Zilapro®

Cefprozil
Powder for Suspension

Zilapro® is a preparation of Cefprozil, which is a semi synthetic, second-generation cephalosporin antibiotic indicated for the treatment of patients with mild to moderate infections caused by susceptible strains.

- Ensures treatment success in pediatric GAS pharyngitis/tonsillitis
- A drug of choice for pediatric patients with tonsilopharyngitis
- Guarantees treatment success in SSTI

Description:
Cefprozil is a semi synthetic, second-generation cephalosporin antibiotic. Cefprozil is active in vitro against both gram positive and gram negative bacteria. The bactericidal activity of cefprozil results from the inhibition of cell wall synthesis via affinity for penicillin-binding proteins (PBPs).

Indications
Cefprozil is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains.
Infections include:

- Lower respiratory tract infections: acute bronchitis, acute exacerbations of chronic bronchitis, community acquired pneumonia.
- Upper respiratory tract and ear infections: otitis media, sinusitis, tonsillitis and pharyngitis.
- Uncomplicated skin and soft tissue infections.

Dosage and Administration
Cefprozil is administered orally

Population/Infection	Dosage (mg)	Duration (days)
Adults (13 years and older)		
Upper Respiratory Tract		
Pharyngitis/Tonsillitis	500 q 24h	10*
Acute Sinusitis	250 q 12h or 500 q 12h	10
(For moderate to severe infections the higher dose should be used)		
Lower Respiratory Tract		
Secondary Bacterial infection of Acute Bronchitis and Acute Bacterial Exacerbation of Chronic Bronchitis	500 q 12h	10
Skin and Structure		
Uncomplicated Skin and Skin Structure Infections	250 q 12h or 500 q 24h or 500 q 12h	10

Children (2 years-12 years)
Upper Respiratory Tract†
Pharyngitis/Tonsillitis 7.5 mg/kg q 12h 10*
Skin and Structure†
Uncomplicated Skin and 20 mg/kg q 24h 10
Skin Structure Infections
In the treatment of infections due to Streptococcus pyogenes, Cefprozil should be administered for at least 10 days.
Not to exceed recommended adult doses.

Population/Infection Dosage (mg) Duration (days)
Infants & Children (6 months-12 years)
Upper Respiratory Tract†
Otitis Media 15 mg/kg q 12h 10
Acute Sinusitis 7.5 mg/kg q 12h 10
15 mg/kg q 12h
For moderate to severe infections, (the higher dose should be used)
In the treatment of infections due to Streptococcus pyogenes. Cefprozil should be administered for at least 10 days.
Not to exceed recommended adult doses.
*In the treatment of infections due to Streptococcus pyogenes, Cefprozil should be administered for at least 10 days.

Contraindications
Hypersensitivity to cephalosporin antibiotics.

Use in Pregnancy and Lactation
Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Small amounts of cefprozil (<0.3% of dose) have been detected in human milk following administration of a single 1 gram dose to lactating women. Caution should be exercised when cefprozil is administered to a nursing woman, since the effect of cefprozil on nursing infants is unknown.

Adverse Effects
The adverse reactions to cefprozil are similar to those observed with other orally administered cephalosporins. Cefprozil was usually well tolerated in controlled clinical trials. The most common adverse effects of cefprozil are diarrhea, nausea, vomiting, abdominal pain, rash, urticaria, dizziness, hyperactivity, insomnia, confusion etc.

Precautions
In patients with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be done prior to and during therapy. Prolonged use of cefprozil may result in the overgrowth of nonsusceptible organisms. Cefprozil should be prescribed with caution in individuals with a history of gastrointestinal disease particularly colitis.

Drug Interactions
Nephrotoxicity has been reported following concomitant administration of aminoglycoside antibiotics and cephalosporin antibiotics. Concomitant administration of probenecid doubled the AUC for cefprozil.

Pharmaceutical Precautions
Zilapro® powder for suspension should be stored in a cool, dry place (preferably below 30°C) and should be protected from light. Keep out of reach of children.

Commercial Pack
Zilapro® Powder for Suspension: Amber glass bottle containing powder for the preparation of 50 ml Suspension. After reconstitution each 5 ml suspension contains Cefprozil USP equivalent to 250 mg anhydrous Cefprozil.

Manufactured by
Beximco Pharmaceuticals Ltd.
TONGI, Bangladesh

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