Antibiotica

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Tetracyclines	Quinolone & Fluoroquinolones	Macrolides	Cephalosporins
Doxycycline	Ciprofloxacin	Azithromycin	Ceftriaxone
Tigecycline	Moxifloxacin	Clindamycin	Cefixime
	Gatifloxacin	Erythromycin	Cefotaxime
	Levofloxacin	Clarithromycin	Cefuroxime
	Norfloxacin	Spiramycin	Cefazolin
	Ofloxacin	Daptomycin	Ceftazidime
			Cefpodoxime
			Cefdinir
			Cefadroxil
			Cefepime
			Cephalexin

Carbapenems	Penicillin's	Nitroimidazoles	Antifungals
Imipenem	Penicillin G	Metronidazole	Fluconazole
Meropenem	Penicillin V	Tinidazole	Clotrimazole
Doripenem	Ampicillin		Miconazole
Ertapenem	Amoxicillin		Voriconazole
Aztreonam	Benzathine Penicillin		Natamycin
	Ticarcillin		Nystatin
	Cloxacillin		Amphotericin B
			Flucytosine
			Echinocandin

Glycopeptides	Aminoglycosides	Anti-viral	Anti-Influenza
Teicoplanin	Tobramycin	Acyclovir	Oseltamivir
Vancomycin	Gentamicin	Famciclovir	Zanamivir
	Amikacin	Valacyclovir	
		Ganciclovir	
		Trifluridine	

Others	Combinations
Chloramphenicol	Piperacillin-Tazobactam
Linezolid	Amoxycillin-Clavulanate
Nitrofurantoin	Cotrimoxazole (Trimethoprim/sulfamethoxazole)
Trimethoprim	Imipenem cilastatin
	Cefoperazone-Sulbactam
	Pyrimethamine + sulphadiazine

Tetracyclines:

Doxycycline

Contraindication:

- Hypersensitivity to the tetracyclines class of drugs.

Special Population:

Pregnancy:

- It is contraindicated in pregnancy as it can affect teeth and skeletal development of the fetus.

Lactation:

- Tetracyclines can be excreted via breast milk. Hence, contraindicated in lactating mothers.

Pediatric:

- Use of tetracycline class drugs (especially long term) during tooth development may cause permanent discoloration of the teeth (yellow-grey-brown). Hence, use of doxycycline should be justified.

Use in patients with hepatic impairment:

- Abnormal hepatic function has been reported rarely. Hence, should be administered with caution.

Use in patients with renal impairment:

- Percentage of drug excretion may fall in individuals with severe renal insufficiency (creatinine clearance below 10ml/min).
- However, as per studies no significant difference in the serum half-life was observed in normal and impaired renal function patients (severe condition).

Use in elderly:

- No special precaution required.

Warnings & Precautions:
• Caution is advised as patients may experience serious skin reactions, photosensitivity, benign intracranial hypertension, esophagitis, porphyria, venereal disease, myasthenia gravis, systemic lupus erythematosus and Jarisch-Herxheimer reaction.

Interactions:

• Penicillin	• Isotretinoin or other systemic retinoids
• Warfarin	• Alcohol
• Oral contraceptives	• Barbiturates, carbamazepine or phenytoin
• Ciclosporin	• Drugs containing aluminum, calcium, magnesium, zinc, iron or bismuth.

Adverse Reactions:

System Class	Adverse Reaction
Hematopoietic:	• Hemolytic anemia, neutropenia, thrombocytopenia, eosinophilia
Allergic:	• Hypersensitivity reactions
Metabolism and nutrition	• Anti-anabolic effect, diabetes insipidus, porphyria, decreased appetite
Nervous system	• Increased intracranial pressure, headache, anxiety
Vestibular toxicity	• Ataxia, vertigo, nystagmus, tinnitus
Gastrointestinal	• Nausea/vomiting, dyspepsia
Liver/Biliary	• Fatty infiltration of liver, jaundice, hepatic function abnormal, fatal acute hepatic necrosis.
Skin/Appendages:	• Photosensitivity reaction
Musculoskeletal	• Arthralgia, myalgia, temporary suppression of bone growth
Renal	• Blood urea increased, worsen renal failure,
Teeth	• Brown discoloration, ill-formed teeth,
Superinfection	• Intestinal superinfection by Candida albicans, pseudomembranous and proteus.

Tigecycline

Contraindication:

- Hypersensitivity to tigecycline.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.

Lactation:

- No specific information. Caution advised while prescribing the drug to lactating women.

Pediatric:

- Not recommended in individuals under 18 years of age as there might be an effect on tooth development.

Use in patients with hepatic impairment:

- No dosage adjustment required in patients with mild to moderate hepatic impairment

Use in patients with renal impairment:

- No data available about use in patients with renal impairment.

Use in elderly:

- No dose adjustments suggested.

Warnings & Precautions:

- Patient may experience tooth discoloration, *clostridium difficile* -associated diarrhea, anaphylactic reactions, hepatic adverse effects, pancreatitis, sepsis/septic shock in patients with intestinal perforation, development of drug-resistant bacteria and tetracycline-class adverse effects.

Interactions:

• Warfarin	• Oral Contraceptives

Adverse Reactions:

Body as a Whole	• Injection site- inflammation, pain, edema, phlebitis, allergic reaction, chills, septic shock
Digestive System	• Nausea, vomiting, epigastric distress, diarrhea, anorexia, jaundice, abnormal stools
Metabolic/Nutritional System	• Increased creatinine, hypocalcemia, hypoglycemia
Special Senses	• Taste perversion
Hemic and Lymphatic System	• prolonged activated partial thromboplastin time (aPTT), prolonged prothrombin time (PT), eosinophilia, increased international normalized ratio (INR), thrombocytopenia
Skin and Appendages	• Skin reactions, photosensitivity
Superinfection	• Intestinal superinfection by Candida albicans, pseudomembranous and proteus.

Quinolone & Fluoroquinolones:

Ciprofloxacin

Contraindication:

- Hypersensitivity to any drug of the quinolone class.
- Concomitant administration with tizanidine.

Special Population:

Pregnancy:

- Use in pregnancy did not identify any drug-associated risks (e.g., birth defects, miscarriage, or adverse reactions)

Lactation:

- Ciprofloxacin can be excreted in breast milk as per published literatures.
- Due to the potential risk of serious adverse reactions in infants, breast feeding is not recommended during treatment with ciprofloxacin.

Pediatric:
• Ciprofloxacin not considered as first drug of choice in the pediatric population due to incidence of adverse reactions.

Use in patients with hepatic impairment:
• No significant changes in pharmacokinetics of ciprofloxacin have been observed in patients with stable chronic liver cirrhosis.

Use in patients with renal impairment:
• In patients with severe renal dysfunction, modification of dosage is recommended.

Use in elderly:
• Increased risk for severe tendon disorders. • Caution advised when prescribing ciprofloxacin to geriatric patients especially those on corticosteroids. • May be more susceptible to development of QT interval prolongation.

Warnings & Precautions:
• Caution is advised as patients may experience tendinitis and tendon rupture, peripheral neuropathy, central nervous system effects (e.g., seizures (convulsions) risks increase, intracranial pressure increase, dizziness, and tremors etc.) exacerbation of myasthenia gravis, hypersensitivity reactions, hepatotoxicity and Clostridioides difficile-associated diarrhea.

Interactions:

• Theophylline	• Methotrexate
• Drugs Known to Prolong QT Interval	• Ropinirole
• Oral antidiabetic drugs	• Clozapine
• Phenytoin	• NSAIDs
• Cyclosporine	• Sildenafil
• Anti-coagulant drugs	• Duloxetine
• Caffeine/Xanthine Derivatives	• Antacids, Sucralfate and Iron salts
• Zolpidem	• Probenecid

Adverse Reactions:

Cardiovascular	• QT prolongation, Torsade de Pointes and ventricular arrhythmia
Nervous System	• Dizziness, headache, restlessness, anxiety, insomnia, impairment of concentration and dexterity
Eye Disorders	• Nystagmus
Gastrointestinal	• Nausea, vomiting, bad taste, anorexia
Hemic/Lymphatic	• Pancytopenia, methemoglobinemia
Hepatobiliary	• Hepatic failure
Superinfections	• Candidiasis, Pseudomembranous colitis
Musculoskeletal	• Tendonitis, tendon rupture.
Psychiatric Disorders	• Agitation, confusion, delirium
Skin/Hypersensitivity	• Rash, pruritus, photosensitivity, urticaria, swelling of lips, etc. and serious cutaneous reactions

Moxifloxacin

Contraindication:

- Hypersensitivity to moxifloxacin or any member of the quinolone class of anti-bacterial.

Special Population:

Pregnancy:

- No available human data but pregnant women should be informed about the potential risk to the fetus.

Lactation:

Oral and Parenteral

- May be excreted in human milk. Hence, caution advised while prescribing.

Ophthalmic

- Low levels of drug may be present in maternal milk following topical ocular administration.

Pediatric:

Oral and Parenteral

- Limited safety data available.

Ophthalmic

- Safe and effective in all ages.

Use in patients with hepatic impairment:

Oral and Parenteral

- Caution advised when used in hepatic insufficiency patient due to risk of potential QT prolongation.

Use in patients with renal impairment:

Oral and Parenteral

- No risk observed.

Use in elderly:
Oral and Parenteral • When treated with fluoroquinolones, especially those on corticosteroids there is an increased risk of developing severe tendon disorders. • Increased rate of aortic aneurysm and dissection within two months.
Ophthalmic • No overall differences in safety and effectiveness have been observed

Warnings & Precautions:
Oral and Parenteral • Can cause serious adverse reactions, such as tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects
Ophthalmic • Severe hypersensitivity reactions to quinolones can be observed and may require immediate treatment. • Prolonged use may lead to overgrowth of resistant organisms. In case of superinfection, drug should be discontinued and alternative treatment should be initiated.

Interactions:

• Antacids	• Warfarin
• Sucralfate	• Antidiabetic Agents
• Multivitamins	• Nonsteroidal Anti-Inflammatory Drugs
• Other Products Containing Multivalent Cations	• Drugs that Prolong QT

Adverse Reactions:

Oral and Parenteral

System Organ Class	Adverse Reactions
Blood and Lymphatic System Disorders	• Agranulocytosis, pancytopenia
Cardiac Disorders	• Ventricular tachyarrhythmias
Ear and Labyrinth Disorders	• Hearing impairment, including deafness
Eye Disorders	• Vision loss
Hepatobiliary Disorders	• Hepatitis (Majorly cholestatic), hepatic failure (including fatal), jaundice and acute hepatic necrosis
Immune System Disorders	• Anaphylactic reaction, anaphylactic shock, angioedema
Musculoskeletal and Connective Tissue Disorders	• Tendon rupture
Nervous System Disorders	• Altered coordination, abnormal gait, myasthenia gravis (exacerbation of), muscle weakness, peripheral neuropathy and polyneuropathy
Psychiatric Disorders	• Psychotic reaction
Renal and Urinary Disorders	• Interstitial nephritis
Respiratory, Thoracic and Mediastinal Disorders	• Allergic pneumonitis
Skin and Subcutaneous Tissue Disorders	• Photosensitivity, Stevens-Johnson syndrome, Toxic epidermal necrolysis

Ophthalmic.	
• Conjunctivitis	• Dry eye
• Decreased visual acuity	• Keratitis
• Ocular discomfort	• Ocular hyperemia
• Ocular pain	• Ocular pruritus
• Subconjunctival hemorrhage	• Tearing

Gatifloxacin (ophthalmic)

Contraindication:

- Hypersensitivity to gatifloxacin, to other quinolones, or to any of the components in the medication

Special Population:

Pregnancy:

- There are no available data on the use in pregnant women.

Lactation:

- There are no available data on the use in lactating women.

Pediatric:

In Infants: Safety and effectiveness not established

In one year or elder: Safe and effective for the treatment of bacterial conjunctivitis

Use in patients with hepatic impairment:

- There are no available data on the use in patients with hepatic impairment.

Use in patients with renal impairment:

- There are no available data on the use in patients with renal impairment.

Use in elderly:

- No special precaution is required.

Warnings & Precautions:

• Patient may experience hypersensitivity, growth of resistant organisms with prolonged use, corneal endothelial cell injury

Interactions:

• There are no available data on the interactions.

Adverse Reactions:

Hypersensitivity	• Anaphylactic reactions, dyspnea, urticaria, and itching. • Stevens-Johnson Syndrome (rarely)
Superinfection	• Overgrowth of non-susceptible organisms, including fungi.
Eye	• Corneal Endothelial Cell Injury

Levofloxacin

Contraindication:

Oral & Ophthalmic
• Hypersensitivity to levofloxacin, or other quinolone anti-bacterial.

Special Population:

Pregnancy:
Oral
• Drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes were not identified.
Ophthalmic
• No adequate and well-controlled studies in pregnant women.

Lactation:
Oral
• Levofloxacin can be excreted in human milk following oral administration. However, no information about effects of levofloxacin on the breastfed infant.
Ophthalmic
• Caution advised while administering levofloxacin to a nursing mother.

Pediatric:
Oral
• Safety and effectiveness below the age of 6 months have not been established.
Ophthalmic
• No information available about the use in pediatric population.

Use in patients with hepatic impairment:
• No special precaution required.

Use in patients with renal impairment:
• Requires dosage adjustment in patients to avoid accumulation.

Use in elderly:
Oral
• Increased risk of developing severe tendon disorders including tendon rupture while on treatment with levofloxacin. • This risk is increased in patients receiving concomitant corticosteroid therapy.
Ophthalmic:
• No special precaution required.

Warnings & Precautions:

Oral
• Caution advised as patients may develop disabling and irreversible tendinitis, tendon rupture, peripheral neuropathy, and central nervous system effects. • Risk of tendinitis and tendon rupture can be observed in all age groups.
Ophthalmic
• Hypersensitivity / anaphylactic reactions (severe and occasionally fatal) have been reported. • May result in superinfection with prolonged use • If patients have signs and symptoms of bacterial conjunctivitis, use of contact lenses should be avoided.

Interactions:

• Antacids	• Sucralfate	• Metal Cations
• Antidiabetic Agents	• Warfarin	• Multivitamins
• Non-Steroidal Anti-Inflammatory Drugs	• Theophylline	• Cyclosporine
• Digoxin	• Probenecid and Cimetidine	• Opiates

Adverse Reactions:

Oral

System/Organ Class	Adverse Reaction
Superinfections	• Moniliasis
Psychiatric Disorders	• Insomnia
Nervous System Disorders	• Headache, dizziness
Respiratory, Thoracic and Mediastinal Disorders	• Dyspnea
Gastrointestinal Disorders	• Nausea, diarrhea, constipation, abdominal pain, vomiting and dyspepsia
Skin and Subcutaneous Tissue Disorders	• Rash, pruritus
General Disorders and Administration Site Conditions	• Edema, injection site reaction, chest pain

Ophthalmic
Common: • Transient decreased vision or ocular burning • Ocular pain or discomfort • Fever • Foreign body sensation • Headache • Pharyngitis • Photophobia
Uncommon: • Allergic reactions • Lid edema • Ocular dryness • Ocular itching.

Norfloxacin

Contraindication:

- History of hypersensitivity or tendon disorders with the use of norfloxacin or any member of the quinolone group of antimicrobial agents.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.

Lactation:

- Not known if norfloxacin is excreted in human milk.

Pediatric:

- The safety and effectiveness of norfloxacin in patients below the age of 18 years have not been established.

Use in patients with hepatic impairment:

- No special precaution required.

Use in patients with renal impairment:

- Dose adjustments required as per patient's renal function.

Use in elderly:

- Elderly patients with impaired renal function may require dose adjustments.

Warnings & Precautions:

- Use of norfloxacin increases the risk of tendinitis and tendon rupture in all ages.
- Patient's may also experience exacerbation of myasthenia gravis.

Interactions:

• Clozapine	• Ropinirole
• Theophylline	• Tacrine
• Tizanidine	• Caffeine

Adverse Reactions:

System Class	Adverse Reaction
Skin & Hypersensitivity	• Toxic epidermal necrolysis, Stevens-Johnson syndrome and erythema multiforme, exfoliative dermatitis, photosensitivity/phototoxicity reactions, leukocytoclastic vasculitis and DRESS syndrome
	• Anaphylactoid reactions, angioedema, dyspnea, vasculitis, urticaria, arthritis, arthralgia and myalgia
Nervous system	• Peripheral neuropathy that may be irreversible, Guillain-Barré syndrome, ataxia, paresthesia, hypoesthesia, psychotic reactions and confusion.
Special Senses	• Hearing loss, tinnitus, diplopia, dysgeusia. uveitis
Cardiovascular	• Rare causes prolonged QTc interval and ventricular arrhythmia including torsade's de pointes.
Gastrointestinal	• Pseudomembranous colitis, hepatitis, jaundice including cholestatic jaundice and elevated liver function tests, pancreatitis (rare), stomatitis.
Liver/Biliary:	• Hepatic failure, including fatal cases.
Musculoskeletal	• Tendinitis, tendon rupture; exacerbation of myasthenia gravis, elevated creatine kinase (CK), muscle spasms.
Genitourinary:	• Interstitial nephritis, renal failure.
Hematologic	• Neutropenia; leukopenia; agranulocytosis; hemolytic anemia, thrombocytopenia.
Other Adverse Reactions	• Agranulocytosis, albuminuria, crystalluria, renal casts, dysphagia, elevation of blood glucose, elevation of serum cholesterol, elevation of serum triglycerides, hematuria, hepatic necrosis, nystagmus, postural hypotension, prolongation of prothrombin time.

Ofloxacin

Contraindication:

- History of hypersensitivity associated with the use of ofloxacin or any member of the quinolone group of antimicrobial agents.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.

Lactation:

- The drug can be excreted in human milk. However, no information about effects of levofloxacin on the breastfed infant.

Pediatric:

- Safety and effectiveness in pediatric patients below the age of 18 years have not been established.
- Ofloxacin causes arthropathy (arthrosis) and osteochondrosis in juvenile animals of several species.

Use in patients with hepatic impairment:

- Dose adjustments may be required in patients with hepatic insufficiency/impairment.

Use in patients with renal impairment:

- Dose adjustments may be required in patients with renal insufficiency/impairment.

Use in elderly:

- Elderly patients are at increased risk for developing tendon disorders including tendon rupture when being treated with ofloxacin.
- This risk is increased in patients receiving concomitant corticosteroid therapy.
- Elderly patients may be more sensitive to drug-associated effects on the QT interval.

Warnings & Precautions:

- Caution advised as patients may develop disabling and irreversible tendinitis, tendon rupture, peripheral neuropathy, and central nervous system effects.
- Prescribing ofloxacin prophylactically may not provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
- Adequate hydration of patients is advised to prevent the formation of a highly concentrated urine.

Interactions:

• Antacids, Sucralfate, Metal Cations, Multivitamins	• Drugs Metabolized by Cytochrome P450 Enzymes
• Caffeine	• Probenecid
• Cimetidine	• Theophylline
• Cyclosporine	• Warfarin
• Insulin	• glyburide/glibenclamide

Adverse Reactions:

Cardiovascular System:	• Torsade's de pointes
Endocrine/Metabolic:	• Hyper- or hypoglycemia, especially in diabetic patients on insulin or oral hypoglycemic agents
Gastrointestinal System:	• Hepatic dysfunction including: hepatic necrosis, jaundice (cholestatic or hepatocellular), hepatitis; intestinal perforation; hepatic failure (including fatal cases); GI hemorrhage; hiccough, painful oral mucosa, pyrosis
Superinfection	• Vaginal candidiasis, pseudomembranous colitis (the onset of symptoms may occur during or after antimicrobial treatment)
Hematopoietic:	• Anemia, including hemolytic and aplastic; hemorrhage, pancytopenia, agranulocytosis, leukopenia, reversible bone marrow depression, thrombocytopenia, thrombotic thrombocytopenic purpura, petechiae,

	ecchymosis/bruising.
Musculoskeletal:	• Tendinitis/rupture; weakness; rhabdomyolysis
Nervous System:	• Nightmares; suicidal thoughts or acts, disorientation, psychotic reactions, paranoia; phobia, agitation, restlessness, aggressiveness/hostility, manic reaction, emotional lability; peripheral neuropathy that may be irreversible, ataxia, incoordination; exacerbation of myasthenia gravis and extrapyramidal disorders; dysphasia, lightheadedness.
Skin/Hypersensitivity:	• Anaphylactic (-toid) reactions/shock; purpura, serum sickness, erythema multiforme/Stevens-Johnson Syndrome, erythema nodosum, exfoliative dermatitis, hyperpigmentation, toxic epidermal necrolysis, conjunctivitis, photosensitivity/phototoxicity reaction, vesiculobullous eruption
Special Senses:	• Diplopia, nystagmus, blurred vision, disturbances of: taste, smell, hearing and equilibrium, usually reversible following discontinuation, uveitis.
Renal System:	• Anuria, polyuria, renal calculi, renal failure, interstitial nephritis, hematuria
Hematopoietic:	• Prolongation of prothrombin time
Serum chemistry:	• Acidosis, elevation of: serum triglycerides, serum cholesterol, serum potassium, liver function tests including: GGTP, LDH, bilirubin

Macrolides:

Azithromycin

Contraindication:

- Hypersensitivity to any macrolide or ketolide drug.
- In patients with a history of azithromycin use associated hepatic dysfunction

Special Population:

Pregnancy:

- Use in pregnancy did not identify any drug-associated risks (e.g., birth defects, miscarriage, or adverse reactions)

Lactation:

- Drug can be excreted in breast milk.
- Lactating mothers receiving azithromycin observed non-serious adverse reactions in infants (e.g., diarrhea, vomiting, or rash)

Pediatric:

- No special precaution is required.

Use in patients with hepatic impairment:

- No significant information observed.

Use in patients with renal impairment:

- No significant information observed.

Use in elderly:

- May be more susceptible to development of torsade's de pointes arrhythmias.

Warnings & Precautions:

- Caution is advised as patients may experience hypersensitivity reactions, hepatotoxicity, infantile hypertrophic pyloric stenosis, QT prolongation, Clostridioides difficile-associated diarrhea, and exacerbation of myasthenia gravis.

Interactions:

• Nelfinavir	• Theophylline
• Warfarin	• Terfenadine and cisapride

Adverse Reactions:

System	Adverse Reaction
Allergic:	• Arthralgia, edema, urticaria, pruritus, and serious skin reactions and anaphylaxis / angioedema
Cardiovascular:	• Arrhythmias, including ventricular tachycardia, and hypotension.
Gastrointestinal:	• Anorexia, constipation, dyspepsia, vomiting/diarrhea pseudomembranous colitis, pancreatitis, and oral candidiasis
Renal:	• Interstitial nephritis, acute renal failure
Hematopoietic:	• Thrombocytopenia.
Liver/Biliary:	• Abnormal liver function, hepatitis, cholestatic jaundice and hepatic failure.
Nervous System:	• Convulsions, dizziness/vertigo, headache, somnolence, hyperactivity, nervousness, agitation, and syncope.
Special Senses:	• Hearing disturbances

Clindamycin

Contraindication:

- Hypersensitivity to preparations containing clindamycin or lincomycin.

Special Population:

Pregnancy:

- Use only during the first trimester of pregnancy, if needed.

Lactation:

- May cause adverse effects on the breast-fed infants.

Pediatric:

- Administration to individuals less than 16 years requires appropriate monitoring of organ

functions.

Use in patients with hepatic impairment:

- The elimination half-life is increased slightly in patients with markedly reduced hepatic function.

Use in patients with renal impairment:

- The elimination half-life is increased slightly in patients with markedly reduced renal function.

Use in elderly:

- Caution advised if patient's have a history of gastrointestinal disease or renal disease.

Warnings & Precautions:

- Patient may experience Clostridioides Difficile-Associated Diarrhea (CDAD), anaphylactic shock and anaphylactic reactions.

Interactions:

- Rifampicin

Adverse Reactions:

Superinfections	• *Clostridioides difficile* colitis
Gastrointestinal	• Abdominal pain, esophagitis, nausea, vomiting, and diarrhea
Hypersensitivity Reactions	• Rashes, Vesiculobullous rashes, urticaria, and severe skin reactions • Pruritus, angioedema and DRESS
Liver	• Jaundice and abnormal liver function test
Renal	• Acute kidney injury
Hematopoietic	• Transient neutropenia and eosinophilia, agranulocytosis and thrombocytopenia
Musculoskeletal	• Polyarthritis

Erythromycin

Contraindication:

- Known hypersensitivity to erythromycin.
- Concomitant use of HMG CoA reductase inhibitors, terfenadine, astemizole, cisapride, pimozide, ergotamine, or dihydroergotamine.

Special Population:

Pregnancy:

- Cardiovascular malformations may be observed after exposure to drug during early pregnancy.

Lactation:

- May excrete in human milk. Hence, caution advised when administered to a nursing woman.

Pediatric:

- Use in infants may cause infantile hypertrophic pyloric stenosis (IHPS)

Use in patients with hepatic impairment:

- Caution advised when erythromycin is administered to patients with impaired hepatic function.

Use in patients with renal impairment:

- In patients receiving erythromycin concomitantly with lovastatin, rhabdomyolysis with or without renal impairment can be observed.

Use in elderly:

- Elderly patients with reduced renal or hepatic function have increased risk for erythromycin-induced hearing loss.
- Also, more susceptible to develop of torsade's de pointes.
- Increased effects of oral anticoagulant therapy can be observed while undergoing treatment with erythromycin.

Warnings & Precautions:

- Caution is advised due to risk of hepatotoxicity, QT prolongation, syphilis in pregnancy, *Clostridium difficile* Associated Diarrhea, development of drug-resistant bacteria, exacerbation of symptoms of myasthenia gravis and new onset of symptoms of myasthenic syndrome.
- Prolonged or repeated use can result in superinfection.

Interactions:

• Theophylline	• Ergotamine/dihydroergotamine
• Triazolobenzodiazepines and related benzodiazepines	• HMG-CoA Reductase Inhibitors
• Sildenafil	• Colchicine

Adverse Reactions:

Gastrointestinal	• Nausea, Vomiting, Abdominal Pain, Diarrhea and Anorexia, Pseudomembranous Colitis Symptoms
Cardiovascular	• QT prolongation and ventricular arrhythmias
Allergic reactions	• Urticaria to anaphylaxis • Mild eruptions to erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis

Clarithromycin

Contraindication:

- Hypersensitivity to clarithromycin, erythromycin, or any of the macrolide antibiotics.
- In patients with a history of cholestatic jaundice or hepatic dysfunction associated with prior use of clarithromycin.

Special Population:

Pregnancy:
• Not recommended for use in pregnant women unless no alternative available.

Lactation:
• Clarithromycin can be excreted in human milk.

Pediatric:
• Safety and effectiveness of clarithromycin in pediatric patients under 6 months of age have not been established.

Use in patients with hepatic impairment:
• No dosage adjustment required in patients with hepatic impairment.

Use in patients with renal impairment:
• No dosage adjustment required in patients with hepatic impairment. • However, in the presence of severe renal impairment with or without coexisting hepatic impairment, decreased dosage or prolonged dosing intervals may be appropriate

Use in elderly:
• No special precaution required. However, reports of colchicine toxicity with concomitant use of clarithromycin and colchicine have been reported.

Warnings & Precautions:
• Patients may experience severe acute hypersensitivity reactions- severe acute hypersensitivity reactions, such as anaphylaxis, Stevens-Johnson Syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS), Henoch-Schonlein Purpura, and acute generalized exanthematous pustulosis.
• Prolongation of the QT interval and infrequent cases of arrhythmia have also been reported. Hence, advise to avoid clarithromycin in patients with history to arrhythmias
• Hepatic dysfunction, including increased liver enzymes, and hepatocellular and/or cholestatic hepatitis, with or without jaundice, has been reported with clarithromycin.

• Clostridium difficile Associated Diarrhea has been reported with use of nearly all antibacterial agents, including clarithromycin, and may range in severity from mild diarrhea to fatal colitis
• Exacerbation of Myasthenia Gravis
• Development of Drug Resistant Bacteria

Interactions:

• **Anti arrhythmics:** Disopyramide, Quinidine, Dofetilide, Amiodarone, Sotalol, Procainamide	• **Digoxin**
• **Oral Anticoagulants:** Warfarin	• **Antiepileptics:** Carbamazepine
• **Antifungals**: Itraconazole, Fluconazole	• **Anti-Gout Agents:** Colchicine
• **Antipsychotics**: Pimozide, Quetiapine	• **Antispasmodics:** Tolterodine
• **Antivirals**: Atazanavir, Saquinavir, Ritonavir Etravirine, Maraviroc, Boceprevir , Didanosine, Zidovudine	• **Calcium Channel Blockers:** Verapamil, Amlodipine, Diltiazem, Nifedipine
• **Ergot Alkaloids:** Ergotamine, Dihydroergotamine	• **Gastroprokinetic Agents:** Cisapride
• Lipid-lowering agents: Lomitapide, Lovastatin Simvastatin, Atorvastatin, Pravastatin, Fluvastatin	• **Hypoglycemic Agents:** Nateglinide, Pioglitazone, Repaglinide, Rosiglitazone, Insulin
• Immunosuppressants	• Phosphodiesterase inhibitors
• Proton Pump Inhibitors	• Xanthine Derivatives
• Triazolobenzodiazepines and Other Related Benzodiazepines	• Cytochrome P450 Inducers
• Other Drugs Metabolized by CYP3A	

Adverse Reactions:

Hypersensitivity Reactions
Cardiac: QT Prolongation
Hepatic dysfunction
Superinfection: Clostridium difficile Associated Diarrhea
Nervous system: reversible hearing loss and exacerbation of myasthenia gravis

Spiramycin

Contraindication:

- Hypersensitivity to spiramycin or any of the macrolide antibiotics.

Special Population:

Pregnancy:

- Safety and effectiveness of this product for use during pregnancy has not been established.

Lactation:

- No information available for use in lactating women.

Pediatric:

- No information available for use in pediatric population.

Use in patients with hepatic impairment:

- No information available for use in patients with hepatic impairment.

Use in patients with renal impairment:

- No information available for use in patients with renal impairment.

Use in elderly:

- No information available for use in elderly patients.

Warnings & Precautions:

- Possibility of superinfection.
- Development of Drug Resistant Bacteria

Interactions:

• Carbidopa	• Levodopa

Adverse Reactions:

System Class	Adverse Reaction
Hematopoietic:	• Acute hemolysis
Allergic / Skin	• Rash, urticaria, pruritus, angioedema and anaphylactic shocks (rarely). • Vasculitis, including Henoch-Schonlein purpura (very rare)
Nervous system	• Transient paresthesia
Gastrointestinal	• Nausea, vomiting, diarrhea and very rare cases of pseudomembranous colitis.
Liver/Biliary:	• Liver function tests abnormalities.

Daptomycin

Contraindication:

- Hypersensitivity to daptomycin

Special Population:

Pregnancy:

- Limited data available on use of daptomycin in pregnant women. Data is insufficient to confirm a drug-associated risk for major birth defects and miscarriage.

Lactation:

- Limited data available on use of daptomycin in lactating women. However, the drug can be excreted in human milk.

Pediatric:

- Safety and effectiveness in pediatric patients below the age of 1 year have not been established.
- Also caution advised in pediatric patients with renal impairment and dosage regimen has not been established in these patients.

Use in patients with hepatic impairment:

- No data available on use of daptomycin in patients with hepatic impairment:

Use in patients with renal impairment:
• Dose adjustments may be required in patients receiving hemodialysis or continuous ambulatory peritoneal dialysis (CAPD).

Use in elderly:
• No dose adjustments required for elderly patients.

Warnings & Precautions:
• Patient may experience anaphylaxis/hypersensitivity reactions, myopathy and rhabdomyolysis, eosinophilic pneumonia, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), tubulointerstitial nephritis (TIN) and peripheral neuropathy. • Potential nervous system and/or muscular system effects in pediatric patients younger than 12 months • *Clostridioides difficile*-Associated Diarrhea, Increased International Normalized Ratio (INR)/prolonged prothrombin time, development of drug-resistant bacteria.

Interactions:

• HMG-CoA Reductase Inhibitors
• Drug-Laboratory Test Interactions

Adverse Reactions:

• **Hypersensitivity Reactions**: Eosinophilic Pneumonia, anaphylaxis, DRESS
• **Musculoskeletal:** Myopathy and Rhabdomyolysis
• **Renal system:** Tubulointerstitial Nephritis
• **Nervous system:** Peripheral Neuropathy

Cephalosporins:

Ceftriaxone

Contraindication:

• Hypersensitivity to ceftriaxone, any of its excipients or to any other cephalosporin • Previous hypersensitivity reactions to penicillin and other beta lactam antibacterial agents • Intravenous administration of ceftriaxone solutions containing lidocaine

Special Population:

Pregnancy:
• No adequate and well-controlled studies in pregnant women hence should be used during pregnancy only if clearly needed.

Lactation:
• Low concentrations of the drug can be excreted in human milk. Caution should be exercised when administered to a nursing woman.

Pediatric:
• Use in hyperbilirubinemia neonates may lead to bilirubin encephalopathy.

Use in patients with hepatic impairment:
• In patients with hepatic dysfunction caution should be exercised and the dosage should not exceed 2 g daily.

Use in patients with renal impairment:
• In patients with significant renal disease, caution should be exercised and the dosage should not exceed 2 g daily.

Use in elderly:
• Dosage adjustments are not necessary in elderly patients.

Warnings & Precautions:
• Caution is advised as patients may experience hypersensitivity and neurological reactions, *clostridium-difficile* associated diarrhea (CDAD), hemolytic anemia, development of drug-resistant bacteria, gallbladder pseudolithiasis, urolithiasis and pancreatitis.

Interactions:

- Calcium-Containing Products- Ringer's solution, Hartmann's solution

Adverse Reactions:

Local Reactions and Administration Site Conditions	• Pain, Induration and Tenderness, Phlebitis After I.V Administration, Tightness • Injection Site Pain
Hypersensitivity	• Rash, Pruritus, Fever or Chills.
Infections And Infestations	• Superinfections
Hematologic Disorders	• Eosinophilia, Thrombocytosis, Leukopenia, Anemia, Hemolytic Anemia, Neutropenia, Lymphopenia, Thrombocytopenia and Prolongation of The Prothrombin Time, Coagulopathy
Gastrointestinal	• Diarrhea
Hepatic	• Elevations Of Aspartate Aminotransferase (AST) Or Alanine Aminotransferase (ALT)
Renal	• Elevations Of The BUN, Blood Creatinine Increased
Nervous System	• Headache, Dizziness

Cefixime

Contraindication:

- Hypersensitivity to cefixime or other cephalosporins.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women

Lactation:

- No specific data available about use in lactating women.

Pediatric:

- Safety and effectiveness have not been established in pediatric patient’s aged less than 6 months.

Use in patients with hepatic impairment:
• No specific data available about use in patients with hepatic impairment.

Use in patients with renal impairment:
• Dose adjustments required in patients undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD).

Use in elderly:
• No dosage adjustment required in the elderly patients.

Warnings & Precautions:

• Caution advised as patients can experience hypersensitivity reactions, Clostridium Difficile-Associated Diarrhea (CDAD), coagulation effects, development of drug-resistant bacteria

Interactions:

• Carbamazepine
• Warfarin and Anticoagulants

Adverse Reactions:

Infections	• Superinfections
Hypersensitivity Reactions	• Anaphylactic reactions, skin rashes, urticaria, pruritus. erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions
Gastrointestinal	• Diarrhea
Hepatic	• Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, jaundice, hyperbilirubinemia.
Renal	• Transient elevations in BUN or creatinine, acute renal failure.
Nervous System	• Headaches, dizziness, seizures.
Hemic and Lymphatic System	• Transient thrombocytopenia, leukopenia, neutropenia, prolongation in prothrombin time, elevated LDH, pancytopenia

Cefotaxime

Contraindication:

- Hypersensitivity to cefotaxime sodium, or the cephalosporin group of antibiotics.

Special Population:

Pregnancy:

- There are no well-controlled studies in pregnant women. Should be used during pregnancy only if clearly needed.

Lactation:

- In low concentrations the drug can be excreted in human milk. Hence, when administered to a nursing woman caution is advised.

Pediatric:

- May cause local irritation to tissues with perivascular extravasation. To minimize the risk, infusion sites should be monitored and changed.

Use in patients with hepatic impairment:

- No specific data available about use in patients with hepatic impairment.

Use in patients with renal impairment:

- The risk of toxic reactions may be greater in patients with renal impairment.

Use in elderly:

- No differences in safety or effectiveness were observed between elderly and younger patients. But greater sensitivity in some elderly patients cannot be ruled out.

Warnings & Precautions:

- Patient may experience type I hypersensitivity reactions, *clostridium difficile* associated diarrhea (CDAD), development of drug-resistant bacteria. Caution advised while prescribing for patients with a history of gastrointestinal disease (especially colitis).

Interactions:

• Aminoglycosides
• NSAIDs
• Furosemide
• Probenecid

Adverse Reactions:

Cardiovascular System	• Arrhythmias after rapid bolus administration via central venous catheter.
Nervous System	• Encephalopathy in patients with renal impairment. • Dizziness
Hypersensitivity	• Anaphylaxis, urticaria, Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, acute generalized exanthematous pustulosis (AGEP).
General disorders and administration site conditions	• Phlebitis/thrombophlebitis.
Hematologic System	• Hemolytic anemia, agranulocytosis, thrombocytopenia, pancytopenia, bone marrow failure.
Kidney	• Interstitial nephritis, transient elevations of creatinine, acute renal failure.
Liver	• Hepatitis, jaundice, cholestasis and bilirubin.

Cefuroxime

Contraindication:

• Hypersensitivity to the cephalosporin group of antibiotics.

Special Population:

Pregnancy:
• No adequate and well-controlled studies in pregnant women.

Lactation:
• Cefuroxime can be excreted in human milk. Hence, caution advised when administered to a nursing woman.

Pediatric:
• Safety and effectiveness in pediatric patients below 3 months of age have not been established.

Use in patients with hepatic impairment:
• May be associated with a fall in prothrombin activity in patients with hepatic impairment.

Use in patients with renal impairment:
• Rarely alters kidney function, hence evaluation of renal function during therapy is recommended. Especially in seriously ill patients receiving the maximum doses.

Use in elderly:
• No overall differences in safety or effectiveness were observed between elderly and younger patients.

Warnings & Precautions:

- *Clostridioides difficile* associated diarrhea (CDAD) has been reported with use of cephalosporin group of antibiotics.
- Cephalosporins should be used with caution in patients receiving concurrent treatment with diuretics as these regimens may affect the renal function.
- Use of cefuroxime prophylactically increases the risk of the development of drug-resistant bacteria.

Interactions:

• False-negative result may occur in the ferricyanide test	• False-positive reaction for glucose in the urine may occur with copper reduction tests
• Diuretics	

Adverse Reactions:

Local Reactions	• Thrombophlebitis
Gastrointestinal	• Diarrhea, nausea, pseudomembranous colitis
Hypersensitivity Reactions	• Rash, Pruritus, urticaria, angioedema and positive Coombs' test
Blood	• Decrease in hemoglobin and hematocrit
Hepatic	• Transient rise in SGOT and SGPT, alkaline phosphatase, LDH, and bilirubin levels
Kidney	• Elevations in serum creatinine and/or blood urea nitrogen and a decreased creatinine clearance
Nervous System Disorders	• Seizure

Cefazolin

Contraindication:

- Hypersensitivity to the cephalosporin group of antibiotics.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.

Lactation:

- Cefazolin can be present in low concentrations in the milk of nursing mothers. Hence, caution advised when cefazolin is administered to a nursing woman

Pediatric:

- Safety and effectiveness for use in pre-matures, infants and neonates have not been established.

Use in patients with hepatic impairment:

- No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:

- No data available about use in patients with renal impairment.

Use in elderly:
• No data available about use in elderly patients.

Warnings & Precautions:
• Prolonged use of cefazolin may result in superinfections. • Increases the risk of the development of drug-resistant bacteria. • Cefazolin, as with all cephalosporins, should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Interactions:

• Probenecid
• Drug/laboratory test interactions

Adverse Reactions:

Gastrointestinal	• Diarrhea, oral candidiasis, vomiting, nausea, stomach cramps, anorexia and pseudomembranous colitis
Allergic	• Anaphylaxis, eosinophilia, itching, drug fever, skin rash, Stevens-Johnson syndrome.
Hematologic	• Neutropenia, leukopenia, thrombocytopenia, thrombocythemia.
Hepatic and Renal	• Transient rise in SGOT, SGPT, BUN and alkaline phosphatase levels have been observed without clinical evidence of renal or hepatic impairment.
Local Reactions	• Rare instances of phlebitis at the site of injection. Pain at the site of injection after intramuscular administration

Ceftazidime

Contraindication:

• Hypersensitivity to ceftazidime or the cephalosporin group of antibacterial drugs.

Special Population:

Pregnancy:
• Drug should be used during pregnancy only if clearly needed.

Lactation:
• Ceftazidime can be excreted in human milk in low concentrations. Hence, caution advised when ceftazidime is administered to a nursing woman.

Pediatric:
• Safety and effectiveness for use in pediatric population have not been established.

Use in patients with hepatic impairment:
• No adjustment in dosage is required for patients with hepatic dysfunction.

Use in patients with renal impairment:
• Dosage adjustment is advised in patients with impaired renal function.

Use in elderly:
• Elderly patients are more likely to have decreased renal function. Hence, care should be taken in dose selection, and it may be useful to monitor renal function

Warnings & Precautions:

- Prolonged use of ceftazidime may result in superinfections.
- Prescribing ceftazidime prophylactically may increase the risk of the development of drug-resistant bacteria.

Interactions:

• Aminoglycoside	• Potent diuretics such as furosemide
• Drug-Laboratory Test Interactions	

Adverse Reactions:

Local Effects	• Phlebitis and inflammation at the site of injection
Hematological	• Neutropenia, thrombocytopenia
Hypersensitivity Reactions	• Pruritus, rash, and fever
Gastrointestinal Symptoms	• Diarrhea, nausea, vomiting, abdominal pain
Hepatic	• Increase in plasma transaminases
Renal	• Increase in blood urea
Nervous System Reactions	• Headache, dizziness, and paresthesia, encephalopathy, coma, asterixis, neuromuscular excitability, and myoclonia

Cefpodoxime

Contraindication:

- Hypersensitivity to cefpodoxime or to the cephalosporin group of antibiotics.

Special Population:

Pregnancy:

- No adequate and well-controlled studies of cefpodoxime use in pregnant women.

Lactation:

- Cefpodoxime is excreted in human milk. Hence, possibility of potential serious reactions in nursing infants.

Pediatric:

- Safety and efficacy in infants less than 2 months of age have not been established.

Use in patients with hepatic impairment:

- No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:
• Total daily dose of cefpodoxime should be reduced because high and prolonged serum antibiotic concentrations can occur in patients with renal impairment following usual doses.

Use in elderly:
• No overall differences in effectiveness or safety were observed. • Dose adjustment not necessary.

Warnings & Precautions:

- Caution advised because in penicillin sensitive patients, cross hypersensitivity among beta-lactam antibiotics has been reported and may occur in up to 10% of patients with a history of penicillin allergy.
- *Clostridium difficile* associated diarrhea (CDAD) can be observed.
- Development of drug-resistant bacteria

Interactions:

• Antacids or H2 blockers	• Probenecid
• Nephrotoxic drugs:	• Occasionally induce a positive direct Coombs' test.

Adverse Reactions:

Hypersensitivity / Skin	• Rash, urticaria, angioedema, anaphylaxis
Gastrointestinal	• Diarrhea due to gut flora alteration • Pseudomembranous colitis
Hepatic & Renal	• Acute liver injury • Nephrotoxicity

Cefdinir

Contraindication:

- Hypersensitivity to the cephalosporin class of antibiotics.

Special Population:

Pregnancy:
• No adequate and well-controlled studies in pregnant women.

Lactation:
• Cefdinir was not detected in human breast milk.

Pediatric:
• Safety and efficacy in neonates and infants less than 6 months of age have not been established.

Use in patients with hepatic impairment:
• No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:
• Total daily dose should be reduced because high and prolonged serum antibiotic concentrations can occur in patients with renal impairment following usual doses.

Use in elderly:
• Well-tolerated in elderly group. Dose adjustment in elderly patients is not required unless renal function is markedly compromised.

Warnings & Precautions:

- *Clostridium difficile* associated diarrhea (CDAD) has been reported.
- Risk of the development of drug resistant bacteria.
- Caution advised when prescribing to individuals with a history of colitis.

Interactions:

• Antacids	• Probenecid
• Iron Supplements and Foods Fortified with Iron	• False-positive reaction for ketones in the urine may occur with tests using nitroprusside

Adverse Reactions:

Superinfections	• *Clostridium difficile* associated diarrhea
Gastrointestinal	• Diarrhea, nausea, abdominal pain
Hypersensitivity	• Rash, urticaria, angioedema, anaphylaxis

Cefadroxil

Contraindication:

- Hypersensitivity to the cephalosporin group of antibiotics.

Special Population:

Pregnancy:

- No adequate and well controlled studies in pregnant women.

Lactation:

- Caution should be exercised when cefadroxil is administered to a nursing mother.

Pediatric:

- Safety and efficacy in neonates and infants less than 6 months of age have not been established.

Use in patients with hepatic impairment:

- No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:

- Dosage should be adjusted according to creatinine clearance rates to prevent drug accumulation.

Use in elderly:

- No overall differences in safety were observed. As elderly patients are more likely to have decreased renal function caution advised while prescribing

Warnings & Precautions:
• *Clostridium difficile* associated diarrhea (CDAD) has been reported • Risk of the development of drug-resistant bacteria. • Caution in individuals with history of gastrointestinal disease particularly colitis.

Interactions:

• Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics.

Adverse Reactions:

Gastrointestinal	• Pseudomembranous colitis symptoms, diarrhea, dyspepsia, nausea and vomiting
Hypersensitivity	• Rash, urticaria, angioedema, and pruritus, anaphylaxis
Liver	• Hepatic dysfunctions - cholestasis and elevations in serum transaminase
Others	• Agranulocytosis, thrombocytopenia, idiosyncratic hepatic failure, erythema multiforme, Stevens-Johnson syndrome, serum sickness, and arthralgia

Cefepime

Contraindication:

• Hypersensitivity reactions to cefepime or the cephalosporin class of antibacterial, penicillins or other beta-lactam antibacterial drugs.

Special Population:

Pregnancy:
• No data available about cefepime exposure during pregnancy.

Lactation:
• No data available about cefepime exposure during lactation. Caution advised while prescribing to lactating women.

Pediatric:
• The safety and effectiveness of cefepime have been established in the age groups 2 months up to 16 years. However, data not available for pediatric patients below the age of 2 months.

Use in patients with hepatic impairment:
• Fall in prothrombin activity in patients with hepatic impairment can be observed.

Use in patients with renal impairment:
• Dose adjustments requirement when used in patients with renal impairment.

Use in elderly:
• No overall differences in safety were observed. • Serious adverse events have been reported elderly patients with renal impairment given unadjusted doses of cefepime.

Warnings & Precautions:

• Caution is advised as patients may experience neurotoxicity, *Clostridioides difficile* Associated Diarrhea and development of drug-resistant bacteria

Interactions:

• Drug/Laboratory Test Interactions-false-positive reaction for glucose in the urine with certain methods	
• Aminoglycosides	• Diuretics

Adverse Reactions:

Allergic / Skin	• Hypersensitivity reactions
Nervous System	• Neurotoxicity
Gastrointestinal	• *Clostridioides difficile*-associated diarrhea (CDAD)

Cephalexin

Contraindication:

- Hypersensitivity to cephalexin or other members of the cephalosporin class of antibacterial drugs.

Special Population:

Pregnancy:

- Use in pregnant women have not established drug-associated risks of major birth defects, miscarriage, or adverse maternal or fetal outcomes

Lactation:

- No data available about cephalexin exposure during lactation. Caution advised while prescribing to lactating women.

Pediatric:

- The safety and effectiveness of cefepime have been established in the age groups 2 months up to 16 years.

Use in patients with hepatic impairment:

- Cephalosporins may be associated with prolonged prothrombin time.

Use in patients with renal impairment:

- Cephalexin should be administered with careful monitoring in the presence of renal impairment.

Use in elderly:

- No overall differences in safety or effectiveness were observed.

Warnings & Precautions:

- Caution is advised as patient may experience Clostridium Difficile-Associated Diarrhea, triggering seizures, particularly in patients with renal impairment, prolonged prothrombin time, development of drug-resistant bacteria.

Interactions:

• Metformin	• Probenecid
• Interaction with Laboratory or Diagnostic Testing	

Adverse Reactions:

Hypersensitivity / Skin	• Rash, urticaria, angioedema, anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis
Gastrointestinal	• *Clostridium difficile* -associated diarrhea
Nervous System	• Triggering seizures.
Others	• Prolonged prothrombin time.
	• Aplastic anemia, renal dysfunction, and toxic nephropathy.

Carbapenems:

Imipenem

Contraindication:

• Hypersensitivity to imipenem or other members of the carbapenem class.

Special Population:

Pregnancy:
• Use in pregnant women have risk of drug-associated major birth defects, miscarriage, or adverse maternal or fetal outcomes

Lactation:
• No sufficient data available about the presence of imipenem in human milk. Hence, caution advised while prescribing to lactating women.

Pediatric:
• Imipenem not recommended in pediatric patients with history of CNS infections and renal impairment.

Use in patients with hepatic impairment:
• No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:
• Imipenem should be administered with careful monitoring and dose adjustments advised in patients with renal impairment.

Use in elderly:
• No overall differences in safety or effectiveness were observed.

Warnings & Precautions:
• Caution is advised as patient may experience Clostridium Difficile-Associated Diarrhea, seizures and increased seizure potential due to interaction with valproic acid and may develop of drug-resistant bacteria.

Interactions:

• Ganciclovir	• Probenecid
• Valproic Acid	

Adverse Reactions:

Hypersensitivity / Skin	• Rash, urticaria, angioedema, anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis
Gastrointestinal	• *Clostridium difficile* -associated diarrhea
Nervous System	• Seizures.
Others	• Prolonged prothrombin time.
	• Aplastic anemia, renal dysfunction, and toxic nephropathy.

Meropenem

Contraindication:

- Hypersensitivity to meropenem or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to beta (β)-lactams.

Special Population:

Pregnancy:

- No sufficient human data to confirm drug-associated risk of major birth defects or miscarriages with meropenem in pregnant women.

Lactation:

- No information is available on the effects of meropenem on the breast-fed child or on milk production.

Pediatric:

- The safety and effectiveness have been established for pediatric patients 3 months of age and older.

Use in patients with hepatic impairment:

- No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:

- Dosage adjustment is necessary in patients with creatinine clearance 50 mL/min or less

Use in elderly:

- No overall differences in safety or effectiveness were observed between these subjects and younger subjects; spontaneous reports and other reported clinical experience have not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Warnings & Precautions:
• Patients may experience hypersensitivity reactions, severe cutaneous adverse reactions, seizure potential, risk of breakthrough seizures due to drug interaction with valproic acid, Clostridium difficile-associated Diarrhea, development of drug-resistant bacteria, overgrowth of non-susceptible organisms, thrombocytopenia, potential for neuromotor impairment.

Interactions:

• Probenecid
• Valproic Acid

Adverse Reactions:

• **Hypersensitivity / Skin reactions**	• Anaphylactic reactions, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (EM) and acute generalized exanthematous pustulosis (AGEP)
• **Nervous System**	• Seizure (commonly in patients with CNS disorders and/or compromised renal function and motor impairment.
• **Haemopoietic**	• Thrombocytopenia

Doripenem

Contraindication:

• Hypersensitivity to Doripenem or to any other carbapenem antibacterial agent

Special Population:

Pregnancy:
• Limited clinical data available on exposure during pregnancy.

Lactation:
• It is unknown if Doripenem is excreted in human breast milk.

Pediatric:
• The safety and efficacy of Doripenem in children aged less than 18 years have not yet been established.

Use in patients with hepatic impairment:
• No dose adjustment is necessary.

Use in patients with renal impairment:
• No dose adjustment is necessary in patients with mild renal impairment.

Use in elderly:
• No dose adjustment is necessary in elderly patients, except in cases of moderate to severe renal impairment.

Warnings & Precautions:
• Patient may experience hypersensitivity reactions, seizures, pseudomembranous colitis, overgrowth of non-susceptible bacteria, drug interaction with valproic acid, pneumonitis with inhalational use, continuous renal replacement therapy.

Interactions:

• Valproic Acid
• Probenecid

Adverse Reactions:

Superinfections	• Oral candidiasis, vulvomycotic infection
Blood and lymphatic system disorders	• Thrombocytopenia, neutropenia
Hypersensitivity reactions	• Pruritus, rash, anaphylaxis, Toxic epidermal necrolysis, Stevens-Johnson syndrome
Nervous system disorders	• Headache, seizures
Gastrointestinal disorders	• Nausea, diarrhea, C. difficile colitis
Hepatobiliary disorders	• Hepatic enzyme increased

Ertapenem

Contraindication:

- Hypersensitivity to ertapenem or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to beta-lactams.

Special Population:

Pregnancy:

- Limited clinical data available to confirm any drug-associated risks for major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation:

- No data available on the effects ertapenem on the breastfed infant or the effects on milk production.

Pediatric:

- Safety and effectiveness not established in infants under 3 months of age.
- Ertapenem not recommended in the treatment of meningitis in the pediatric population due to lack of sufficient CSF penetration.

Use in patients with hepatic impairment:

- The pharmacokinetics of ertapenem in patients with hepatic impairment have not been established.
- The incidence of adverse experiences in patients with hepatic impairment was similar between the ertapenem group and the comparator groups.

Use in patients with renal impairment:

- Dosage adjustment is necessary in patients with creatinine clearance 30 mL/min or less

Use in elderly:

- No overall differences in safety or effectiveness were observed except in cases of moderate to severe renal impairment.

Warnings & Precautions:
Patient may experience hypersensitivity reactions, seizure, interaction with valproic acid, *Clostridioides Difficile*-Associated Diarrhea (CDAD), caution with intramuscular administration, development of drug-resistant bacteria.

Interactions:

- Probenecid
- Valproic Acid

Adverse Reactions:

Hypersensitivity / Skin reactions	• Anaphylactic reactions, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (EM) and acute generalized exanthematous pustulosis (AGEP)
Nervous System	• Seizure (commonly in patients with CNS disorders and/or compromised renal function and motor impairment.
Haemopoietic	• Thrombocytopenia

Aztreonam

Contraindication:

- Hypersensitivity to aztreonam or any other component in the formulation.

Special Population:

Pregnancy:
• No adequate and well-controlled studies of aztreonam on human pregnancy outcomes are available. However, in pregnant women, aztreonam can cross the placenta and enter the fetal circulation.

Lactation:
• Aztreonam can be excreted in human milk in minor concentrations. Temporary discontinuation of nursing and use of formula feedings advised.

Pediatric:

- Sufficient data are not available for pediatric patients under 9 months of age

Use in patients with hepatic impairment:

- In patients with impaired hepatic or renal function, appropriate monitoring is recommended during therapy.

Use in patients with renal impairment:

- The risk of toxic reactions may be greater in patients with impaired renal function.

Use in elderly:

- No differences in responses amongst the elderly patients.

Warnings & Precautions:

- *Clostridium difficile*-associated diarrhea (CDAD) has been reported.
- Prescribing aztreonam prophylactically increases the risk of the development of drug-resistant bacteria.

Interactions:

- If an aminoglycoside (in higher doses) is used concurrently with aztreonam or if therapy is prolonged, renal function should be monitored because of the potential nephrotoxicity and ototoxicity of aminoglycoside antibiotics.

Adverse Reactions:

Local reactions	• Phlebitis/thrombophlebitis and discomfort/swelling at the injection site
Hypersensitivity	• Rash, anaphylaxis, angioedema, bronchospasm, Toxic epidermal necrolysis, purpura, erythema multiforme, exfoliative dermatitis, urticaria, petechiae, pruritus.
Hematologic	• Pancytopenia, neutropenia, thrombocytopenia, anemia, eosinophilia, leukocytosis, thrombocytosis
Gastrointestinal	• Diarrhea, nausea and/or vomiting, abdominal cramps; rare cases of C. difficile-associated diarrhea, including pseudomembranous colitis, or gastrointestinal bleeding
Cardiovascular	• Hypotension, transient ECG changes
Hepatobiliary	• Hepatitis, jaundice, elevated serum aminotransferases
Nervous System	• Seizure, confusion, encephalopathy, vertigo, paresthesia, insomnia, dizziness
Special Sense	• Tinnitus, diplopia, mouth ulcer, altered taste, numb tongue, sneezing, nasal congestion, halitosis

Penicillin's

Penicillin G

Contraindication:

- Hypersensitivity (anaphylactic) reaction to any penicillin.

Special Population:

Pregnancy:

- No adequate and well controlled studies of Penicillin G on human pregnancy outcomes are available. Hence, caution advised.

Lactation:

- Penicillins are excreted in human milk. Hence, caution advised.

Pediatric:

- Dosage and frequency of administration should be adjusted in these patients as renal function in this population may not completely developed.

Use in patients with hepatic impairment:
• Dosage adjustments advised if any hepatic impairment is suspected or known to exist.

Use in patients with renal impairment:
• Dosage adjustments advised if any renal impairment is suspected or known to exist.

Use in elderly:
• No special precaution is required except in patients with renal impairment.

Warnings & Precautions:
• Caution is advised as the patient may experience *Clostridium difficile* associated diarrhea (CDAD).

Interactions:

• Bacteriostatic antibacterial	• Indomethacin	• Aspirin
• Phenylbutazone	• Sulfonamides	• Thiazide diuretics
• Furosemide	Ethacrynic acid	

Adverse Reactions:

Local reactions	• Phlebitis, thrombophlebitis, exacerbation of cutaneous lesions, • Vasodilation with flushing and mild hypotension.
Hypersensitivity Reactions	• Urticaria and pruritus to angioneurotic edema, laryngospasm, bronchospasm, hypotension, Jarisch-Herxheimer reaction. • Delayed: serum sickness-like symptoms • Contact dermatitis has been observed in individuals who prepare penicillin solutions.
Gastrointestinal System	• Nausea, vomiting, stomatitis
Hematologic System	• Bleeding, neutropenia, Coombs-positive hemolytic anemia
Nervous System	• Hyperreflexia, myoclonic twitches, seizures and coma • Mental confusion
Renal System	• Renal tubular damage and interstitial nephritis
Superinfections	• Alteration in bowel, respiratory and cutaneous microflora (rarely)

Penicillin V

Contraindication:

- Hypersensitivity reaction to any penicillin is a contraindication.

Special Population:

Pregnancy:

- No special precaution required.

Lactation:

- No special precaution required.

Pediatric:

- No special precaution required.

Use in patients with hepatic impairment:

- No special precaution required.

Use in patients with renal impairment:

- No special precaution required.

Use in elderly:

- No special precaution required.

Warnings & Precautions:

- Caution is advised as the patient may experience *Clostridium difficile* associated diarrhea (Rare).

Interactions:

- No data available on interactions.

Adverse Reactions:

Gastrointestinal System	• Nausea, vomiting, epigastric distress and diarrhea.
Hypersensitivity Reactions	• Hypersensitivity reactions reported are skin eruptions (maculopapular to exfoliative dermatitis), urticaria and other serum-sickness like reactions, laryngeal edema, and anaphylaxis.
Body as a Whole	• Fever and eosinophilia
Hematologic System	• Hemolytic anemia, leukopenia, thrombocytopenia
Renal System	• Nephropathy
Neurological	• Neuropathy

Ampicillin

Contraindication:

- Hypersensitivity reaction to any of the penicillins.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.

Lactation:

- Ampicillin is excreted in trace amounts in human milk. Hence, caution advised.

Pediatric:

- No special precaution advised when used in pediatric group.

Use in patients with hepatic impairment:

- No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:

- No data available about

Use in elderly:
• No data available about use in elderly patients.

Warnings & Precautions:
• Caution is advised as the patient may experience *Clostridium difficile* associated diarrhea (CDAD), superinfections with mycotic organisms or bacterial pathogens.

Interactions:

- Allopurinol

Adverse Reactions:

Gastrointestinal	• Diarrhea, glossitis, stomatitis, nausea, vomiting, enterocolitis, pseudomembranous colitis.
Hypersensitivity Reactions	• Skin rashes and urticarial, anaphylaxis
Liver	• moderate rise in serum glutamic oxaloacetic transaminase (SGOT), mild transitory SGOT elevations
Hemic and Lymphatic Systems	• Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis

Amoxicillin

Contraindication:

• Hypersensitivity to any of the penicillins.

Special Population:

Pregnancy:
• No adequate and well-controlled studies in pregnant women.

Lactation:
• Amoxicillin can be excreted in human milk and may lead to sensitization of infants. Hence, caution advised when amoxicillin is administered to a nursing woman.

Pediatric:
• Dosage and frequency adjustment required as renal function may not completely developed.

Use in patients with hepatic impairment:
• No special precaution required in patients with hepatic impairment:

Use in patients with renal impairment:
• Dosage adjustments advised if any renal impairment is suspected or known to exist.

Use in elderly:
• No special precaution is required except in patients with renal impairment.

Warnings & Precautions:
• Caution is advised as the patient may experience *Clostridium difficile* associated diarrhea (CDAD), superinfections with mycotic organisms or bacterial pathogens.

Interactions:

• Probenecid	• Sulfonamides	• Chloramphenicol
• Macrolides	• Tetracyclines	

Adverse Reactions:

Superinfections	• Mucocutaneous candidiasis
Gastrointestinal	• Nausea, vomiting, diarrhea and hemorrhagic/pseudomembranous colitis
Hypersensitivity Reactions	• Anaphylaxis, Serum sickness-like reactions, erythematous maculopapular rashes, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, toxic epidermal necrolysis, acute generalized exanthematous pustulosis and urticaria
Liver	• Rise in AST (SGOT) and/or ALT (SGPT)
Renal	• Crystalluria
Hemic and Lymphatic Systems	• Anemia, thrombocytopenia, eosinophilia, leukopenia, and agranulocytosis
Nervous System	• Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and/or dizziness

Benzathine Penicillin

Contraindication:

- Hypersensitivity reaction to any of the penicillins.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.

Lactation:

- Caution advised when penicillin G benzathine is administered to a nursing woman.

Pediatric:

- Dosage and frequency of administration should be adjusted in these patients as renal function in this population may not completely developed.

Use in patients with hepatic impairment:

- No special precaution required in patients with hepatic impairment.

Use in patients with renal impairment:

- Dosage adjustments advised if any renal impairment is suspected or known to exist.

Use in elderly:

- No special precaution is required except in patients with renal impairment.

Warnings & Precautions:

- Caution is advised as the patient may experience anaphylaxis, severe cutaneous adverse reactions and *Clostridioides difficile* Associated Diarrhea.

Interactions:

- Tetracycline
- **Probenecid**

Adverse Reactions:

Skin and Appendages	• Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS)
Hypersensitivity reactions	• Skin eruptions, urticaria, laryngeal edema, fever, eosinophilia; other serum sickness-like and anaphylaxis including shock and death: severe cutaneous adverse reactions (SCAR), such as toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP)
Gastrointestinal	• Pseudomembranous colitis
Hematologic	• Hemolytic anemia, leukopenia, thrombocytopenia.
Neurologic	• Neuropathy
Renal	• Nephropathy

Ticarcillin

Contraindication:

- Hypersensitivity to any of penicillin's class of antibiotics.

Special Population:

Pregnancy:

- No adequate and well controlled studies of ticarcillin on human pregnancy outcomes are available. Hence, caution advised.

Lactation:

- No adequate available about excretion of ticarcillin in human milk. Hence, caution advised.

Pediatric:

- The safety and effectiveness of ticarcillin have been established in the age group of 3 months to 16 years. Insufficient data to support the use in pediatric patients under 3 months of age.

Use in patients with hepatic impairment:

- No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:
• Dosage adjustments advised if any renal impairment is suspected or known to exist.

Use in elderly:
• No overall differences in safety or efficacy were observed. No special precaution is required except in patients with renal impairment.

Warnings & Precautions:
• Caution is advised as the patient may experience *Clostridium difficile* associated diarrhea (CDAD).

Interactions:

• Aminoglycosides	• Probenecid

Adverse Reactions:

Hypersensitivity Reactions	• Skin rash, pruritus, urticaria, arthralgia, myalgia, drug fever, chills, chest discomfort, erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome, and anaphylactic reactions.
Gastrointestinal System	• Disturbances of taste and smell, stomatitis, flatulence, nausea, vomiting and diarrhea, epigastric pain, and pseudomembranous colitis.
Hematologic System	• Thrombocytopenia, leukopenia, neutropenia, eosinophilia, reduction of hemoglobin or hematocrit, and prolongation of prothrombin time and bleeding time.
Nervous System	• Headache, giddiness, neuromuscular hyperirritability, or convulsive seizures
Renal System	• Hemorrhagic cystitis, elevation of serum creatinine and/or BUN, hypernatremia, reduction in serum potassium, and uric acid.
Local Reactions	• Pain, burning, swelling, and induration at the injection site and thrombophlebitis
Hepatic	• Elevation of serum aspartate aminotransferase (SGOT), serum alanine aminotransferase (SGPT), serum alkaline phosphatase, serum LDH, serum bilirubin.

Cloxacillin

Contraindication:

- Hypersensitivity to any of penicillin or cephalosporins class of antibiotics.

Special Population:

Pregnancy:

- No adequate and well controlled studies on human pregnancy outcomes are available. Hence, caution advised.

Lactation:

- No adequate available about excretion in human milk. Hence, caution advised.

Pediatric:

- The safety and effectiveness data in pediatric age group is limited. Hence, caution advised.

Use in patients with hepatic impairment:

- No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:

- No data available about use in patients with renal impairment.

Use in elderly:

- No data available about use in elderly.

Warnings & Precautions:

- During long-term therapy, renal, hepatic and hematopoietic functions should be monitored.
- Candidiasis and other superinfections may occur

Interactions:

- Probenecid

Adverse Reactions:

Hypersensitivity Reactions	• Allergic reactions (rash, urticaria) including wheezing and sneezing
Gastrointestinal System	• Nausea, vomiting, epigastric discomfort, flatulence and loose stools
Hematologic System	• Eosinophilia, leucopenia, anemia, thrombocytopenia, thrombocytopenic, purpura, neutropenia and agranulocytosis

Nitroimidazoles

Metronidazole

Contraindication:

- Hypersensitivity to metronidazole or other nitroimidazole derivatives.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.
- Use of metronidazole for trichomoniasis during pregnancy should be avoided if alternative treatment is available.

Lactation:

- Metronidazole is secreted in human milk in concentrations similar to those found in plasma.

Pediatric:

- Safety and effectiveness in pediatric patients have not been established, except for the treatment of amebiasis.

Use in patients with hepatic impairment:

- Plasma clearance of metronidazole is decreased in patients with decreased liver function.

Use in patients with renal impairment:

- Decreased renal function does not alter the single-dose pharmacokinetics of metronidazole

Use in elderly:
• In elderly patients, monitoring of serum levels may be necessary to adjust the metronidazole dosage.

Warnings & Precautions:
• Patients may experience convulsive seizures and peripheral neuropathy.

Interactions:

• Warfarin	• Cimetidine
• Coumarin anticoagulants	• Lithium
• Phenytoin	• Disulfiram
• Phenobarbital, Rifampicin	• Alcohol

Adverse Reactions:

Gastrointestinal	• Unpleasant metallic taste, anorexia, abdominal cramps, glossitis, and stomatitis
Hematopoietic	• Reversible neutropenia (leukopenia), reversible thrombocytopenia.
Cardiovascular	• Flattening of the T-wave
Nervous System	• Convulsive seizures, peripheral neuropathy, dizziness, vertigo, incoordination, ataxia, confusion, irritability, depression, weakness, and insomnia.
Hypersensitivity	• Fixed drug eruption, urticaria, erythematous rash, flushing, nasal congestion, dryness of the mouth (or vagina or vulva), and fever.
Renal	• Dysuria, cystitis, polyuria, incontinence, and a sense of pelvic pressure.
Other	• Injection site thrombophlebitis

Tinidazole

Contraindication:

- Hypersensitivity to tinidazole or other nitroimidazole derivatives.
- In patients with Cockayne syndrome.

Special Population:

Pregnancy:
• No adequate and well-controlled studies in pregnant women.

Lactation:
• No reports of adverse effects on the breastfed infant and no information on the effects of tinidazole on milk production.

Pediatric:
• Safety and effectiveness of tinidazole in pediatric patients have not been established. Other than for use in the treatment of giardiasis and amebiasis in pediatric patients older than three years of age.

Use in patients with hepatic impairment:
• Usual recommended doses of tinidazole should be administered cautiously in patients with hepatic dysfunction

Use in patients with renal impairment:
• No dose adjustments are necessary in these patients. • **Patients undergoing hemodialysis:** If tinidazole is administered on the same day as and prior to hemodialysis, it is recommended that an additional dose of tinidazole equivalent to one half of the recommended dose be administered after the end of the hemodialysis.

Use in elderly:
• No confirmed data available about use in elderly.

Warnings & Precautions:
• There is potential for genotoxicity and carcinogenicity.

Interactions:

• Warfarin and Other Oral Coumarin Anticoagulants	• CYP3A4 Inducers and Inhibitors
• Alcohols, Disulfiram	• Cholestyramine
• Lithium	• Oxytetracycline
• Phenytoin	• Cyclosporine, Tacrolimus
• Fluorouracil	

Adverse Reactions:

Nervous System	• Numbness, paresthesia, vertigo, ataxia, giddiness, insomnia, drowsiness
Gastrointestinal	• Tongue discoloration, stomatitis, diarrhea
Hypersensitivity	• Urticaria, pruritis, rash, flushing, sweating, dryness of mouth, fever, burning sensation, thirst, salivation, angioedema
Renal	• Darkened urine
Cardiovascular	• Palpitations
Hematopoietic	• Transient neutropenia, transient leukopenia
Other	• *Candida* overgrowth, increased vaginal discharge, oral candidiasis, hepatic abnormalities including raised transaminase level, arthralgias, myalgias, and arthritis.

Antifungals

Fluconazole

Contraindication:

- Hypersensitivity to fluconazole or to any of its excipients and other azoles.
- Coadministration of other drugs known to prolong the QT interval and which are metabolized via the enzyme CYP3A4 (e.g., erythromycin, pimozide, and quinidine) are contraindicated.

Special Population:

Pregnancy:
• Use in pregnancy should be avoided except in patients with severe or potentially life-threatening fungal infections.

Lactation:
• No data available on fluconazole levels in human milk. Hence, caution is advised when fluconazole is administered to a nursing woman.

Pediatric:
• Available data suggests fluconazole to be effective in the treatment of oropharyngeal candidiasis in children 6 months to 13 years of age. • Efficacy of fluconazole has not been established in infants less than 6 months of age.

Use in patients with hepatic impairment:
• Should be administered with caution in patients with hepatic impairment. As rare cases of serious hepatic toxicity, including fatalities primarily in patients with serious underlying medical conditions have been reported.

Use in patients with renal impairment:
• Fluconazole is primarily cleared by renal excretion as unchanged drug. Patients who are likely to have decreased renal function, care should be taken to adjust dose based on creatinine clearance.

Use in elderly:
• No significant difference in terms of safety and effectiveness was observed between the older and younger patients. • Elderly patients are more likely to have decreased renal function, care should be taken to adjust dose based on creatinine clearance.

Warnings & Precautions:
• There is a potential for fetal harm.

Interactions:

• Erythromycin	• Amiodarone	• Amitriptyline, nortriptyline
• Alfentanil	• Amphotericin B	• Azithromycin
• Calcium channel blockers	• Carbamazepine	• Celecoxib
• Coumarin-type anticoagulants	• Cyclophosphamide	• Cyclosporine
• Fentanyl	• HMG-CoA reductase inhibitors	• Hydrochlorothiazide
• Ibrutinib	• Ivacaftor and fixed dose ivacaftor combinations	• Lemborexant
• Losartan	• Lurasidone	• Methadone
• Non-steroidal anti-inflammatory drugs	• Olaparib	• Oral contraceptives
• Oral hypoglycemics:	• Phenytoin	• Pimozide
• Prednisone	• Quinidine	• Rifabutin
• Rifampin	• Saquinavir	• Short-acting benzodiazepines
• Sirolimus	• Tacrolimus	• Theophylline
• Tofacitinib	• Zidovudine	• Triazolam
• Vinca alkaloids:	• Vitamin A	• Voriconazole

Adverse Reactions:

Skin and Appendages / Immunologic	• Anaphylaxis (including angioedema, face edema and pruritus) • Acute generalized exanthematous pustulosis, drug eruption including fixed drug eruption, increased sweating, exfoliative skin disorders including Stevens-Johnson syndrome and toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), alopecia
Cardiovascular	• QT prolongation, torsade de pointes.
Nervous System	• Seizures, dizziness.
Hematopoietic and Lymphatic	• Leukopenia, including neutropenia and agranulocytosis, thrombocytopenia.
Metabolic	• Hypercholesterolemia, hypertriglyceridemia, hypokalemia.
Gastrointestinal	• Nausea, vomiting, abdominal pain, elevated transaminases, cholestasis, dry mouth, hepatocellular damage, dyspepsia.
Nervous System	• Insomnia, paresthesia, somnolence, tremor, vertigo.

Clotrimazole

Contraindication:

- Hypersensitivity to clotrimazole or to any of its formulation.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.

Lactation:

- No information available about the drug excretion in human milk. Hence, caution is advised in nursing woman.

Pediatric:

- Safety and effectiveness in children have been established for clotrimazole when used as indicated and in the recommended dosage.

Use in patients with hepatic impairment:

- No information available about use in hepatic impairment patients.

Use in patients with renal impairment:

- No information available about use in renal impairment patients.

Warnings & Precautions:

- If irritation or sensitivity develops with the use of Clotrimazole, treatment should be discontinued and appropriate treatment should be initiated.

Use in elderly:

- No information available about use in elderly patients.

Interactions:

- Nystatin
- Amphotericin B
- Flucytosine

Adverse Reactions:

• Hypersensitivity / Skin reactions	• Erythema, stinging, blistering, peeling, edema, pruritus, urticaria, burning, and general irritation of the skin.

Miconazole

Contraindication:

- Hypersensitivity to miconazole, milk protein concentrate, or any other component of the product.

Special Population:

Pregnancy:

- No available data about miconazole use in pregnant women to evaluate for a drug-associated risks and adverse reactions.

Lactation:

- No available information on the presence of miconazole in human milk, or the effects on the breastfed child, or the effects on milk production.

Pediatric:

- Safety and effectiveness of miconazole in pediatric patients below the age of 16 years have not been established.

Use in patients with hepatic impairment:

- Miconazole should be administered with caution in patients with hepatic impairment.

Use in patients with renal impairment:

- No dose adjustment is necessary in patients with renal impairment.

Use in elderly:

- No information available about use in elderly patients.

Warnings & Precautions:
• No specific information.

Interactions:

• Warfarin
• Drugs Metabolized Through CYP 2C9 and 3A4

Adverse Reactions:

Hypersensitivity reactions	• Allergic reactions, including anaphylactic reactions and hypersensitivity.

Voriconazole

Contraindication:

• Hypersensitivity to voriconazole or its excipients.

Special Population:

Pregnancy:
• Voriconazole can cause fetal harm when administered to a pregnant woman. However, no confirmed data available about use in pregnancy.

Lactation:
• No data are available regarding the presence of voriconazole in human milk, the effects of voriconazole on the breastfed infant, or the effects on milk production.

Pediatric:
• The safety and effectiveness of voriconazole have been established in pediatric patients aged 12 to 14 years. • Safety and effectiveness in pediatric patients below the age of 2 years has not been established.

Use in patients with hepatic impairment:
• Hepatic reactions, including hepatitis and jaundice have been reported in patients with no identifiable medical history.

Use in patients with renal impairment:
• If patients have identifiable concurrent conditions or being treated concomitantly with nephrotoxic medications and voriconazole, renal function may be decreased. Hence, caution is advised.

Use in elderly:
• Overall safety profile of voriconazole in elderly patients was comparable to that of the young patients. Hence, no dosage adjustment is recommended.

Warnings & Precautions:
• Patient may experience embryo-fetal toxicity, clinically significant drug interactions and galactose intolerance.

Interactions:

• Rifampin and Rifabutin	• St. John's Wort	• Carbamazepine
• Efavirenz	• Oral Contraceptives	• Other HIV Protease Inhibitors
• Ritonavir	• Fluconazole	• Long-Acting Barbiturates
• Phenytoin	• Letermovir	• Other NNRTIs

Adverse Reactions:

Hepatic	• Increase in hepatic enzymes, hepatitis, cholestasis and fulminant hepatic failure.
Cardiovascular	• Prolongation of the QT interval
Eye	• Optic neuritis and papilledema
Skin	• Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms and photosensitivity
Renal	• Acute renal failure
Infusion Related Reactions	• Visual disturbances, anaphylactoid-type reactions, including tachycardia, chest tightness, dyspnea, pruritus and rash

Natamycin

Contraindication:

- Hypersensitivity to natamycin or to any of its formulation.

Special Population:

Pregnancy:

- No available data about natamycin use in pregnant women to evaluate for a drug-associated risks and adverse reactions.

Lactation:

- No available information on the presence of natamycin in human milk, or the effects on the breastfed child, or the effects on milk production.

Pediatric:

- Safety and effectiveness in pediatric patients have not been established.

Use in patients with hepatic impairment:

- No information available about use in patients with hepatic impairment.

Use in patients with renal impairment:

- No information available about use in patients with renal impairment.

Use in elderly:

- No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Warnings & Precautions:

- No Specific information.

Interactions:

- No information available about interactions.

Adverse Reactions:

Eye	• Allergic reaction, change in vision, corneal opacity, eye discomfort, eye edema, eye hyperemia, eye irritation, eye pain, foreign body sensation, paresthesia, and tearing.
Respiratory	• Chest pain, dyspnea

Nystatin

Contraindication:

- Hypersensitivity to nystatin or any of its formulation.

Special Population:

Pregnancy:

- No available data about nystatin use in pregnant women to evaluate for a drug-associated risks and adverse reactions.

Lactation:

- No available information on the presence nystatin in human milk. Hence, caution is advised when nystatin is administered to a nursing woman.

Pediatric:

- No data available about use in pediatric population.

Use in patients with hepatic impairment:

- No data available about use in hepatic impairment.

Use in patients with renal impairment:

- No data available about use in renal impairment.

Use in elderly:

- No data available about use in elderly population.

Warnings & Precautions:
• Nystatin not to be used for the treatment of systemic mycoses. • Discontinue treatment if sensitization or irritation is reported during use.

Interactions:

- No data available

Adverse Reactions:

Gastrointestinal	• Diarrhea, nausea, vomiting, gastrointestinal upset/disturbances.
Dermatologic	• Rash, including urticaria has been reported rarely. Stevens-Johnson syndrome has been reported very rarely.
Other	• Tachycardia, bronchospasm, facial swelling, and non-specific myalgia have also been rarely reported.

Amphotericin B

Contraindication:

- Hypersensitivity to amphotericin B or any other constituents of the product.

Special Population:

Pregnancy:
• No adequate and well-controlled studies of amphotericin B use in pregnant women available.

Lactation:
• No available information on the presence of amphotericin B in human milk, or the effects on the breastfed child, or the effects on milk production.

Pediatric:
• 1 month to 16 years, with presumed fungal infection (empirical therapy), confirmed systemic fungal infections or with visceral leishmaniasis have been successfully treated with amphotericin B.

Use in patients with hepatic impairment:
• No data available about use in hepatic impairment.

Use in patients with renal impairment:
• No data available about use in renal impairment.

Use in elderly:
• Dose adjustments not necessary elderly population

Warnings & Precautions:
• During the initial dosing period, patients should be under close clinical observation.

Interactions:

• Antineoplastic Agents
• Corticosteroids and Corticotropin (ACTH)
• Digitalis Glycosides
• Flucytosine
• Azoles
• Leukocyte Transfusions
• Other Nephrotoxic Medications
• Skeletal Muscle Relaxants

Adverse Reactions:

Gastrointestinal System	• Diarrhea, gastrointestinal hemorrhage, nausea, vomiting
Metabolic and Nutritional Disorders	• Alkaline phosphatase increased, bilirubinemia, edema, hyperglycemia, hypernatremia, hypervolemia, hypocalcemia, hypokalemia, hypomagnesemia, peripheral edema
Nervous System	• Nerve palsy, anxiety, confusion, headache, insomnia
Hypersensitivity	• Acute reaction with chills, fever, aches, nausea, vomiting, dyspnea, pruritus, rash, sweating due to release of cytokines.
Renal System	• Nephrotoxicity - azotemia, reduced GFR, acidosis, hypocalcemia, inability to concentrate urine, hematuria. • Nephrotoxicity reverses slowly and often incompletely after drug withdrawal.
Haemopoietic	• Anemia due to bone marrow depression which is reversible.

Flucytosine

Contraindication:

- Hypersensitivity to the flucytosine and known history of complete dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.

Special Population:

Pregnancy:
• There are no adequate and well-controlled studies in pregnant women.

Lactation:
• No available information on the presence of amphotericin B in human milk, or the effects on the breastfed child, or the effects on milk production.

Pediatric:
• The efficacy and safety of flucytosine has not been studied in pediatric patients.

Use in patients with hepatic impairment:
• No data available about use in hepatic impairment.

Use in patients with renal impairment:
• Extreme caution is advised when administrating to patients with impaired renal function.

Use in elderly:
• No data available about use in elderly population.

Warnings & Precautions:
• Caution is advised when prescribing to patients with impaired renal function and Dihydropyrimidine dehydrogenase deficiency

Interactions:

• Cytosine arabinoside

Adverse Reactions:

Dermatologic	• Rash, pruritus, urticaria, photosensitivity.
Gastrointestinal	• Nausea, emesis, abdominal pain, diarrhea, anorexia, dry mouth, duodenal ulcer, gastrointestinal hemorrhage, acute hepatic injury including hepatic necrosis with possible fatal outcome in debilitated patients, hepatic dysfunction, jaundice, ulcerative colitis, enterocolitis, bilirubin elevation, increased hepatic enzymes.
Renal	• Azotemia, creatinine and BUN elevation, crystalluria, renal failure.
Hematologic	• Anemia, agranulocytosis, aplastic anemia, eosinophilia, leukopenia, pancytopenia, thrombocytopenia, and fatal cases of bone marrow aplasia.
Neurologic	• Ataxia, hearing loss, headache, paresthesia, parkinsonism, peripheral neuropathy, pyrexia, vertigo, sedation, convulsions.

Echinocandins (E.g., caspofungin)

Contraindication:

- Hypersensitivity to echinocandins or to any component in the formulation.

Special Population:

Pregnancy:

- Insufficient human data to confirm if there is a drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation:

- No data available about the presence of echinocandin drugs in human milk, the effects on the breast-fed child, or the effects on milk production.

Pediatric:

- The safety and effectiveness in pediatric patients 3 months to 17 years of age are supported by evidence from adequate and well-controlled studies.

Use in patients with hepatic impairment:
• No data available about use in hepatic impairment.

Use in patients with renal impairment:
• No dosage adjustment is necessary for patients with renal impairment.

Use in elderly:
• No dose adjustment is recommended for the elderly.

Warnings & Precautions:
• Patient may experience hypersensitivity, hepatic effects, elevated liver enzymes during concomitant use with cyclosporine.

Interactions:

• Cyclosporine
• Tacrolimus
• Rifampin

Adverse Reactions:

Hypersensitivity	• Anaphylaxis, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), rash, facial swelling, angioedema, pruritus, sensation of warmth or bronchospasm
Hepatic	• Laboratory abnormalities in liver function tests have been reported
Interaction with Cyclosporine	• Elevated liver enzymes have occurred
Electrolytes	• Hypokalemia

Glycopeptides

Teicoplanin

Contraindication:

- Previous hypersensitivity to teicoplanin.

Special Population:

Pregnancy:

- Insufficient human data to confirm if there is a drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcomes. Hence, caution is advised.

Lactation:

- No data available about the presence of teicoplanin in human milk, the effects on the breast-fed child, or the effects on milk production.

Pediatric:

- No special precaution advised. The dose recommendations are the same in adults and children above 12 years of age.

Use in patients with hepatic impairment:

- No data available about use in hepatic impairment.

Use in patients with renal impairment:

- Dosage adjustment is necessary for patients with renal impairment.

Use in elderly:

- No dose adjustment required, unless there is renal impairment

Warnings & Precautions:

- No specific information.

Interactions:

- No data available.

Adverse Reactions:

Infections and infestations	• Superinfection
Blood and the lymphatic System disorders	• Leucopenia, thrombocytopenia, eosinophilia
Immune system / Skin disorders	• Anaphylactic reaction • Rash, erythema, pruritus, red man syndrome, toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, angioedema, dermatitis exfoliative, urticaria
Nervous system disorders	• Dizziness, headache, seizures
Ear and Labyrinth disorders	• Deafness, hearing loss, tinnitus, vestibular disorder
Vascular disorders	• Phlebitis, thrombophlebitis
Respiratory, thoracic and Mediastinal disorders	• Bronchospasm
Gastrointestinal disorders	• Diarrhea, vomiting, nausea
	•
Renal and Urinary disorders	• Blood creatinine increased, renal failure
Investigations	• Transaminases increased; blood alkaline phosphatase increased

Vancomycin

Contraindication:

- Previous history of hypersensitivity to vancomycin.

Special Population:

Pregnancy:

- Not recommended for use during the first or second trimester of pregnancy and advise pregnant women of the potential risk to the fetus.

Lactation:

- Insufficient data to about the presence of drug in human milk and the effects of vancomycin on the breastfed infant or milk production.

Pediatric:
• Indicated in pediatric patients of 1 month and older. Advise to monitor vancomycin serum concentration and renal function.

Use in patients with hepatic impairment:
• No data available about use in hepatic impairment.

Use in patients with renal impairment:
• Frequent monitoring is recommended in patients with comorbidities that predispose to impairment in renal function or are concomitantly receiving other nephrotoxic drugs.

Use in elderly:
• Known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function.

Warnings & Precautions:
• No specific information.

Interactions:

• Anesthetic Agents	• Piperacillin-Tazobactam	• Ototoxic and/or Nephrotoxic Drugs

Adverse Reactions:

Renal	• Acute kidney injury (Dose related)
Ear	• Tinnitus, hearing loss (permanent, concentration dependent), dizziness or vertigo
Skin	• Toxic epidermal necrolysis, Stevens-Johnson syndrome, Drug reaction with eosinophilia and systemic symptoms, acute generalized exanthematous pustulosis, and linear IgA bullous dermatosis
Eye	• Permanent loss of vision
Haemopoietic	• Reversible neutropenia has been reported
Others	• Infusion reaction due to rapid I.V – Redman syndrome (hypotension, including shock and cardiac arrest, wheezing, dyspnea, muscular and chest pain)

Aminoglycosides

Tobramycin

Contraindication:

- Previous history of hypersensitivity to tobramycin or to any aminoglycoside.

Special Population:

Pregnancy:

- When administered to a pregnant woman aminoglycoside class of drugs can cause fetal harm.
- They can cross the placenta and cause total irreversible bilateral congenital deafness.

Lactation:

- Insufficient data about the presence of drug in human milk and the effects on the breastfed infant or milk production.

Pediatric:

- Safety and effectiveness in pediatric patients below the age of 2 months has not been established.

Use in patients with hepatic impairment:

- No data available about use in hepatic impairment

Use in patients with renal impairment:

- Increased incidence of nephrotoxicity has been reported following concomitant administration of aminoglycoside antibiotics and cephalosporins. Hence, monitoring of renal function is advised.

Use in elderly:

- Elderly patients are at a higher risk of developing nephrotoxicity and ototoxicity.
- Monitoring of renal function is advised.

Warnings & Precautions:
• Patients may experience *Clostridium difficile* associated diarrhea (CDAD), ototoxicity, neurotoxicity. • Prescribing prophylactically increases the risk of the development of drug-resistant bacteria.

Interactions:

• Ethacrynic acid
• Furosemide

Adverse Reactions:

Neurotoxicity	• Dizziness, vertigo, tinnitus, roaring in the ears, and hearing loss
Nephrotoxicity	• Oliguria and increased proteinuria
Others	• Anemia, granulocytopenia, and thrombocytopenia; and fever, rash, exfoliative dermatitis, itching, urticaria, nausea, vomiting, diarrhea, headache, lethargy, pain at the injection site, mental confusion, and disorientation.
Laboratory abnormalities	• Increased serum transaminases (SGOT, SGPT); increased serum LDH and bilirubin; decreased serum calcium, magnesium, sodium, and potassium; and leukopenia, leukocytosis, and eosinophilia.

Gentamicin

Contraindication:

• Previous history of hypersensitivity to gentamicin.

Special Population:

Pregnancy:
• When administered to a pregnant woman aminoglycoside class of drugs can cause fetal harm. They can cross the placenta and cause total irreversible bilateral congenital deafness.

Lactation:
• No data available about drug use in lactation.

Pediatric:
• Reports of total irreversible bilateral congenital deafness in children whose mothers' received streptomycin during pregnancy

Use in patients with hepatic impairment:
• No data available about use in hepatic impairment

Use in patients with renal impairment:
• The risk of nephrotoxicity is greater in patients with impaired renal function.

Use in elderly:
• No data available about drug use in elderly.

Warnings & Precautions:
• In the absence of a proven or strongly suspected bacterial infection or a prophylactic indication can increase the risk of the development of drug-resistant bacteria, neuromuscular disorders precipitation.

Interactions:

• Ethacrynic acid
• Furosemide
• Concurrent and/or sequential systemic or topical use of cisplatin, cephaloridine, kanamycin, amikacin, neomycin, polymyxin B, colistin, paromomycin, streptomycin, tobramycin, vancomycin and viomycin, should be avoided.

Adverse Reactions:

Renal	• Adverse renal effects, as demonstrated by the presence of casts, cells or protein in the urine or by rising BUN, NPN, serum creatinine or oliguria, have been reported
Nervous System	• Dizziness, vertigo, tinnitus, roaring in the ears and also hearing loss • Numbness, skin tingling, muscle twitching, convulsions and a myasthenia gravis-like syndrome • Lethargy, confusion, depression, visual disturbances
Allergic Reactions	• Rash, itching, urticaria, generalized burning, laryngeal edema and anaphylactoid reactions
Other	• Decreased appetite, weight loss and hypotension and hypertension; nausea, vomiting, increased salivation and stomatitis; purpura, pseudotumor cerebri, acute organic brain syndrome, pulmonary fibrosis, alopecia, joint pain, transient hepatomegaly and splenomegaly.
Laboratory abnormalities	• Increased levels of serum transaminase (SGOT, SGPT), serum LDH and bilirubin; decreased serum calcium, magnesium, sodium and potassium; anemia, leukopenia, granulocytopenia, transient agranulocytosis, eosinophilia, increased and decreased reticulocyte counts and thrombocytopenia.

Amikacin

Contraindication:

- Previous history of hypersensitivity to amikacin.

Special Population:

Pregnancy:

- When administered to a pregnant woman aminoglycoside class of drugs can cause fetal harm. They can cross the placenta and cause total irreversible bilateral congenital deafness.

Lactation:

- Insufficient data about the presence of drug in human milk and the effects on the breastfed infant or milk production.

Pediatric:

- Aminoglycosides should be used with caution in premature and neonatal infants because of the renal immaturity of these patients and the resulting prolongation of serum half-life of these drugs.

Use in patients with hepatic impairment:

- No data available about use in hepatic impairment

Use in patients with renal impairment:

- Neurotoxicity, manifested as vestibular and permanent bilateral auditory ototoxicity, can occur in patients with preexisting renal damage and in patients with normal renal function treated at higher doses and/or for periods longer than those recommended.

Use in elderly:

- No data available about use in elderly.

Warnings & Precautions:

No Specific Information

Interactions:

- Ethacrynic acid
- Furosemide
- Concurrent and/or sequential systemic or topical use of cisplatin, cephaloridine, kanamycin, neomycin, polymyxin B, colistin, paromomycin, streptomycin, tobramycin, vancomycin and viomycin, should be avoided.

Adverse Reactions:

Ear	• Hearing loss, loss of balance, or both, Cochlear damage includes high frequency deafness
Nervous System	• Acute muscular paralysis and apnea
Renal	• Elevation of serum creatinine, albuminuria, presence of red and white cells, casts, azotemia, and oliguria
Other	• Rare occasions are skin rash, drug fever, headache, paresthesia, tremor, nausea and vomiting, eosinophilia, arthralgia, anemia, hypotension and hypomagnesemia. Macular infarction sometimes leading to permanent loss of vision.

Anti-Viral

Acyclovir

Contraindication:

• Previous history of hypersensitivity to acyclovir or valacyclovir.

Special Population:

Pregnancy:
• No adequate and well-controlled studies in pregnant women.

Lactation:
• Acyclovir should be administered to a nursing mother with caution and only when indicated.

Pediatric:
• Safety and effectiveness of acyclovir in pediatric patients less than 2 years of age have not been established.

Use in patients with hepatic impairment:
• No data available about use in hepatic impairment

Use in patients with renal impairment:
• Dosage adjustment is recommended when administering acyclovir to patients with renal impairment

Use in elderly:
• Elderly patients are more likely to have reduced renal function and CNS adverse events thus require dose reduction.

Warnings & Precautions:
• Patient may experience Renal failure, Thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS).

Interactions:

- Probenecid

Adverse Reactions:

Allergic Reactions	Anaphylaxis, angioedema, peripheral edema Alopecia, erythema multiforme, photosensitive rash, pruritus, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria.
Nervous	Aggressive behavior, agitation, ataxia, coma, confusion, decreased consciousness, delirium, dizziness, dysarthria, encephalopathy, hallucinations, paresthesia, psychosis, seizure, somnolence, tremors.
Digestive	Diarrhea, gastrointestinal distress, nausea.
Hematologic and Lymphatic	Anemia, leukocytoclastic vasculitis, leukopenia, lymphadenopathy, thrombocytopenia.
Hepatobiliary Tract and Pancreas:	Elevated liver function tests, hepatitis, hyperbilirubinemia, jaundice.
Musculoskeletal	Myalgia
Special Senses	Visual abnormalities.
Urogenital	Renal failure, renal pain (may be associated with renal failure), elevated blood urea nitrogen, elevated creatinine, hematuria

Famciclovir

Contraindication:

- Previous history of hypersensitivity to famciclovir.

Special Population:

Pregnancy:

- Use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

Lactation:

- Famciclovir should be administered to a nursing mother with caution and only when indicated.

Pediatric:

- The efficacy of famciclovir has not been established in pediatric patients

Use in patients with hepatic impairment:

- No dosage adjustment is recommended for patients with mild or moderate hepatic impairment.

Use in patients with renal impairment:

- Dosage adjustment required in patients with renal impairment.

Use in elderly:

- No dosage adjustment is recommended unless renal function is impaired

Warnings & Precautions:

- Patient may experience acute renal failure with inappropriate high doses of famciclovir.

Interactions:

• Digoxin	• Raloxifene
• Probenecid	• Penciclovir

Adverse Reactions:

Cardiac disorders	• Palpitations
Blood and lymphatic system disorders	• Thrombocytopenia
Hepatobiliary disorders	• Abnormal liver function tests, cholestatic jaundice
Immune system disorders	• Anaphylactic shock, anaphylactic reaction
Nervous system disorders	• Dizziness, somnolence, seizure
Psychiatric disorders	• Confusion (including delirium, disorientation, and confusional state occurring predominantly in the elderly), hallucinations
Skin and subcutaneous tissue disorders	• Urticaria, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, angioedema (e.g., face, eyelid, periorbital, and pharyngeal edema), hypersensitivity vasculitis

Valacyclovir

Contraindication:

- Previous history of hypersensitivity reaction (e.g., anaphylaxis) to valacyclovir.

Special Population:

Pregnancy:

- No adequate and well-controlled studies of valacyclovir in pregnant women.

Lactation:

- Valacyclovir should be administered to a nursing mother with caution and only when indicated.

Pediatric:

- Valacyclovir is indicated for treatment of cold sores in pediatric patients ≥12 years of age and for treatment of chickenpox in pediatric patients 2 to <18 years of age

Use in patients with hepatic impairment:

- No special precaution needed. However, central nervous system adverse reactions have been reported both adult and pediatric patients with or without reduced renal function.

Use in patients with renal impairment:
• Dosage reduction is recommended when administering valacyclovir to patients with renal impairment.

Use in elderly:
• Dose reduction required as elderly patients are more likely to have reduced renal function and are more likely to have renal or CNS adverse events.

Warnings & Precautions:
Patients as they may experience thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), acute renal failure, central nervous system effects.

Interactions:

- No clinically significant drug-drug or drug-food interactions with valacyclovir are known.

Adverse Reactions:

Renal	Acute Renal Failure
Nervous System Effects	Agitation, hallucinations, confusion, delirium, seizures, and encephalopathy
Haemopoietic	Thrombotic thrombocytopenic purpura/hemolytic uremic syndrome

Ganciclovir

Contraindication:

- Previous history of hypersensitivity reaction (e.g., anaphylaxis) to ganciclovir, valganciclovir or acyclovir.

Special Population:

Pregnancy:
• No adequate human data are available to confirm the pregnancy outcomes.

Lactation:
• No data are available regarding the presence of ganciclovir in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric:
• Safety and efficacy of ganciclovir have not been established in pediatric patients.

Use in patients with hepatic impairment:
• The safety and efficacy of ganciclovir have not been studied in patients with hepatic impairment.

Use in patients with renal impairment:
• Dose reduction is recommended when administering ganciclovir to patients with renal impairment.

Use in elderly:
• Elderly patients are more likely to have decreased renal function. Hence, care should be taken in dose selection.

Warnings & Precautions:
• Patients as they may experience hematologic toxicity, impairment of renal function, impairment of fertility, fetal toxicity, mutagenesis and carcinogenesis.

Interactions:

• Imipenem-cilastatin
• Zidovudine
• Dapsone, pentamidine, flucytosine, vincristine, vinblastine, Adriamycin, amphotericin B, trimethoprim/sulfamethoxazole combinations or other nucleoside analogues
• Didanosine
• Probenecid
• Cyclosporine or amphotericin B

Adverse Reactions:

Hematological	Granulocytopenia (neutropenia), anemia, thrombocytopenia, and pancytopenia
Renal	Increased serum creatinine levels

Trifluridine

Contraindication:

- Contraindicated for patients who develop hypersensitivity reactions or chemical intolerance to trifluridine.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.

Lactation:

- It is unlikely that trifluridine is excreted in human milk.

Pediatric:

- Safety and effectiveness in pediatric patients below six years of age have not been established.

Use in patients with hepatic impairment:

- No data available about trifluridine use in hepatic impairment.

Use in patients with renal impairment:

- No data available about trifluridine use in renal impairment.

Use in elderly:

- No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Warnings & Precautions:
• The drug can cause mild local irritation of the conjunctiva and cornea when instilled but these effects are usually transient. • Recommended dosage and frequency of administration should not be exceeded.

Interactions:

• No data available about interactions.

Adverse Reactions:

Eye	Common: • Mild, transient burning or stinging upon instillation, palpebral edema
	Less Common: • Superficial punctate keratopathy, epithelial keratopathy, hypersensitivity reaction, stromal edema, irritation, keratitis sicca, hyperemia, and increased intraocular pressure.

Anti-Influenza

Oseltamivir

Contraindication:

• Contraindicated in patients with known serious hypersensitivity to oseltamivir or any component of the product.

Special Population:

Pregnancy:
• No adequate and well-controlled studies with oseltamivir in pregnant women to inform a drug-associated risk of adverse developmental outcomes.

Lactation:
• Based on limited published data, oseltamivir has been shown to be present in human milk at low levels considered unlikely to lead to toxicity in the breastfed infant.

Pediatric:
• The safety and efficacy of oseltamivir for the treatment of influenza in pediatric patients 2 weeks old to 17 years of age has been established.

Use in patients with hepatic impairment:
• No dosage adjustment is required in patients with mild to moderate hepatic impairment.

Use in patients with renal impairment:
• Dosage adjustment is recommended as patients with renal impairment had higher blood levels of oseltamivir compared to patients with normal renal function. • Oseltamivir is not recommended for patients with ESRD not undergoing dialysis.

Use in elderly:
• No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects.

Warnings & Precautions:
• Patient may experience serious skin/hypersensitivity reactions, neuropsychiatric events and risk of bacterial infections.

Interactions:

• Influenza Vaccines-_Live Attenuated Influenza Vaccine
• No dose adjustments are needed for either oseltamivir or the concomitant drug when co-administering oseltamivir with amoxicillin, acetaminophen, aspirin, cimetidine, antacids (magnesium and aluminum hydroxides and calcium carbonates), rimantadine, amantadine, or warfarin

Adverse Reactions:

• **Serious skin and hypersensitivity reactions**	• Cases of anaphylaxis and serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme have been reported.
• **Neuropsychiatric**	• Hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes.

Zanamivir

Contraindication:

- Contraindicated in patients with history of allergic reaction to any ingredient of Zanamivir formulation, including milk proteins.

Special Population:

Pregnancy:

- Available data from published studies suggest that use of Zanamivir during pregnancy is not associated with an increased risk of birth defects or adverse maternal or fetal outcome

Lactation:

- There are no data on the presence of Zanamivir in human milk or the effects on milk production.
- Limited data from post-marketing case reports have not suggested a safety concern in infants exposed to breast milk of mothers using Zanamivir.

Pediatric:

- Safety and effectiveness of Zanamivir for treatment of influenza have not been assessed in pediatric patients younger than 7 years.

Use in patients with hepatic impairment:

- Safety and efficacy have not been documented in patients with hepatic impairment.

Use in patients with renal impairment:

- Safety and efficacy have not been documented in the presence of severe renal insufficiency.

Use in elderly:

- No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects.

Warnings & Precautions:

- Patient may experience bronchospasm, allergic reactions, neuropsychiatric events and bacterial infections.

Interactions:

• Influenza Vaccines-_Live Attenuated Influenza Vaccine

Adverse Reactions:

Allergic Reactions	• Allergic or allergic-like reaction, including oropharyngeal edema • Facial edema; rash, including serious cutaneous reactions (e.g., erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis); urticaria
Psychiatric	• Delirium, including symptoms such as altered level of consciousness, confusion, abnormal behavior, delusions, hallucinations, agitation, anxiety, nightmares
Cardiac	• Arrhythmias, syncope.
Neurologic	• Seizures. Vasovagal-like episodes have been reported

Combinations

Piperacillin-Tazobactam

Contraindication:

• Previous history of allergic reactions to any of the penicillin's, cephalosporin's, or beta-lactamase inhibitors.

Special Population:

Pregnancy:
• Piperacillin and tazobactam cross the placenta in humans. • Insufficient data available about use of piperacillin and/or tazobactam in pregnant women to confirm a drug-associated risk for major birth defects and miscarriage.

Lactation:
• Piperacillin is excreted in human milk; tazobactam concentrations in human milk have not been studied. • No information is available on the effects of piperacillin and tazobactam on the breast-fed child or on milk production.

Pediatric:
• The safety and effectiveness of piperacillin and tazobactam have not been established in pediatric patients less than 2 months of age • Dosage of piperacillin and tazobactam for injection in pediatric patients with renal impairment has not been determined

Use in patients with hepatic impairment:
• No dosage adjustment is required in patients with hepatic cirrhosis.

Use in patients with renal impairment:
• Impaired kidney function patients receiving piperacillin and tazobactam are at greater risk of toxic reactions.

Use in elderly:
• No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects. • Dosage should be adjusted in the presence of renal impairment

Use in patients with cystic fibrosis:
• Piperacillin therapy has been associated with an increased incidence of fever and rash in cystic fibrosis patients.

Warnings & Precautions:
• Patient may experience hypersensitivity adverse reactions, severe cutaneous adverse reactions, hemophagocytic lymphohistiocytosis, hematologic adverse reactions, central nervous system adverse reactions, nephrotoxicity in critically ill patients, electrolyte effects, *Clostridioides Difficile*-Associated Diarrhea (CDAD) and development of drug-resistant bacteria.

Interactions:

• Aminoglycosides	• Vecuronium
• Probenecid	• Methotrexate
• Vancomycin	• Anticoagulants

Adverse Reactions:

Hypersensitivity and Skin	• Fatal hypersensitivity (anaphylactic/anaphylactoid) reactions (including shock)
	• Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis
Hematologic	• Hemophagocytic lymphohistiocytosis (HLH) have been reported in pediatric and adult patients
	• Bleeding manifestations have occurred in some patients receiving beta-lactam drugs, including piperacillin.
Nervous System	• Neuromuscular excitability or seizures.
Renal	• Risk factor for renal failure and was associated with delayed recovery of renal function
Gastrointestinal and Metabolism	• Possibility of hypokalemia
	• Reported with use of nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis.

Cotrimoxazole (Trimethoprim/sulfamethoxazole)

Contraindication:

- Previous hypersensitivity to trimethoprim or sulfonamides or history of drug-induced immune thrombocytopenia with use of trimethoprim and/or sulfonamides.
- Documented megaloblastic anemia due to folate deficiency.
- Concomitant administration with Dofetilide

Special Population:

Pregnancy:
• Sulfamethoxazole and trimethoprim may interfere with folic acid metabolism, sulfamethoxazole and trimethoprim should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation:
• Caution should be exercised when sulfamethoxazole and trimethoprim is administered to a nursing woman, especially when breastfeeding jaundiced, ill, stressed, or premature infants because of the potential risk of bilirubin displacement and kernicterus.

Pediatric:
• Sulfamethoxazole and trimethoprim are contraindicated for infants younger than 2 months of age

Use in patients with hepatic impairment:
• Impaired liver function patients receiving high doses of sulfamethoxazole and trimethoprim may experience adverse hepatic reactions.

Use in patients with renal impairment:
• Impaired kidney function patients receiving high doses of sulfamethoxazole and trimethoprim need to be monitored.

Use in elderly:
• No sufficient clinical studies of sulfamethoxazole and trimethoprim to determine overall differences in safety or effectiveness between elderly subjects and younger subjects.

Warnings & Precautions:
• Embryofetal toxicity if taken during pregnancy.

Interactions:

• Diuretics	• Warfarin
• Phenytoin	• Methotrexate
• Cyclosporine	• Digoxin
• Indomethacin	• Pyrimethamine
• Tricyclic Antidepressants (TCAs)	• Oral Hypoglycemics
• Amantadine	• Angiotensin Converting Enzyme Inhibitors
• Zidovudine	• Dofetilide
• Procainamide	• Serum methotrexate assay

Adverse Reactions:

Hematologic	• Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, neutropenia, hemolytic anemia, megaloblastic anemia, hypoprothrombinemia, methemoglobinemia, eosinophilia, thrombotic thrombocytopenic purpura, idiopathic thrombocytopenic purpura
Allergic Reactions	• Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis, allergic myocarditis, erythema multiforme, exfoliative dermatitis, angioedema, drug fever, chills, Henoch-Schoenlein purpura, serum sickness-like syndrome, generalized allergic reactions, generalized skin eruptions, photosensitivity, conjunctival and scleral injection, pruritus, urticaria, rash, periarteritis nodosa, systemic lupus erythematosus, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized erythematous pustulosis (AGEP), and acute febrile neutrophilic dermatosis (AFND)
Gastrointestinal	• Hepatitis (including cholestatic jaundice and hepatic necrosis), elevation of serum transaminase and bilirubin, pseudomembranous enterocolitis, pancreatitis, stomatitis, glossitis, nausea, emesis, abdominal pain, diarrhea, anorexia
Genitourinary	• Renal failure, interstitial nephritis, BUN and serum creatinine elevation, renal insufficiency, oliguria and anuria, crystalluria and nephrotoxicity in association with cyclosporine.
Metabolic and Nutritional	• Hyperkalemia, hyponatremia, metabolic acidosis.
Neurologic	• Aseptic meningitis, convulsions, peripheral neuritis, ataxia, vertigo, tinnitus, headache.
Psychiatric	• Hallucinations, depression, apathy, nervousness.
Endocrine	• Goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents. Cross-sensitivity may exist with these agents. Diuresis and hypoglycemia have occurred.
Musculoskeletal	• Arthralgia, myalgia, rhabdomyolysis.
Cardiovascular System	• QT prolongation resulting in ventricular tachycardia and *torsade's de pointes*, circulatory shock

Amoxycillin- Clavulanate

Contraindication:

- In patients with previous history of hypersensitivity reactions or medical conditions such cholestatic jaundice/hepatic dysfunction.

Special Population:

Pregnancy:

- No adequate and well-controlled studies conducted in pregnant women.

Lactation:

- Caution is advised when amoxicillin and clavulanate potassium is administered to a nursing woman.

Pediatric:

- The safety and effectiveness of amoxicillin and clavulanate potassium for oral suspension and chewable tablets have been established in pediatric patients.
- Because of incompletely developed renal function in neonates and young infants, the elimination of amoxicillin may be delayed; clavulanate elimination is unaltered in this age group.

Use in patients with hepatic impairment:

- Amoxicillin and clavulanate potassium are contraindicated in patients with a previous history of cholestatic jaundice/hepatic dysfunction associated with amoxicillin and clavulanate potassium.

Use in patients with renal impairment:

- Amoxicillin is primarily eliminated by the kidney and dosage adjustment is usually required in patients with severe renal impairment.

Use in elderly:

- No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects.

Warnings & Precautions:
• No Specific Information

Interactions:

• Probenecid
• Oral Anticoagulants
• Allopurinol
• Oral Contraceptives

Adverse Reactions:

Hypersensitivity / Skin	• Fatal hypersensitivity (anaphylactic) reactions
	• Severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP).
Hepatic	• Hepatitis and cholestatic jaundice
Gastrointestinal	• *Clostridioides difficile* Associated Diarrhea (CDAD)

Imipenem cilastatin

Contraindication:

• Previous history of hypersensitivity to any component of the product.

Special Population:

Pregnancy:
• All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. • The background risk of major birth defects is 2-4% and of miscarriage is 15-20% of clinically recognized pregnancies within the general population.

Lactation:
• There are insufficient data on the presence of imipenem/cilastatin in human milk, and no data on the effects on the breastfed child, or the effects on milk production.

Pediatric:
• Imipenem and Cilastatin for Injection (I.V.) is not recommended in pediatric patients with CNS infections because of the risk of seizures. • Imipenem and Cilastatin for Injection (I.V.) is not recommended in pediatric patients less than 30 kg with renal impairment, as no data are available.

Use in patients with hepatic impairment:
• No data available about use in patients with hepatic impairment.

Use in patients with renal impairment:
• Dosage adjustment is necessary in patients with renal impairment.

Use in elderly:
• No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects.

Warnings & Precautions:
• Increased seizure potential due to interaction with valproic acid.

Interactions:

• Ganciclovir
• Probenecid
• Valproic Acid

Adverse Reactions:

Hypersensitivity / Skin reactions	• Serious and occasionally fatal hypersensitivity (anaphylactic) reactions.
Nervous System	• Seizures and other CNS adverse experiences, such as confusional states and myoclonic activity
Gastrointestinal	• Clostridioides difficile-Associated Diarrhea (CDAD)
Others	• Result in overgrowth of non-susceptible organisms

Cefoperazone-Sulbactam

Contraindication:

- Previous history of hypersensitivity to sulbactam, Cefoperazone, beta-lactams or to any of the excipients.

Special Population:

Pregnancy:

- No adequate and well-controlled studies conducted in pregnant women.

Lactation:

- Only small quantities of sulbactam and Cefoperazone are excreted in human milk.
- Although both drugs pass poorly into breast milk of nursing mothers, caution should be exercised when Sulbactam/Cefoperazone is administered to a nursing mother.

Pediatric:

- Sulbactam/Cefoperazone has been effectively used in infants. It has not been extensively studied in premature infants or neonates.
- In neonates with kernicterus, Cefoperazone does not displace bilirubin from plasma protein binding sites.

Use in patients with hepatic impairment:

- Cefoperazone is extensively excreted in bile
- Dose modification may be necessary in cases of severe biliary obstruction, severe hepatic disease or in cases of renal dysfunction coexistent with either of those conditions.

Use in patients with renal impairment:
• No significant differences have been observed in the pharmacokinetics of Cefoperazone in renal failure patients. • Dosage regimens of Sulbactam/Cefoperazone should be adjusted in patients with marked decrease in renal function (creatinine clearance of less than 30 ml/min) to compensate for the reduced clearance of sulbactam.

Use in elderly:
• Both sulbactam and Cefoperazone exhibited longer half-life, lower clearance, and larger volumes of distribution in elderly patients when compared to data from normal volunteers.

Warnings & Precautions:
• Those at risk include patients with poor diet, malabsorption conditions and in patients receiving oral anticoagulants, prothrombin time (or INR) on prolonged intravenous alimentation regimens.

Interactions:

• Aminoglycoside
• Alcohol
• False-positive reaction for glucose in the urine

Adverse Reactions:

Blood and lymphatic system disorders	• Neutropenia, leukopenia, Coombs direct test positive, hemoglobin decreased, hematocrit decrease, thrombocytopenia, coagulopathy, eosinophilia.
Immune system disorders	• Anaphylactic shock, anaphylactic reaction, anaphylactoid reaction including shock, hypersensitivity.
Nervous system disorders	• Headache
Vascular disorders	• Hemorrhage (including fatal), hypotension
Gastrointestinal disorders	• Diarrhea nausea vomiting, pseudomembranous colitis
Hepatobiliary disorders	• Alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased, blood bilirubin increased, jaundice
Skin and subcutaneous tissue disorders	• Pruritus, urticaria toxic epidermal necrolysis, Stevens-Johnson syndrome, dermatitis exfoliative, maculopapular rash
Renal and urinary disorders	• Hematuria
General disorders and administration site conditions	• Infusion site phlebitis injection site pain pyrexia chills

Pyrimethamine + sulphadiazine

Contraindication:

- Previous history of hypersensitivity to pyrimethamine, sulfonamides or to any component of the product.
- Use of the drug is also contraindicated in patients with documented megaloblastic anemia due to folate deficiency.

Special Population:

Pregnancy:

- No adequate and well-controlled studies conducted in pregnant women.
- Concurrent administration of folinic acid is strongly recommended when used for the treatment of toxoplasmosis during pregnancy.

Lactation:

- Pyrimethamine is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from pyrimethamine and from sulfonamide component, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
- Sulfadiazine may cause kernicterus.

Pediatric:

- The safety and effectiveness of pyrimethamine + sulphadiazine have not been established in infants less than 2 months of age.

Use in patients with hepatic impairment:

- Pyrimethamine + sulphadiazine should be used with caution in patients with impaired hepatic function.

Use in patients with renal impairment:

- Pyrimethamine + sulphadiazine should be used with caution in patients with impaired renal function.

Use in elderly:

- No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects.

Warnings & Precautions:

- The dosage of pyrimethamine required for the treatment of toxoplasmosis is 10 to 20 times the recommended antimalaria dosage and approaches the toxic level. If signs of folate deficiency develop, reduce the dosage or discontinue the drug according to the response of the patient.
- Folinic acid (leucovorin) should be administered until normal hematopoiesis is restored.
- A small “starting” dose for toxoplasmosis is recommended in patients with convulsive disorders to avoid the potential nervous system toxicity of pyrimethamine.
- Hemolysis may occur in individuals deficient in glucose-6-phosphate dehydrogenase.
- Adequate fluid intake must be maintained in order to prevent crystalluria and stone formation.

Interactions:

• Proguanil	• Oral anticoagulants
• Zidovudine	• Sulfonylureas
• Methotrexate	• Thiazide
• Uricosuric	• Indomethacin
• Probenecid	• Salicylates

Adverse Reactions:

Blood and lymphatic system disorders	• Megaloblastic anemia, hemolytic anemia, aplastic anemia, leukopenia, thrombocytopenia, pancytopenia • Agranulocytosis, thrombocytopenia, purpura, and methemoglobinemia.
Nervous system disorders	• Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia.
Cardiovascular disorders	• Disorders of cardiac rhythm
Gastrointestinal disorders	• Anorexia, vomiting, nausea, emesis, abdominal pains, hepatitis, diarrhea, atrophic glossitis, pancreatitis and stomatitis.
Immune / Skin and subcutaneous tissue disorders	• Photosensitization, arthralgia, allergic myocarditis, drug fever and chills. • Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, and anaphylaxis
Renal and urinary disorders	• Crystalluria, stone formation, toxic nephrosis with oliguria and anuria, hematuria

Others

Chloramphenicol

Contraindication:

- History of previous hypersensitivity and/or toxic reaction to chloramphenicol.

Special Population:

Pregnancy:

- Chloramphenicol has been shown to cross the placental barrier. Because of potential toxic effects on the fetus (Gray syndrome) chloramphenicol should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.

Lactation:

- Chloramphenicol is excreted in human milk. They have the potential to cause serious adverse reactions in nursing infants.

Pediatric:

- Precaution is advised when used in premature and full-term neonates and infants to avoid "gray syndrome" toxicity.

Use in patients with hepatic impairment:

- Dose adjustments is necessary in patients with impaired liver function.

Use in patients with renal impairment:

- Dose adjustments is necessary in patients with impaired renal function.

Use in elderly:

- Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Warnings & Precautions:

- Repeated courses of chloramphenicol treatment should be avoided if at all possible.

Interactions:

- Concurrent therapy with other drugs that may cause bone marrow depression should be avoided.

Adverse Reactions:

Haemopoietic	• Aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia, paroxysmal nocturnal hemoglobinuria
Gastrointestinal Reactions	• Nausea, vomiting, glossitis and stomatitis, diarrhea and enterocolitis
Neurotoxic Reactions	• Headache, mild depression, mental confusion, and delirium
Hypersensitivity Reactions	• Fever, macular and vesicular rashes, angioedema, urticaria, and anaphylaxis, Herxheimer's reactions occurred during therapy for typhoid fever.
Other	• Toxic reactions including fatalities have occurred in the premature and neonate

Linezolid

Contraindication:

- Previous history of hypersensitivity to linezolid or any of the other product components.
- Should not be used in patients taking any medicinal product which inhibits monoamine oxidases A or B (e.g., phenelzine, isocarboxazid) or within two weeks of taking any such medicinal product.

Special Population:

Pregnancy:

- Linezolid use in pregnant women has not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation:

- There is no information on the effects of linezolid on the breastfed infant; however, diarrhea and vomiting were the most common adverse reactions reported in clinical trials in infants receiving linezolid therapeutically

Pediatric:

- The safety and effectiveness of linezolid for the treatment of pediatric patients with the following infections are supported by evidence:
  nosocomial pneumonia
  complicated skin and skin structure infections
  community-acquired pneumonia (also supported by evidence from an uncontrolled study in patients ranging in age from 8 months through 12 years)
  vancomycin-resistant *Enterococcus faecium* infections
- The safety and effectiveness of linezolid for the treatment of pediatric patients with the following infection have been established in a comparator-controlled study in pediatric patients ranging in age from 5 through 17 years:
  uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible strains only) or *Streptococcus pyogenes*

Use in elderly:

No overall differences in safety or effectiveness were observed between elderly patients and younger patients.

Use in patients with hepatic impairment:

- No data available about linezolid use in hepatic impairment patients.

Use in patients with renal impairment:

- No data available about linezolid use in renal impairment patients.

Warnings & Precautions:

- No Specific Information

Interactions:

- Monoamine Oxidase Inhibitors
- Adrenergic and Serotonergic Agents

Adverse Reactions:

Haemopoietic	• Anemia, leukopenia, pancytopenia, and thrombocytopenia
Nervous System / Eye	• Peripheral and optic neuropathies, convulsion, loss of vision, visual blurring, visual acuity, changes in color vision, blurred vision, visual field defect
Gastrointestinal	• *Clostridioides difficile*-Associated Diarrhea (CDAD), repeated episodes of nausea and vomiting
Others	• Serotonin syndrome associated with the co-administration of serotonergic agents, hypoglycemia, SIADH

Nitrofurantoin

Contraindication:

- Patients with known hypersensitivity to nitrofurantoin.

Special Population:

Pregnancy:

- No adequate and well-controlled studies in pregnant women.
- Because of the possibility of hemolytic anemia due to immature erythrocyte enzyme systems (glutathione instability), nitrofurantoin is contraindicated in pregnant patients at term.

Lactation:

- Nitrofurantoin has been detected in human breast milk in trace amounts.
- Because of the potential for serious adverse reactions from nitrofurantoin in nursing infants under one month of age, contraindicated in neonates less than one month of age.

Pediatric:

- Contraindicated in infants below the age of one month.
- Safety and effectiveness in pediatric patients below the age of twelve years have not been established.

Use in patients with hepatic impairment:
• Spontaneous reports also suggest an increased proportion of severe hepatic reactions, including fatalities, in elderly patient • The onset of chronic active hepatitis may be insidious, and patients should be monitored periodically for changes in biochemical tests that would indicate liver injury.

Use in patients with renal impairment:
• Nitrofurantoin is known to be substantially excreted by the kidney. Hence, contraindicated in patients with anuria, oliguria, or significant impairment of renal function

Use in elderly:
• Higher proportion of pulmonary reactions, including fatalities, in elderly patients receiving long- term nitrofurantoin therapy. • Increased proportion of severe hepatic reactions, including fatalities, in elderly patients.

Warnings & Precautions:
• No Specific Information

Interactions:

• Antacids containing magnesium trisilicate
• Uricosuric drugs: probenecid and sulfinpyrazone

Adverse Reactions:

Gastrointestinal	• Diarrhea, dyspepsia, abdominal pain, constipation, emesis, sialadenitis, pancreatitis.
Neurologic	• Dizziness, drowsiness, amblyopia, peripheral neuropathy, Vertigo, and nystagmus, confusion, depression and psychotic reactions.
Allergic	• Pruritus, urticarial, lupus-like syndrome, hypersensitivity reactions.
Dermatologic	• Alopecia, exfoliative dermatitis and erythema multiforme
Hepatic	• Hepatitis, cholestatic jaundice, chronic active hepatitis, and hepatic necrosis
Hematologic	• Cyanosis secondary to methemoglobinemia
Miscellaneous	• Superinfections

Trimethoprim

Contraindication:

- Previous history of hypersensitivity to trimethoprim and in those with documented megaloblastic anemia due to folate deficiency.

Special Population:

Pregnancy:

- Trimethoprim should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation:

- Trimethoprim is excreted in human milk.
- Because trimethoprim may interfere with folic acid metabolism, caution should be exercised when trimethoprim is administered to a nursing woman.

Pediatric:

- Safety and effectiveness in pediatric patients below the age of 2 months have not been established.
- The effectiveness of trimethoprim as a single agent has not been established in pediatric patients less than 12 years of age.

Use in patients with hepatic impairment:

- Trimethoprim should be given with caution to patients with hepatic function

Use in patients with renal impairment:

- Trimethoprim should be given with caution to patients with impaired renal

Use in elderly:

- Not identified differences in response between the elderly and younger patients.
- Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Warnings & Precautions:
• Trimethoprim should be given with caution to patients with possible folate deficiency. Folates may be administered concomitantly without interfering with the antibacterial action of trimethoprim.

Interactions:

- Phenytoin

Adverse Reactions:

Hypersensitivity	• Rash, pruritus, and phototoxic skin eruptions. • Exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell Syndrome), and anaphylaxis
Gastrointestinal	• Epigastric distress, nausea, vomiting, and glossitis
Hematologic	• Thrombocytopenia, leukopenia, neutropenia, megaloblastic anemia, and methemoglobinemia.
Metabolic	• Hyperkalemia, hyponatremia.
Neurologic	• Aseptic meningitis
Miscellaneous	• Fever, and increases in BUN and serum creatinine levels.