

DEXPANTHENOL: Apply topically to affected area every day or every 12hour.

DEXTROMETHORPHAN: 0.5-1 mg/kg every 6-8 hours.

DEXTROSE: Less than 6 months, 0.5-0.25g/kg/dose i.v. not to exceed 25 g/dose. Infants more than 6 months and Children 0.5-1 g/kg up to 25 g i.v. not to exceed 25 g/dose.

DIAZEPAM: 0.04-0.3 mg/kg every 4-12 hours.

DICLOFENAC: 1-3 mg/kg/day in divided doses.

DIENOGEST: Not indicated in pediatrics.

Digoxin: Loading 20-30 mcg/kg in divided doses; maintenance 5-10 mcg/kg/day.

DILOXANIDE: 20 mg/kg/day in divided doses.

DILTIAZEM: 1-5 mg/kg/day in divided doses.

DIMETHINEDENE: 0.1 mg/kg i.e. 1-2 drops/kg/day divided into 3 doses.

DINOPROSTONE: Dose and route vary by indication.

DIOSMIN: Not indicated in pediatrics.

DIPHENHYDRAMINE: 1-2 mg/kg every 6-8 hours.

DIPYRIDAMOLE: 2-5 mg/kg/day in divided doses.

DOBUTAMIN: 2.5-15 mcg/kg/minute i.v. infusion.

DOCETAXEL: Safety and efficacy not established.

DOMPERIDONE: 0.2-0.3 mg/kg every 4-8 hours.

DONEPEZIL: Not recommended in pediatrics.

DOPAMINE: 2-20 mcg/kg/ minute i.v. infusion.

DORZOLAMIDE: 1 drop in the affected eye 2-3 times daily.

DOXAZOSIN: 1-4 mg once daily.

DOXORUBICIN: 35-75 mg/m² i.v. every 21days or 20-30 mg/m²/dose every week or 60-90 mg/m² I.v. over 96 hours every 3-4 weeks.

DOXYCYCLIN: 2-5 mg/kg/day in divided doses.

DRIED IVY LEAF: Children 1-5 years 2.5 mL 3 times daily. Children 6-9 years and adolescents more than 10 years 5 mL 3 times daily.

Dulaglutide: More than 10 years with type 2 diabetes mellitus 0.75 mg s.c. once weekly.

DULOXETINE: 30-60 mg once daily.

DUTASTERIDE: Safety and efficacy not established.

DYDROGESTERONE: Not recommended for use in children below age 18 years.

ECONAZOLE: Topically less than 3 months, safety and efficacy not established.

EMICLZUMAB: 3 mg/kg s.c. every week for the first 4 weeks. Maintenance dose 1.5mg/kg s.c. every week or 3mg/kg s.c. every 2 weeks or 6 mg/kg s.c. every 4 weeks.

EMPAGLIFLOZIN: Less than 10 years, safety and efficacy not established. More than 10 years 10 mg orally every morning may increase to 25 mg/day if needed and tolerated.

ENALAPRIL: 0.08-0.6 mg/kg/day in 1-2 divided doses.

ENOXAPARIN: Deep vein thrombosis (Off-label), prophylaxis less than 2 months 0.5 mg/kg s.c. every 12hours. More than 2 months 0.75 mg/kg s.c. every 12hours. Treatment less than 2 months 1.5 mg/kg s.c. every 12hours. More than 2 months 1 mg/kg s.c. every 12hours.

ENTECAVIR: 0.015 mg/kg once daily, maximum 0.5 mg/day.

ENZALUTAMIDE: Safety and efficacy not established.

EPIRUBICIN: Safety and efficacy not established.

EPOETIN ALFA: Less than 1 month, safety and efficacy not established. More than 1 month 50 units/kg i.v./s.c. 3 times weekly.

ERGOCALCIFEROL (VITAMIN D): 1000-5000 IU daily.

ERLOTINIB: Safety and efficacy not established.

ERTUGLIFLOZIN: Safety and efficacy not established.

ERYTHROMYCIN: 30-50 mg/kg/day in divided doses.

ESCITALOPRAM: 10 mg once daily.

ESOMEPRAZOLE: 1-2.5 mg/kg once daily.

ESTRADIOL: Safety and efficacy not established.

ETANERCEPT: 0.4 mg/kg (maximum 25 mg) subcutaneously once weekly.

ETONOGESTREL: Implant delivers approximately 60-70 mcg/day.

ETOPOSIDE: AML Induction (Off-label) less than 3 years 3.3 mg/kg/day i.v. continuous infusion for 4 days. More than 3 years 100 mg/m²/day i.v. continuous infusion for 4 days.

ETORICOXIB: Safety and efficacy not established.

Evening primrose oil: A conservative approach might be 100 mg to 500 mg per day, divided into smaller doses, but this should be individualized.

EVEROLIMUS: Less than 2 years, safety and efficacy not established. More than 2 years 4.5-5 mg/m² orally every day.

EZETIMIBE: 10 mg once daily.

Factor IX: For Prophylaxis: Approximately 25-40 IU/kg every 3-4 days, though this can vary based on the patient's needs and specific product guidelines. For Treatment of Bleeding Episodes: initial dose of 20-50 IU/kg .

FACTOR VIII: Minor hemorrhage 15 IU/kg loading dose. Moderate hemorrhage 25 IU/kg loading dose. Severe hemorrhage 40-50 IU/kg loading dose.

Factor XIII: Typical Dosage: Dose Range: Commonly administered at 20-40 IU/kg every 4 weeks. The exact frequency and dosage may be adjusted based on the patient's response and clinical requirements.

FAMOTIDINE: 0.25-0.5 mg/kg twice daily.

Febuxostat: Safety and efficacy have not been established for children.

FENOFIBRATE: Safety and efficacy not established.

FENTANYL: 0.5-2 mcg/kg i.v.

FEXOFENADINE: 15-30 mg twice daily depending on age.

FILGRASTIM: 5-10 mcg/kg/day subcutaneously.

FINASTERIDE: Not indicated in pediatrics.

Fingolimod: 0.25-0.5 mg once daily based on weight.

FLAVOXATE: Less than 12 years, not recommended and safety and efficacy not established. More than 12 years 100-200 mg orally every 6-8 hours.

FLUCONAZOLE: 3-12 mg/kg daily.

FLUDARABINE: Safety and efficacy not established.

Fluorouracil: Safety and efficacy not established.

FLUOXETINE: 10-20 mg once daily.

FLUPHENAZINE: Safety and efficacy not established.

FLURBIPROFEN: 5-10 mg/kg/day in divided doses.

FLUTICASONE PROPIONATE: Less than 4 years, safety and efficacy not established. 4-11 years 1 spray in each nostril every day for up to 2 months.

FOLIC ACID: 1 mg daily.

FONDAPARINUX SODIUM: Safety and efficacy not established.

FOSFOMYCIN: 40-80 mg/kg once.

FULVESTRANT: Precocious puberty (off-label) 4 mg/kg i.m. every month.

Fusidic Acid: For Oral Administration: Typical Dose: 20-30 mg/kg per day, divided into 2 or 3 doses. Maximum Dose: Generally, not to exceed 2 grams per day in total. For Topical Administration: Apply a thin layer of fusidic acid cream or ointment to the affected area 2-3 times daily. Avoid applying to large areas or broken skin unless directed by a healthcare provider.

FUROSEMIDE: 1-6 mg/kg/day in 1-2 divided doses.

GABAPENTIN: 10-15 mg/kg/day, up to 50 mg/kg/day.

GADOBUTROL: 0.1 mmol/kg (0.1 mL/kg) i.v. bolus, then infuse at rate 1.5-2 mL/second

Gadoteric acid: 0.1 mL/kg body weight, which is equivalent to 0.1 mmol/kg body weight. This dosage provides adequate enhancement for most imaging procedures. The maximum dose should not exceed 0.3 mL/kg body weight, based on the type of MRI examination and clinical judgment.

GALSULFASE: 1 mg/kg i.v. weekly.

GANCICLOVIR: 5 mg/kg i.v. every 12 hours.

GANIRELIX: Safety and efficacy not established.

Gatifloxacin: Typical Dose: 5 to 10 mg/kg per day, administered as a single daily dose or divided into two or three doses. Maximum Dose: The maximum recommended dose is 400 mg per day

GEFITINIB: Safety and efficacy not established.

GEMCITABINE: Safety and efficacy not established.

GEMIFLOXACIN: Safety and efficacy not established.

GENTAMICIN: 2-2.5 mg/kg every 8 hours.

GLIBENCLAMIDE: Safety and efficacy not established.

GLIMEPIRIDE: Safety and efficacy not established.

GLIPIZIDE: Safety and efficacy not established.

Glucagon: Children < 25 kg: Dosage: 0.5 mg (0.5 mL of a 1 mg/mL solution) administered intramuscularly (IM) or subcutaneously (SC). Children ≥ 25 kg: Dosage: 1 mg (1 mL of a 1 mg/mL solution) administered IM or SC.

Glucose: Intravenous Glucose: Dose: 10% dextrose solution is commonly used. For infants, administer 2-4 mL/kg of Dextrose 10% (D10) IV bolus. For older children, the dose can be adjusted based on the severity of hypoglycemia and response. Oral Glucose: Typically, 1-2 grams of glucose per kilogram of body weight per day can be used for dietary supplementation.

GLYCERIN: 2-6 years 1g suppository, more than 6 years 2-2.8 g.

Glyceryl trinitrate: Safety and efficacy have not been established to children.

Golimumab: 80 mg/m^2 IV at weeks 0 and 4, and q8Weeks thereafter.

Goserelin Acetate: vary based on the child's weight and clinical condition.

GRANISETRON: 10 mcg/kg or 40 mcg/kg for chemotherapy-induced nausea and vomiting.

HALOPERIDOL: 0.05-0.15 mg/kg/day in 2-3 divided doses.

HEPARIN: Venous thromboembolic prophylaxis (Off-label) 100-150 units/kg i.v. once. Venous thromboembolic treatment (Off-label) less than 1 year, loading dose of 75 units/kg i.v. then 28 units/kg/hour i.v. as initial maintenance dose. More than 1 year, loading dose of 75 units/kg i.v. then 20 units/kg/hour i.v. as initial maintenance dose. Catheter patency (Off-label) initially give 50-100 units/kg i.v. infusion, then 100 units/kg i.v. infusion every 4 hour as maintenance dose.

Human Chorionic Gonadotropin: Cryptorchidism (Undescended Testicles): 5,000 to 10,000 units administered intramuscularly (IM) 2 to 3 times per week. for 3 to 6 weeks. Delayed Puberty: 1,000 to 2,000 units IM 2 to 3 times per week.

Human Tetanus Immunoglobulin: Infants and Children: 250 units (intramuscularly, IM) administered once.

HYDRALAZINE: 0.75-20 mg/kg/day in divided doses.

HYDROCHLOROTHIAZIDE: 1-2 mg/kg/day.

HYDROCORTISONE 1-5 mg/kg/day i.m./i.v. divided every 12-24 hours.

HYDROQUINONE: Safety and efficacy not established.

HYDROXOCOBALAMIN: Initial 100 mcg i.m. every day for 2 weeks (1-5 mg total dose). Maintenance 30-50 mcg i.m. every month.

Hydroxycarbamide Initial dose: 20 mg/kg orally once a day, Increase 5 mg/kg/day every 8 weeks or if a painful crisis occurs; increase only if blood counts are in an acceptable range. Maximum dose: 35 mg/kg/day.

HYDROXYCHLOROQUINE SULFATE: 5 mg/kg/day.

HYDROXYUREA: 10-35 mg/kg/day.

HYOSCINE: 0.3 mg/kg/dose.

HYPROMELLOSE: Safety and efficacy not established.

IBRUTINIB: Chronic graft versus host disease, 1 to 12 years 240 mg/m^2 orally every day (not to exceed 420 mg/dose). More than 12 years 420 mg orally every day.

IBUPROFEN: 5-10 mg/kg every 6-8 hours.

IDURSULFASE: 0.5 mg/kg i.v. weekly.

IFOSFAMIDE: Safety and efficacy not established.

IMATINIB: 260-340 mg/m^2/day.

IMIGLUCERASE: 60 units/kg every two weeks for Gaucher's disease.

IMIQUIMOD: Not generally used for children under 12 years.

INDAPAMIDE: Safety and efficacy not established.

INDOMETHACIN: 1-2 mg/kg/day divided into 2-3 doses.

INFLIXIMAB: 5-10 mg/kg/dose for various conditions.

INFLUENZA VACCINE: Less than 6 months, Safety and efficacy not established. 6 months to 8 years 1-2 dose(s)/season (Children requiring 2 doses); More than 9 years 1 dose/season.

Interferon: 3 million Units/m^2 IM/SC 3 times/wk for 1 wk; increase to 6 million U/m^2 3 times/wk SC for 16-24 wk; not to exceed 10 million Units/dose 3 times/wk.

IPRATROPIUM: Inhalation 125-250 mcg up to 4 times daily.

IRBESARTAN: 6-12 years start with 75 mg/day.

IRINOTECAN: Not recommended for pediatrics.

ISOFLURANE: Safety and efficacy not established.

ISONIAZID: 10-15 mg/kg/day up to 300 mg/day.

ISOSORBIDE: Safety and efficacy not established.

ISOTRETINOIN: 0.5-1 mg/kg/day divided into two doses.

ITRACONAZOL: 3-5 mg/kg/day.

IVABRADINE: Less than 6 months, safety and efficacy not established. More than 6 months 0.05 mg/kg orally twice daily.

IVERMECTIN: 150-200 mcg/kg as a single dose.

Ivy leaves dry extract: For Children 2 to 5 years old: Typically, 2.5 to 5 mL of syrup, 2 to 3 times daily. For Children 6 to 12 years old: Usually, 5 to 10 mL of syrup, 2 to 3 times daily.

KETAMINE: 1-2 mg/kg i.v. for anesthesia induction.

Ketoprofen: Safety and efficacy have not been established to children.

KETOROLAC: 0.5 mg/kg i.v./i.m. every 6 hours.

KETOTIFEN: 0.025 mg/kg twice daily.

LACOSAMIDE: 5-12 mg/kg/day divided into two doses.

LACTULOSE: 1-3 ml/kg/day.

LAMOTRIGINE: 0.3 mg/kg/day.

Lanreotide: Safety and efficacy have not been established to children.

LANSOPRAZOLE: 1-2 mg/kg/day.

LARONIDASE: 0.58 mg/kg i.v. weekly.

LATANOPROST: 1 drop in affected eye(s) once daily.

LENALIDOMIDE: Safety and efficacy not established.

Lercanidipine: Safety and efficacy have not been established to children.

LETROZOLE: Rarely used in pediatrics; Safety and efficacy not established.

LEVAMISOLE: 2.5 mg/kg twice weekly for 2 days.

LEVETIRACETAM 10-20 mg/kg/day.

LEVOCETIRIZINE: Children 2-6 years 1.25 mg once daily; 6-12 years 2.5 mg once daily.

LEVOFLOXACIN: 8-10 mg/kg/dose twice daily.

LEVOTHYROXINE: Start with 10-15 mcg/kg/day.

LIDOCAINE: Depends on procedure, typically not to exceed 3-5 mg/kg for local anesthesia.

LINAGLIPTIN: Safety and efficacy not established.

LINEZOLID: 10 mg/kg/dose every 8 hours.

LIRAGLUTIDE: Less than 10 years, safety and efficacy not studied. More than 10 years, for type 2 diabetes mellitus

(Victoza only) 0.6 mg s.c. every day. Obesity (Saxenda only) 0.6 mg s.c. every day for 1 week; increase by 0.6 mg/day in weekly intervals until a dose of 3 mg/day achieved.

LISINOPRIL: Starting dose 0.07 mg/kg.

LOPERAMIDE: Age 2-5 years 1 mg three times daily; Age 6-8 years 2 mg twice daily; Age 8-12 years 2 mg three times daily.

LORATIDINE: Age 2-5 years 5 mg once daily; Age 6 years and older 10 mg once daily.

LORAZEPAM: 0.05-0.1 mg/kg/dose.

LOSARTAN: Starting dose is 0.7 mg/kg.

LOTEPREDNOL ETABONATE: Apply 1-2 drops into affected eye(s) four times daily.

Magnesium carbonate: 12 years and older: 10 mL (250 mg/5 mL suspension) orally every 3 to 4 hours as needed, Maximum dose: 40 mL/day. 6 to 12 years: 5 mL (250 mg/5 mL suspension) orally every 3 to 4 hours as needed, Maximum dose: 20 mL/day. Duration of therapy: Up to 2 weeks

MAGNESIUM SULFATE: Acute nephritis, 100 mg/kg i.m. every 4-6 hours on neecd or 20-40 mg/kg i.m. on need. Hypomagnesemia 25-50 mg/kg every 4-6 hours for 3-4 doses on need. Bronchospasm (Off-label) 25-50 mg/kg i.v. over 10-20 minutes.

MANITOL: 0.25-2 g/kg i.v. infusion.

MEBENDAZOLE: 100 mg twice daily for 3 days.

MEBEVERINE: 10-20 mg/kg/day in divided doses.

Medroxyprogesterone acetate: 150 mg once every 3 months (13 weeks) in the gluteal or deltoid muscle Subcutaneous injection. 104 mg once every 3 months (12 to 14 weeks) into the anterior thigh or abdomen

MEFENAMIC ACID: 20-30 mg/kg/day in divided doses.

MELOXICAM: 0.125 mg/kg once daily.

MELPHALAN: Safety and efficacy not established.

MEMANTINE: 3 mg/kg/day in two divided doses.

MENOTROPHIN: Safety and efficacy not established.

MERCAPTOPURINE: 50-75 mg/m^2/day.

MEROPENEM: 20-40 mg/kg/dose every 8 hours.

MESALAZINE: 20-30 mg/kg/day in divided doses.

MESNA: Safety and efficacy not established.

METFORMIN: Initial dose 500 mg once daily, titrate up as necessary.

METHOTREXATE: 10 mg/m² orally/i.m./s.c. every week.

METHYLDOPA: 10-20 mg/kg/day in two divided doses.

METHYLERGOMETRINE: Not typically used in pediatrics.

METHYLPHENIDATE: Starting dose is often 5 mg once or twice daily.

METHYLPREDNISOLONE: 1-2 mg/kg/day in divided doses.

METOCLOPRAMIDE: 0.1-0.2 mg/kg/dose every 4-6 hours.

METOPROLOL: 1-2 mg/kg/day in divided doses.

METRONIDAZOLE: 30 mg/kg/day in divided doses.

MICAFUNGIN: 1-4 mg/kg/day.

MICONAZOLE: Less than 2 years, safety and efficacy not established. More than 2 years, apply topically twice daily for up to 1 month.

MIDAZOLAM: 0.05-0.2 mg/kg i.v.

MIGLUSTAT: Safety and efficacy not established.

MINOCYCLINE: 2-4 mg/kg initially, then 1-2 mg/kg every 12 hours.

MINOXIDIL: Safety and efficacy not established.

MIRABEGRON: Less than 3 years, safety and efficacy not established. Aged more than 3 years 24-32 mg orally every day initially; may increase to maximum of 48-64 mg/day.

MIRTAZAPINE: 7.5-15 mg at bedtime.

MISOPROSTOL: Less than 8 years, safety and efficacy not established. More than 8 years 100 mcg orally every 6 hours.

MITOXANTRON: Safety and efficacy not established.

MOMETASONE: Less than 2 years, safety and efficacy not established. 2 years or older apply to affected area every day.

MONTELUKAST: 4 mg (age 1-5) or 5 mg (age 6-14) once daily.

MORPHINE: 0.05-0.2 mg/kg/dose.

MOXIFLOXACIN: 7.5-10 mg/kg/day.

MYCOPHENOLATE MOFETIL: 600 mg/m^2/dose twice daily.

NALOXONE: 0.1 mg/kg/dose i.v.

NANDROLONE: Not typically used in pediatrics.

NAPROXEN: 5-7 mg/kg/dose every 12 hours.

NEBIVOLOL: Safety and efficacy not established.

NEFOPAM: Not typically used in pediatrics.

NEOSTIGMINE: 0.04 mg/kg/dose.

NEPAFENAC: Less than 10 years, safety and efficacy not established. More than 10 years 1 drop three times daily to affected eye(s) beginning 1 day before cataract surgery and through 2 weeks postoperatively.

NIFEDIPINE: 0.25-0.5 mg/kg/dose every 6-8 hours.

NILOTINIB: 230 mg/m^2 orally twice daily, round to the nearest 50mg dose; not to exceed 400 mg/dose.

NINTEDANIB: 150 mg orally every 12 hours.

NITROFURANTOIN: 5-7 mg/kg/day divided into 2 doses.

NOREPINEPHRINE: 0.05-0.1 mcg/kg/minute i.v. infusion; Maximum 1-2 mcg/kg/minute.

NORETHISTERONE: Not typically used in pediatrics.

NORFLOXACIN: 15 mg/kg/day divided into 2 doses.

NYSTATIN: 100,000 to 400,000 units 4 times a day.

OCRELIZUMAB: Safety and efficacy not established.

OCTREOTIDE: 1-2 mcg/kg/dose every 8-12 hours.

OFLOXACIN: 15 mg/kg/day divided into 2 doses.

OLANZAPINE: 2.5-5 mg once daily.

Olmesartan: Adolescent ≤16 yr/child ≥6 yr weighing 20-35 kg: PO 10 mg/day, may increase to max 20 mg/day after 2 wk.

OLOPATADIN: Less than 2 years, safety and efficacy not established. More t6han 2 years 1-2 drop in affected eye(s) twice daily.

OMEPRAZOLE: 0.7-1.4 mg/kg/day.

ONDANSETRON: 0.1-0.15 mg/kg/dose.

ORLISTAT: Less than 12 years, safety and efficacy not established. More than 12 years 60-120 mg orally every 8 hours with each fat-containing meal

Orphenadrine: Safety and efficacy have not been established in children.

OSELTAMIVIR: 30-75 mg twice daily.

OXALIPLATIN: Safety and efficacy not established.

OXYBUTYNIN: 0.1-0.2 mg/kg/dose 2-3 times a day.

OXYMETAZOLINE: Less than 2 years, safety and efficacy not established. More than 2 years 2-3 drops or sprays per nostril every 12 hours, not to exceed 2 doses per24 hours for up to 3 days.

OXYTOCIN: Not typically used in pediatrics.

OZENOXACINE: Less than 2 months, safety and efficacy not established. More than 2 months apply a thin layer topically to affected area every 12 hours for 5 days.

PACLITAXEL: Safety and efficacy not established.

PALBOCICLIB: Safety and efficacy not established.

PALIPERIDONE: Starting dose often 3 mg/day.

PALIVIZUMAB: 15 mg/kg/dose once a month.

Pancreatin: Children 7–12 yr. PO 4,000 to 12,000 units with each meal and snacks. Children 1–6 yr. PO 4,000 to 8,000 units with each meal and snacks.

PANCURONIUM: 0.05-0.1 mg/kg i.v..

PANTOPRAZOLE: 1-1.2 mg/kg/day.

PAROXETINE: 10-20 mg/day.

PEGFILGRASTIM: Less than 10 kg 0.1 mg/kg s.c. once per chemotherapy cycle. 10 to 20 kg 1.5 mg s.c. once per chemotherapy cycle. 21 to 30 kg 2.5 mg s.c. once per chemotherapy cycle. 31 to 44 kg 4 mg s.c. once per chemotherapy cycle. More than 45 kg 6 mg s.c. once per chemotherapy cycle. Beginning at least 24 hours after completion of chemotherapy.

PEMBROLIZUMAB: 2 mg/kg i.v. every 3 weeks; not to exceed 200 mg/dose.

PEMETREXED: Safety and efficacy not established.

Penicillin: Group A Streptococcal Infections: IM FOR ***Children.*** 25,000–50,000 units/kg as a single dose. Prevention of Rheumatic Fever: IM FOR ***Children.*** 25,000–50,000 units/kg every 3–4 wk. Congenital Syphilis: IM FOR ***Children.***

50,000 units/kg weekly for 3 wk.

PERINDOPRIL: 0.625-2.5 mg once daily.

PERTUZUMAB: Safety and efficacy not established.

PETHIDINE: 1-2 mg/kg/dose i.v. or i.m.

PHENOBARBITAL: 3-5 mg/kg/dose for seizures.

PHENYLEPHRINE: More than 2 years 1-3 drop intranasally every 4 hours on need; not to exceed 3 days.

PHENYTOIN: 15-20 mg/kg i.v. or orally.

Phytomenadione: administer 0.5 to 1 mg of vitamin K1 intramuscularly shortly after birth as a single dose.

Pilocarpine: Safety and efficacy have not been established in children.

PIMECROLIMUS: Less than 2 years, safety and efficacy not established. More than 2 years apply a thin layer to the affected area every 12 hours, limit application to the affected area, and continue as long as symptoms persist.

PIOGLITAZONE: Not recommended for pediatrics.

PIRACETAM: 30-80 mg/kg/day divided into 2-3 doses.

PIROXICAM: 0.3-0.6 mg/kg/day.

PIZOTIFEN: 0.5-1.5 mg at bedtime.

PLERIXAFOR: Safety and efficacy not established.

POTASSIUM CHLORIDE: Depends on the deficit, 2-3 mEq/kg/day in divided doses.

POVIDONE IODINE: Safety and efficacy not established.

PRAMIPEXOLE: 0.125 mg three times daily.

PRASUGREL: Not recommended for pediatrics.

PRAVASTATIN: 10-20 mg/day.

PREDNICARBATE: Less than 12 months, safety & efficacy not established. More than 12 months apply every 12 hours not for use more than 3 weeks.

PREDNISOLONE: 1-2 mg/kg/day in single or divided doses.

PREGABALIN: 2.5 mg/kg/day.

PRIFINIUM BROMIDE: Not typically used in pediatrics.

PROCAINE PENICILLIN: 600,000-1,000,000 units i.m. every day.

PROCHLORPERAZINE: 2.5-5 mg 1-2 times/day.

PROCYCLIDINE: Not typically used in pediatrics.

PROGESTERONE: Not recommended for pediatrics.

Promethazine: Allergic Symptoms 0.1 mg/kg/dose (maximum: 12.5 mg) 3 times a day plus 0.5 mg/kg/dose (maximum: 25 mg) at bedtime. Motion Sickness: PO FOR ***Children.*** 0.5 mg/kg 30–60 min before departure; may repeat in 8–12 hr, then every morning on rising and before evening meal.

PROPIVERINE: Not typically used in pediatrics.

PROPOFOL: Induction 2.5-3.5 mg/kg i.v. maintenance 125-300 mcg/kg/minute i.v.

PROPRANOLOL: 2-4 mg/kg/day divided into 2-3 doses.

PROPYLTHIOURACIL: 5-10 mg/kg/day divided into 3 doses.

PYRIDOXINE: Less than 6 months 0.1 mg/day. 6-12 months 0.3 mg/day. 1-3 years 0.5 mg/day. 3-8 years 0.6 mg/day. 8-13 years 1 mg/day.

QUETIAPINE: Starting dose 25 mg/day.

RABEPRAZOLE: Less than 1 year, safety and efficacy not established. 1-11 years 5 mg orally every day. More than 11 years 10 mg orally every day 30 minutes before a meal, for up to 12 weeks.

Rabies antigen: Rabies Vaccine (Pre-exposure Prophylaxis): The dosage is typically the same as for adults. The standard regimen is three doses administered intramuscularly on days 0, 7, and 21 (or 28) of the vaccination schedules. Rabies Post-Exposure Prophylaxis (PEP): The regimen includes a rabies vaccine series and, if indicated, rabies immune globulin (RIG). The vaccine is administered on days 0, 3, 7, and 14. The dosage of RIG depends on the child's weight and is administered on day 0, with the dosage divided between the site of the bite and intramuscularly at a distant site if there's a large amount of RIG.

RAMIPRIL: 0.05 mg/kg/day.

RAMUCIRUMAB: Safety and efficacy not established.

RANOLAZINE: Safety and efficacy not established.

REPAGLINIDE: Initial 0.5 mg before meals.

Rho(D) Immune Globulin: Safety & efficacy not established; but given at doses proportionate with adult dose in childhood ITP.

Ribavirin: ***60 kg or more:*** 1000–1200 mg/day in 2 divided doses. (51–60 kg): 400 mg twice a day. (37–50 kg): 200 mg in morning, 400 mg in evening. (24–36 kg): 200 mg twice a day.

RIFAMPICIN: 10-20 mg/kg/day.

RIFAXIMIN: 200-400 mg twice daily.

RISEDRONATE: Safety and efficacy not established.

RISPERIDONE: Starting 0.25 mg daily.

RITUXIMAB: Safety and efficacy not established..

RIVAROXABAN: Birth to Less than 18 Years, 2.6 to 2.9 kg 0.8 mg orally 3 times a day. 3 to 3.9 kg 0.9 mg orally 3 times a day. 4 to 4.9 kg 1.4 mg orally 3 times a day. 5 to 6.9 kg 1.6 mg orally 3 times a day. 7 to 7.9 kg 1.8 mg orally 3 times a day. 8 to 8.9 kg 2.4 mg orally 3 times a day. 9 to 9.9 kg 2.8 mg orally 3 times a day. 10 to 11.9 kg 3 mg orally 3 times a day. 12 to 29.9 kg 5 mg orally twice a day. 30 to 49.9 kg 15 mg orally once a day. 50 kg 20 mg orally once a day.

ROCURONIUM: 0.6 mg/kg for intubation.

ROMIPLOSTIM: 1 mcg/kg s.c. every week.

ROSUVASTATIN: 5-10 mg/day, adjust based on LDL levels.

ROXITHROMYCIN: 5-8 mg/kg/day in 2 divided doses.

RUXOLITINIB: Less than 12 years, safety and efficacy not established. More than 12 years, initial dose 5 mg orally twice daily may increase to 10 mg twice daily.

SACCHAROMYCES BOULARDII: 1 capsule/packet orally twice daily.

SALBUTAMOL: 100-200 mcg inhalation as needed.

SAXAGLIPTIN: Safety and efficacy not established.

SEMAGLUTIDE: Safety and efficacy not established under 12 years.

SENNA CALCIUM SALT: 2-6 years 4.3-17.2 mg/day orally not to exceed 17.2 mg/day. 6-12 years 6-50 mg/day orally not to exceed 50 mg/day. More than 12 years 12-100 mg/day orally not to exceed 100 mg/day. Not for use more than 1 week.

SERTACONAZOLE NITRATE: Safety and efficacy not established under 12 years.

SERTRALINE: Starting 25 mg daily.

SEVELAMER: Less than 6 years, safety and efficacy not established.More than 6 years initial dose (not taking phosphate binder), BSA ≥0.75 to <1.2 m^2: 800 mg per meal/snack, titrate up or down by 400 mg-increments. BSA ≥1.2 m^2: 1600 mg per meal/snack, titrate up or down by 800 mg-increments.

SEVOFLUORANE: 0-1 month full term neonate 3.3% in oxygen. 1-6 months 3% in oxygen. 6 months to less than 3 years 2.8% in oxygen or 2 % with 65% N_2O/35% oxygen. 3-12 years 2.5% in oxygen or 2.5 % with 65% N_2O/35% oxygen. 12-25 years 2.6% in oxygen or 1.4% with 65% N_2O/35% oxygen.

SILDENAFIL: Pulmonary arterial hypertension, less than 20 kg 10 mg orally three times daily; 20-45 kg 20 mg orally three times daily; More than 45 kg 20 mg orally three times daily.

SILVER SULFADIAZINE: Burn Wound Infections (2°/3°) less than 2 months Contraindicated. More than 2 months apply every day - every 12 hours to burn.

SIMETHICONE: Less than 2 years 20 mg orally every 6 hours after meals and at bedtime; not to exceed 240 mg/day. 2-12 years 40 mg orally every 6 hours after meals and at bedtime; not to exceed 480 mg/day. More than 12 years 40-360 mg orally every 6 hours after meals and at bedtime; not to exceed 500 mg/day.

SIMVASTATIN: 10-20 mg/day, adjust based on LDL levels.

SIROLIMUS: Initial 1 mg/m^2/day; monitor blood levels.

SITAGLIPTIN: Safety and efficacy not established.

SODIUM BICARBONATE: Cardiac Arrest, infants less than 2 years, initial 1 mEq/kg/minute given over 1-2 minutes i.v. then 1 mEq/kg I.v. every 10 minutes of arrest not to exceed 8 mEq/kg/day. More than 2 years initial 1 mEq/kg/dose i.v. once. Metabolic acidosis. older children 2-5 mEq/kg i.v. infusion over 4-8 hours depending on the severity of acidosis.

SODIUM PICOSULPHATE: 2.5-10 mg/day.

SODIUM VALPROATE: 10-30 mg/kg/day; titrate based on response and serum levels.

SOLIFENACIN: Less than 2 years, safety and efficacy not established. More than 2 years 9 to 15 kg: 1mg orally every day initially not to exceed 4mg/day. More than 15 to 30 kg 3mg orally every day initially not to exceed 5mg/day. More than 30 to 45 kg 3mg orally every day initially not to exceed 6mg/day. More than 45 to 60 kg 4mg orally every day initially not to exceed 8mg/day.

SOMATROPIN: Pediatric growth hormone deficiency 0.024 to 0.034 mg/kg s.c. once a day, 6 to 7 times a week.

SORAFENIB: Safety and efficacy not established.

SPIRAMYCIN: 25-50 mg/kg/day in 2-3 divided doses.

SPIRONOLACTONE: 1-3 mg/kg/day in divided doses.

SUGAMMADEX: Less than 2 years, safety and efficacy not established. More than 2 years a dose of 2-4 mg/kg.

SUMATRIPTAN: 10-20 mg nasal spray or 25-50 mg oral.

SUNITINIB: Safety and efficacy not established.

TACROLIMUS: Initial 0.03-0.05 mg/kg/day.

TADALAFIL: Safety and efficacy not established.

TAFLUPROST: One drop in affected eye(s) once daily.

TAMSULOSIN: Safety and efficacy not established.

TEICOPLANIN: Initial 10 mg/kg, maintenance 6 mg/kg every 12 hours.

TELMISARTAN: 0.3-0.7 mg/kg/day.

TEMOZOLOMIDE: Less than 3 years, safety and efficacy have not been established. More than 3 years 200 mg/m^2 orally once a day.

TENECTEPLASE: Safety and efficacy not established.

TENOFOVIR: Based on age and weight; typically 300 mg/day in older children.

TERBINAFIN: 62.5-250 mg/day.

TERIFLUNOMIDE: Safety and efficacy not established.

TETRACAINE: Safety and efficacy not established.

TETRACYCLINE: 25-50 mg/kg/day in divided doses.

THEOPHYLLINE: 5 mg/kg every 6-8 hours; titrate based on serum levels.

THIAMINE: 10-50 mg/day orally in divided doses.

THYROTROPIN ALFA: Safety and efficacy not established.

TICAGRELOR: Safety and efficacy not established.

TIGECYCLINE: Typically 1.2 mg/kg every 12 hours, maximum 50 mg.

TIMOLOL: Less than 2 years, safety and efficacy not established. More than 2 years 1 drop affected eye(s) every 12 hours.

TINIDAZOLE: Around 50 mg/kg/day.

TIOTROPIUM: Less than 6 years, safety and efficacy not established. More than 6 years 2.5 mcg inhaled orally every day.

TIZANIDINE: Not recommended for pediatrics.

TOBRAMYCIN: 5-7 mg/kg/day divided in multiple doses.

TOCILIZUMAB: Less than 2 years, safety and efficacy not established. More than 2 years 8-12 mg/kg i.v. every 2 weeks or 162 mg s.c. every 2 weeks.

TOFACITINIB: Less than 2 years, safety and efficacy not established. More than 2 years 3.2 -4 mg orally twice daily.

TOLNAFTATE: Topical; applied to affected area twice daily.

TOLPERISONE: Not commonly used in children.

TOLTERODINE: 1-2 mg once daily.

TOPIRAMATE: Start at 25 mg nightly, adjust as needed.

TORASEMIDE: 0.1-0.3 mg/kg/day.

TRAMADOL: 1-2 mg/kg every 6 hours as needed.

TRANEXAMIC ACID: 25 mg/kg 2-3 times daily.

TRETINOIN: Topical; Less than 12 years, safety and efficacy not established.

TRIAMCINOLONE: Topical; applied thin film to affected area twice daily/four times daily.

TRIFLUOPERAZINE: 1-2 mg orally every 12 hours.

TRIMETAZIDINE: Not commonly used in pediatrics.

TRIPTORELIN: Less than 2 years, safety and efficacy not established. More than 2 years 22.5 mg i.m. every 6 months.

TROPICAMIDE: Instill 1 or 2 drops into eye(s) 15 or 20 minutes prior to examination.

TROSPIUM: Safety and efficacy not established.

URSODEOXYCHOLIC ACID: 10-15 mg/kg/day divided doses.

USTEKINUMAB: Less than 6 years, safety and efficacy not established. More than 6 years 0.75 mg/kg s.c. at weeks 0 and 4, then every 12 weeks thereafter.

VALSARTAN: 1-2 mg/kg once daily.

VANCOMYCIN: 10-15 mg/kg every 6-8 hours.

VARDENAFIL: Not typically used in pediatrics.

VELAGLUCERASE ALFA: Less than 4 years, safety and efficacy not established. More than 4 years 60 Unit/kg i.v. every other week.

VENLAFAXINE: Start at 37.5 mg daily, adjust as needed.

VERAPAMIL: 2.5-5 mg/kg/day in divided doses.

VERICONAZOLE: 7 mg/kg every 12 hours.

VINCRISTINE: Less than 1 year 1.5–2 mg/m^2/dose i.v. no more frequently than once weekly. More than 1 year 1.5-2 mg/m^2/dose i.v. no more frequently than once weekly

VINORELBINE: Safety and efficacy not established.

VITAMIN A: Infants 7500-15000 units/day for 10 days. 1-8 years 17,500-35,000 units/day for 10 days. More than 8 years, malabsorption 100,000 units/day i.m. for 3 days than 50,000 units/day for 2 weeks follow with oral therapy.

VITAMIN C (ASCORBIC ACID): Infants or children 100 mg orally three times daily for 1 week then 100 mg orally every day until resolved (typically 1-3 months).

VITAMIN E: 1-12 months 40-50 units/day, 1-3 years 80-150 units/day, 4-8 years 100-200 units/day, more than 8 years 200-400 units/day.

VORICONAZOLE: Loading dose 9 mg/kg every 12 hours, then 8 mg/kg every 12 hours.

VORTIOXETINE: Safety and efficacy not established.

XYLOMETAZOLINE: 2-12 years 2-3 drops per nostril every 8-10 hours not to exceed 3 doses/24 hours.

ZINC OXIDE: Topical, apply to thin film to affected area.

ZINC SULFATE: Common Cold (dose expressed as elemental zinc) 4.5-23.7 mg orally every 2 hours.

ZOLEDRONIC ACID: Safety and efficacy not established.

ZOLPIDEM: Not recommended for pediatrics.

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NOTES

تقديم

من دواعي الاعتزاز ان ينبري ثلة من الأطباء والصيادلة المختصين بتأليف كتاب دليل الادوية والذي يعد مصدراً موثوقاً ومهماً للأدوية المقرة في العراق والمعدّة من قبل اللجنة الوطنية لأنتقاء الادوية في وزارة الصحة

ان وزارة الصحة تدرك أهمية اعتماد الصيغة السليمة في الاستعمال العلمي للأدوية والذي يضمن استخدامها بنحو آمن ووصفها بشكل رشيد بالإضافة الى تهيئة مصدر مستقل للأدوية والمستحضرات الصيدلانية بأسمائها العلمية واشكالها الصيدلانية بالإضافة الى معلومات دوائية مهمة وضرورية أخرى

ان وزارة الصحة قد اخذت على عاتقها الارتقاء بالخدمات والرعاية الصحية والتطوير المهني وبما يحقق نظام صحي كفوء وفعّال في بلدنا العزيز

نأمل ان يتم تحديث هذا الدليل باستمرار ليكون مرجعاً دوائياً مهماً وان يحتوي مستقبلاً على جميع المستحضرات الصيدلانية والأدوية العشبية والمكملات الغذائية المقرة رسمياً للاستعمال في العراقوفي الختام كلنا امل ان يحقق الجهود المبذولة في تأليف هذا الدليل الغرض الذي اعد لأجله.

ومن الله التوفيق

الدكتور
صالح مهدي الحسناوي
وزير الصحة

مقدمة

تتقدم هيئة تأليف دليل الادوية العراقي 2024-2025 بالشكر والتقدير للزملاء الذين سبقونا في تأليف كل من دليل الادوية العراقي Iraq Drug Guide 1990 وهم كل من الاستاذ الدكتور علاء الدين العلوان والمرحوم الاستاذ الدكتور يوسف عبّو ، ودليل الادوية العراقي Iraqi Med-icine Guide 2016 وهم كل من الاستاذ الدكتور علاء عبدالحسين عبدالرسول والاستاذ الدكتور عبدالرسول محمود ويّس والاستاذ الدكتور حيدر كاظم عباس والاستاذ الدكتور محمد داخل الركابي والاستاذ الدكتور احمد هاشم حسين والاستاذ الدكتور ضرغام قاسم شهيد والدكتور سامر نوري هاشم وهم نخبة خيّرة من اساتذة الجامعات العراقية والشكر موصول للزملاء الاعزاء من الاطباء والصيادلة واطباء الاسنان والاختصاصات الاخرى الذي ساهموا بمراجعة وتأليف دليل الادوية العراقي 2021 Iraq Drug Guide.

واستكمالا لجهود الاساتذة الذين سبقونا في هذا المجال نقّدم بين ايديكم نسخة محدثة وشاملة لدليل الادوية العراقي2024-2025 Iraq Drug Guide والذي يهدف لتوفير معلومات دقيقة حول الادوية المسجلة في وزارة الصحة العراقية حتى تأريخ البدء بتأليف هذا الدليل، آملين أن يكون مصدرا مفيدا لجميع الزملاء في المجال الطبي

كما نأمل بأستمرار هذا الجهد العلمي ومواصلة اصدار نسخ محدثة منه في المستقبل خدمة للمسيرة العلمية في عراقنا الحبيب


الدكتور علاء الدين علوان


الدكتور يوسف عبو


الدكتور علاء عبد الحسين


الدكتور عبد الرسول ويس


الدكتور سامر نوري


الدكتور محمد داخل


الدكتور حيدر كاظم


الدكتور احمد هاشم


الدكتور ضرغام قاسم

المؤلفين المساهمين

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ا.م.د. وسام مجيد كطوف العالي

الدكتور وسن محمد موسى

الدكتور وصال رؤوف ياسين

ا.م.د. وفاء محمد علي الشيخ حامد

الدكتور وفاء ناصر حسن الحسيني

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الدكتور ابراهيم سلمان جاسم

الدكتور بتول منير الاطرش

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دليـــل
الادوية العراقي

الطبعة الثالثة ٢٠٢٤ - ٢٠٢٥

رئيس التحرير

البروفيسور الدكتور حيدر بهاء الحسني
عميد كلية الصيدلة جامعة النهرين

فريق التحرير

الدكتور عبد الكريم منير الاطرش
الدكتور زياد كاظم عليوي
الدكتور امير عدنان فياض
الدكتور مصطفى علي الحلي

مركز الدكتور سامر نوري
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المنظومة الوطنية للدواء

للمزيد من المعلومات وتحميل التطبيق

INFO@GUDEA.GOV.IQ

GUDEA.GOV.IQ

615.103
ح 599 الحسني , حيدر بهاء
دليل الادوية العراقي 2024 - 2025 / حيدر بهاء الحسني , عبدالكريم الاطرش ... ط 3
النجف : مركز الدكتور سامر نوري للنشر العلمي 2024
775 , 24سم
ا-الادوية -ادلة - أ-العنوان
رقم الايداع 4119/2024

المكتبة الوطنية

الايداع في دار الكتب و الوثائق ببغداد (4119) لسنة 2024

شكر و عرفان

تتقدم مؤسسة الدكتور سامر نوري للنشر العلمي بخالص الشكر والتقدير لمكاتب الاعلام الدوائي والشركات الدوائية التي ساهمت في دعم وإصدار دليل الأدوية العراقي ٢٠٢٤ - ٢٠٢٥ من خلال إعلاناتها ودعمها المستمر. هذا التعاون يعزز من تطوير المحتوى الطبي والعلمي في العراق

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الاصدار الثالث ٢٠٢٤-٢٠٢٥

IRAQ DRUG GUIDE 24-25

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سعر النسخة الواحدة داخل العراق 45,000 دينار عراقي او ما يعادلها بالعملات الاجنبية خارج العراق