Doxiim-AL-Jr

(Cefpodoxime proxetil oral suspension with sterile water for reconstitution)

Each 5 ml of reconstituted suspension contain:

Cefpodoxime Proxetil IP
Eq. to Anhydrous Cefpodoxime ……50mg
Excipients……q.s.

Dosage Form: Dry syrup for oral suspension.

Clinical Pharmacology:

Cefpodoxime Proxetil : Cefpodoxime Proxetil is active against a wide spectrum of Gram-positive and Gram-negative bacteria. Cefpodoxime is stable in the presence of beta-lactamase enzymes. The bactericidal activity of cefpodoxime results from its inhibition of cell wall synthesis. The active metabolite of cefpodoxime binds preferentially to penicillin binding protein 3, which inhibits production of peptidoglycan, the primary constituent of bacterial cell walls.

Indications:

- **Respiratory Tract Infections**: Such as acute otitis media (ear infections), pharyngitis, and tonsillitis, particularly when caused by susceptible bacteria.
- **Sinusitis**: Bacterial sinus infections.
- **Skin and Soft Tissue Infections**: Including cellulitis and impetigo.
- **Urinary Tract Infections**: Such as cystitis and pyelonephritis.
- **Community-Acquired Pneumonia**: Mild to moderate cases.

Contraindications:

- **Allergy to Cephalosporins**: Children who have a known allergy to cephalosporins or any component of the medication should not use cefpodoxime.

- **Severe Renal Impairment**: In children with severe renal impairment, dosage adjustments are necessary.
- **Phenylketonuria (PKU)**: Some formulations of cefpodoxime proxetil oral suspension may contain phenylalanine. Children with PKU, a genetic disorder that affects the metabolism of phenylalanine, should avoid formulations with phenylalanine or use alternative treatments.
- **Severe Allergic Reactions**: Children who have a history of severe allergic reactions to beta-lactam antibiotics (like penicillins or cephalosporins) should be monitored closely, and use might be contraindicated based on individual health history.

Precautions and Warnings:

- **Dosage and Administration**: Ensure proper dosing based on the child's weight and age, as overdosing can lead to adverse effects while underdosing may be ineffective. Adhere to the prescribed dosage instructions carefully.
- **Renal Function**: Monitor renal function in children with pre-existing kidney issues. Cefpodoxime is excreted through the kidneys, so dose adjustments might be necessary for those with renal impairment.
- **Allergic Reactions**: Be vigilant for signs of allergic reactions, such as rash, itching, or swelling. Children with a history of allergies to cephalosporins or penicillins should be monitored closely.
- **Gastrointestinal Issues**: Cefpodoxime can cause gastrointestinal side effects, such as nausea, vomiting, or diarrhea. Monitor for these symptoms and ensure adequate hydration.
- **Superinfection**: Prolonged use of antibiotics can lead to secondary infections, such as yeast infections or Clostridium difficile-associated diarrhea. Monitor for signs of superinfection and report any unusual symptoms to a healthcare provider.
- **Phenylketonuria (PKU)**: Check the formulation for phenylalanine content if the child has PKU. Some formulations may contain phenylalanine, which could be harmful to children with this condition.
- **Drug Interactions**: Be aware of potential drug interactions. Cefpodoxime can interact with other medications, so inform the healthcare provider of all other medications the child is taking.
- **Developmental Considerations**: Use with caution in very young children or infants, and adjust treatment based on the child’s developmental stage and overall health.

Adverse Effects:

- **Gastrointestinal Symptoms**: Nausea, vomiting, diarrhea, and abdominal pain are relatively common. These symptoms are usually mild and may resolve on their own.
- **Rash**: Skin rash can occur, which may be mild or more severe. Monitor for any signs of allergic reactions, such as hives.
- **Clostridium difficile-Associated Diarrhea**: Prolonged use of antibiotics can disrupt the normal gut flora and lead to an overgrowth of Clostridium difficile, which can cause severe diarrhea.
- **Superinfection**: Overgrowth of non-susceptible organisms, such as fungi (e.g., oral or vaginal thrush), may occur during or after treatment.
- **Kidney Effects**: Although uncommon, renal function changes can occur, particularly in children with pre-existing kidney issues. Symptoms might include changes in urine output or swelling.
- **Seizures**: High doses or rapid infusion can sometimes lead to seizures, particularly in individuals with renal impairment or a history of seizures.
- **Liver Effects**: Rarely, liver function abnormalities can occur, which might be indicated by jaundice (yellowing of the skin or eyes) or changes in liver enzyme levels.

Drug Interactions:

- **Antacids and H2-Receptor Antagonists**: Medications that reduce stomach acid, such as antacids containing aluminum or magnesium, or H2-receptor antagonists like ranitidine, can decrease the absorption of cefpodoxime. It is generally recommended to administer these drugs at least 2 hours apart from cefpodoxime.
- **Probenecid**: This medication, used primarily to treat gout, can increase the blood levels of cefpodoxime by inhibiting its renal excretion. This may necessitate dose adjustments to avoid potential toxicity.
- **Other Antibiotics**: Concurrent use of other antibiotics, especially those that can alter gut flora (e.g., oral antibiotics like tetracyclines), might impact the effectiveness of cefpodoxime or increase the risk of superinfections.
- **Warfarin**: Although not a common interaction, cefpodoxime has been reported to potentially increase the effect of anticoagulants like warfarin in some cases. Regular monitoring of INR (International Normalized Ratio) levels might be necessary.

Overdosage:

Symptoms of Overdosage:

- **Gastrointestinal Distress**: Symptoms may include severe nausea, vomiting, and diarrhea.
- **Central Nervous System Effects**: High doses might lead to seizures, especially in individuals with compromised renal function or a history of seizures.
- **Renal Effects**: Overdose can affect kidney function, potentially causing changes in urine output or swelling due to fluid retention.
- **Allergic Reactions**: Although not specific to overdose, severe allergic reactions like anaphylaxis could potentially occur, particularly if the overdose triggers an exaggerated immune response.

Management of Overdosage:

- **Immediate Medical Attention**: Seek immediate medical help if an overdose is suspected. Contact a poison control center or go to the nearest emergency department.
- **Supportive Care**: Treatment is primarily supportive and may include managing symptoms such as gastrointestinal distress and monitoring for adverse effects.
- **Monitoring**: Healthcare providers may monitor kidney function, liver function, and blood counts to detect any potential complications.
- **Potential Interventions**: In some cases, healthcare providers might consider interventions such as activated charcoal to reduce further absorption if the overdose was recent, although this is less common in cases of oral medication due to the risk of aspiration.
- **Hydration and Renal Function**: Ensuring adequate hydration and monitoring renal function are important aspects of managing an overdose, as cefpodoxime is excreted through the kidneys.

Prevention:

- **Follow Dosage Instructions**: Adhere strictly to the prescribed dosage and administration instructions provided by the healthcare provider.
- **Proper Storage**: Keep medications out of reach of children to prevent accidental ingestion.

Route of Administration: Oral. Shake the bottle well after reconstitution before each use.

Dosage: As directed by a physician.

Reconstitution Instructions

Tap the bottle to loosen the powder prepare solution by dissolving entire contents with sterile water inside the pack shake well and store in the refrigerator. Use the prepared suspensions within 4 days.

SCHEDULE H1 PRESCRIPTION DRUG CAUTION: It is dangerous to take this preparation except in accordance with the medical advice. Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Storage: Store protected from light at a temperature not exceeding 30°C. Keep the medicine out of reach of children.

Presentation: Each pack contains 1x20 ml.

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