

APODOX

Cefpodoxime Proxetil Dispersible Tablets 100 mg
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Cefpodoxime Proxetil for Oral Suspension USP 100 mg.

Each uncoated dispersible tablet contains :

Cefpodoxime Proxetil USP
eq. to Cefpodoxime 100 mg
Excipients q.s.
Approved colour added

Each 5 ml of the reconstituted suspension contains:

Cefpodoxime Proxetil USP
eq. to Cefpodoxime 100 mg
Excipients q.s.
in flavoured syrupy base
Approved colour added

Each uncoated dispersible tablet contains :

Cefpodoxime Proxetil USP
eq. to Cefpodoxime 200 mg
Excipients q.s.
Approved colour added

DESCRIPTION: Cefpodoxime is an orally administered, extended spectrum, semisynthetic antibiotic of the cephalosporin class.

Microbiology: Cefpodoxime is active in vitro against a wide range of gram-positive and gram-negative bacteria. Cefpodoxime is highly stable in the presence of β -lactamase enzymes. As a result, many organisms resistant to penicillins and some cephalosporins, due to the presence of β -lactamases, may be susceptible to Cefpodoxime. The bacterial activity of Cefpodoxime results from its inhibition of cell wall synthesis. Cefpodoxime is usually active against the following organisms in vitro and in clinical functions: Gram positive Aerobes: Staphylococcus aureus (including penicillinase-producing strains), Staphylococcus saprophyticus, Streptococcus pyogenes, Streptococcus pneumoniae (excluding penicillin-resistant strains)

Gram Negative Aerobes: Escherichia coli, Haemophilus influenza (including β -lactamase-producing strains), Klebsiella pneumoniae, Moraxella (Branhamella) catarrhalis, Neisseria gonorrhoeae (including penicillinase-producing strains), Proteus mirabilis.

Note: Cefpodoxime is inactive against most strains of Enterococcus, Pseudomonas and Enterobacter.

INDICATIONS: Treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the following conditions: Lower Respiratory Tract Infections : Community acquired pneumonia caused by S. Pneumonia or H. Influenza (including β -lactamase –producing strains). Acute bacterial exacerbation of chronic bronchitis caused by S. Pneumonia, H. Influenza (non β -lactamase –producing strains only) or M. catarrhalis. Sexually Transmitted Diseases: Acute, uncomplicated urethral and cervical gonorrhoea, and ano-rectal infections caused by Neisseria gonorrhoeae (including penicillinase-producing strains)

Skin and skin Structure: Uncomplicated skin and skin structure infections caused by Staphylococcus aureus (including penicillinase-producing strains) or Streptococcus pyogenes)
Urinary Tract Infections: Uncomplicated urinary tract infections (cystitis) caused by Escherichia coli, Klebsiella pneumonia, Proteus mirabilis or Staphylococcus saprophyticus

DOSAGE & ADMINISTRATION: Cefpodoxime Proxetil Tablets should be administered orally with food to enhance absorption (see table1)

Oral Suspension: For administration of suspension, use the calibrated dossier where the dossier cone has the calibrated marks in kg (from 5-25 kg) corresponds to the child weight e.g. The calibration mark “13” corresponds to the quantity (dose) to be administered to a “13” kg child twice daily.

Cefpodoxime Proxetil suspension is recommended to be administered during meals (see Table 2)
Renal Impairment: For patients with severe renal impairment (creatinine clearance <30mL/min), the dosing intervals should be increased to every 24 hrs. In patients maintained on haemodialysis, the dose frequency should be 3 times weekly after haemodialysis.

OVERDOSAGE: In the event of serious toxic reaction from overdose, haemodialysis or peritonealdialysis may aid in the removal of Cefpodoxime from the body, particularly if renal function is compromised.

CONTRAINDICATIONS: Known allergy to Cefpodoxime or to any of the antibiotics in the Cephalosporin group.

WARNINGS: Before therapy with Cefpodoxime is instituted, careful inquiry should be made to determine whether patient has previously hypersensitivity reactions to Cefpodoxime, other cephalosporins, penicillins or other drugs. If Cefpodoxime is to be administered to penicillin sensitive patients, caution should be exercised because cross-hypersensitivity among β -lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to Cefpodoxime occurs, discontinue use.

Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen. IV fluids and antihistamine, and airway management, as clinically indicated. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including Cefpodoxime and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea subsequent to administration of antibacterial agents.

PRECAUTIONS: Carcinogenicity: Long term animal carcinogenesis studies of Cefpodoxime have not been performed.

Mutagenicity: Mutagenesis studies of Cefpodoxime were all negative.

Use in pregnancy: There are no adequate and well controlled studies of Cefpodoxime use in pregnant women; Cefpodoxime should be used during pregnancy only if needed.

Use in lactation: Cefpodoxime is excreted in human milk. Because of the potential for serous reactions in nursing infants, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

Use in children: Safety and efficacy in infants < 5 months have not been established.

ADVERSE REACTIONS: Dispersible Tablets (Multiple Dose): In clinical trials using multiple doses of Cefpodoxime proxetil dispersible tablets, 3338 patients were treated with the recommended dosages of Cefpodoxime (100-400 mg every 12 hrs.). Adverse events thought possibly or probably related to Cefpodoxime in multiple-dose clinical trials were: Incidence > 1%: Diarrhoea 7.2%, nausea 3.8%, vaginal fungal infections 3.1%, abdominal pain 1.6%, rash 1.4%, headache 1.1%, vomiting 1.1%

Incidence < 1% : Cardiovascular: Chest Pain, hypotension.

Dermatologic: Fungal skin infection, skin scaling/ peeling

Endocrine: Menstrual irregularity

Genital: Pruritus

Gastrointestinal: Flatulence, decreased salivation, candidiasis, pseudomembranous colitis.

Hypersensitivity: Anaphylactic shock.

Metabolic: Decreased appetite.

Miscellaneous: Malaise, fever.

Central Nervous System: Dizziness, fatigue, anxiety, insomnia, weakness.

Respiratory: Cough epistaxis.

Special Senses: Altered taste, eye itching, tinnitus.

Oral Suspension (Multiple Dose): In clinical trials using multiple doses of Cefpodoxime proxetil for oral suspension, 1586 paediatric patients (90% of whom were < 12 years) were treated with the recommended dosage of Cefpodoxime (10 mg/kg/ day every 24 hrs or divided every 12 hrs to maximum equivalent adult dose)

Adverse events thought possible or probably related to Cefpodoxime proxetil the oral suspension in multiple-dose clinical trials were: Incidence > 1%: Diarrhoea 5.7%, diaper/ fungal skin rash 2.3%, other skin rashes 1.8%, vomiting 2.1%.

Incidence < 1%: Central Nervous System: Headache, irritability.

Dermatologic: Exacerbation of acne, exfoliative dermatitis.

Genital: Pruritus or vaginitis.

Gastrointestinal: Nausea, abdominal pain, candidiasis, decreased salivation, pseudomembranous colitis.

Metabolic: Decreased appetite.

Miscellaneous: Fever

Psychiatric: Hyperactivity / nervousness

Respiratory: Epistaxis, rhinitis

Laboratory Changes: Significant laboratory changes that have been reported in clinical trials of Cefpodoxime proxetil, without regard to drug relationship were: Hepatic: Transient increased AST (SGOT) ALT (SGPT), GGT, alkaline phosphatase, bilirubin and LDH.

Haematologic: Eosinophilia, leukocytosis, lymphocytosis, granulocytosis, basophilia, monocytosis, thrombocytosis, decreased haemoglobin, leukopenia, neutropenia, lymphocytopenia, thrombocytopenia, positive Coombs' test and prolonged PT and PTT.

Serum Chemistry: Increased glucose, decreased glucose, decreased serum albumin, decreased serum total protein.

Renal: Increased BUN and creatinine levels.

Most of the abnormalities were transient and not clinically significant.

INTERACTIONS: Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminium hydroxide) or H₂- blockers reduces peak plasma levels by 24-42 % and the extent of absorption by 27-32%, respectively.

Probenecid:As with other β -lactam antibiotics , renal excretion of Cefpodoxime was inhibited by probenecid, and resulted in an approximately 31% increase in AUC and 20% increase in peak Cefpodoxime plasma levels, respectively.

Drug/ Laboratory Test Interactions:Cephalosporins , including cefpodoxime proxetil are known to occasionally induce a positive direct Coombs test.

SHELF LIFE:2 Years from the date of Manufacturing

STORAGE : Store below 25 C, Protected from light & moisture.

Keep the medicine out of reach of children.

PRESENTATION: 1 x 10 Alu/Alu blister in a unit carton with package insert.

Powder for Oral Suspension (100mg/5ml)

Glass Bottle containing powder for preparation of 60 ml suspension

Mfg. Lic. No. : MB/06/308

Mfg. In India by :

M/s ASSOCIATED BIOTECH

Vill krishanpura, PO Gurumajra Baddi Distt Solan.