

COMPOSITION :

Zipotil-100 Tablets

Each film-coated tablet contains:

equivalent to Cefpodoxime 100 mg

In a flavored base

Zipotil-200 Tablets

Each film-coated tablet contains:

equivalent to Cefpodoxime 200 mg

In a flavored base

Zipotil-50 mg/5 ml Dry syrup

Each 5 ml of reconstituted suspension contains:

Equivalent to Cefpodoxime 50 mg



PHARMACOLOGY:

Inhibits Mucopeptide synthesis in bacterial cell wall.

Pharmacodynamics Cefpodoxime Proxetil is an orally administered, extended-spectrum, semi-synthetic antibiotic of the cephalosporin class. Cefpodoxime is stable in the presence of betalactamase enzymes. As a result, many organisms resistant to penicillin and cephalosporins, due to their production of beta-lactamase, may be susceptible to cefpodoxime. Cefpodoxime is inactivated by certain extended-spectrum beta-lactamases. The bactericidal activity of cefpodoxime results from its inhibition of cell wall synthesis.

Microbiology Cefpodoxime is active against a wide-spectrum of Gram-positive and Gram-negative bacteria. Cefpodoxime has been shown to be active against most strains of the microorganisms.

Pharmacokinetics Cefpodoxime Proxetil is a prodrug that is absorbed from the gastrointestinal tract and de-esterified to its active metabolite, cefpodoxime. Following oral administration of 100mg of cefpodoxime Proxetil to fasting subjects, approximately 50% of the administered cefpodoxime dose was absorbed systemically. A 100 mg dose of oral suspension produced an average peak cefpodoxime concentration of approximately 1.5 mcg/ml. When a 200 mg dose of the suspension was taken with food, the extent of absorption (mean AUC) and mean peak plasma concentration in fed subjects were not significantly different from fasted subjects, but the rate of absorption was slower with food (48% increase in Tmax). Protein binding of cefpodoxime ranges from 22% to 33% in serum and from 21% to 29% in plasma. Over the recommended dosing range (100–400 mg), approximately 29–33% of the administered cefpodoxime dose was excreted unchanged in the urine in 12 hours. There is minimal metabolism of cefpodoxime in vivo.

Effects of Food The extent of absorption (mean AUC) and the mean peak plasma concentration increased when film-coated tablets were administered with food. Following a 200 mg tablet dose taken with food, the AUC was 21 to 33% higher than under fasting conditions, and the peak plasma concentration averaged 3.1 mcg/ml in fed subjects versus 2.6 mcg/ml in fasted subjects. Time to peak concentration was not significantly different between fed and fasted subjects. When a 200 mg dose of the suspension was taken with food, the extent of absorption (mean AUC) and mean peak plasma concentration in fed subjects were not significantly different from fasted subjects, but the rate of absorption was slower with food (48% increase in Tmax).

INDICATIONS:

ZIPOTIL Tablets/Oral Suspension/DT are indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

- Acute otitis media caused by *Streptococcus pneumoniae*, (excluding penicillin resistant strains), *Streptococcus pyogenes*, *Haemophilus influenzae* (including betalactamase-producing strains), or *Moraxella (Branhamella) catarrhalis* (including betalactamase-producing strains).
- Pharyngitis and/or tonsillitis caused by *Streptococcus pyogenes*.
- Community-acquired pneumonia caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* (including beta-lactamase-producing strains). • Acute bacterial exacerbation of chronic bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (non-beta-lactamase-producing strains only), or *Moraxella catarrhalis*. Data are insufficient at this time to establish efficacy in patients with acute bacterial exacerbations of chronic bronchitis caused by beta-lactamase producing strains of *Haemophilus influenzae*.
- Acute, uncomplicated urethral and cervical gonorrhoea caused by *Neisseria gonorrhoeae* (including penicillinase-producing strains).
- Acute, uncomplicated ano-rectal infections in women due to *Neisseria gonorrhoeae* (including penicillinase-producing strains). NOTE: The efficacy of cefpodoxime in treating male patients with rectal infections caused by *Neisseria gonorrhoeae* has not been established. Data do not support the use of cefpodoxime Proxetil in the treatment of pharyngeal infections due to *Neisseria gonorrhoeae* in men or women.
- Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (including penicillinase-producing strains) or *Streptococcus pyogenes*. Abscesses should be surgically drained as clinically indicated.

- Acute maxillary sinusitis caused by Haemophilus influenzae (including betalactamase-producing strains), Streptococcus pneumoniae, and Moraxella catarrhalis.
- Uncomplicated urinary tract infections (cystitis) caused by Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, or Staphylococcus saprophyticus.

DOSAGE:

Adults and adolescents: (Tablet should be taken with food)

- Pharyngitis/ tonsillitis: 100 mg q 12hrs for 5-10 days.
- Bronchitis, acute exacerbations: 200 mg q 12hrs for 10 days.
- Pneumonia (CAP): 200 mg q 12hrs for 14 days.
- UTI Uncomplicated: 100 mg q 12hrs for 7 days.
- Gonorrhea, cervical, urethral, rectal (women) : 200 mg as a single dose.
- Skin and soft tissue infections: 400 mg q 12 hrs for 7-14 days.

Pediatrics: (5 months to 12 years)

- Otitis media: 5mg/kg (max. 200 mg) q 12 hrs for 10 days.
- Pharyngitis/ tonsillitis: 5mg/kg (max.100mg) q 12 hrs for 5-10 days.

CONTRAINDICATIONS:

Cefpodoxime Proxetil is contraindicated in patients with a known allergy to cefpodoxime or to the cephalosporin group of antibiotics.

PREGNANCY & LACTATION : Studies carried out in several animal species have not shown any teratogenic or fetotoxic effects ; however, Cefpodoxime may be administered to pregnant women only if clearly indicated. Because of the potential for serious reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug.

PRECAUTIONS:

General: It is important to consider the diagnosis of pseudomembranous colitis in patients who present with diarrhea subsequent to the administration of Cefpodoxime proxetil.

Warnings:

Particular care will be needed in patients who have had an anaphylactic response to penicillins. Cefpodoxime should not be given to those patients with a previous history of hypersensitivity to cephalosporins or other beta- lactams. Allergic reactions are particularly likely in patients with a history of allergies.

ADVERSE EFFECTS:

Adverse effects reported in clinical trials are mild and transient and include diarrhea, nausea, vomiting, abdominal pain; colitis and headache. Rarely hypersensitivity reactions, rash, pruritus, dizziness, thrombocytosis, thrombocytopenia, leucopenia or eosinophilia may occur.

DRUG INTERACTIONS:

Plasma concentrations are decreased by approximately 30 % when Cefpodoxime proxetil is administered with antacids or H2 blockers. Close monitoring of renal functions is advised when Cefpodoxime is administered concomitantly with compounds of known nephrotoxic potential. Plasma level of Cefpodoxime increased when Cefpodoxime is given with probenecid.

OVERDOSAGE:

Overdosage with Cefpodoxime proxetil has not been reported. The symptoms following an overdose of beta-lactam antibiotics may include nausea, vomiting, epigastric distress, and diarrhea. In the event of serious toxic reaction from over dosage, hemodialysis or peritoneal dialysis may aid in the removal of cefpodoxime from the body, particularly if renal function is compromised.

PACKAGING INFORMATION:

ZIPOTIL -100/200 mg Tablets : Strip pack of 10 tablets. ZIPOTIL Oral Suspension : Bottle of 30 ml.