Zemicef™

Cefixime Capsule & Suspension

Presentation
Zemicef™ 200 Capsule: Each capsule contains Cefixime USP equivalent to 200 mg Anhydrous Cefixime.
Zemicef™ 400 Capsule: Each capsule contains Cefixime USP equivalent to 400 mg Anhydrous Cefixime.
Zemicef™ Powder for Suspension: Each 5 ml suspension contains Cefixime USP equivalent to 100 mg Anhydrous Cefixime.
Zemicef™DS Powder for Suspension: Each 5 ml suspension contains Cefixime USP equivalent to 200 mg Anhydrous Cefixime.

Description
Cefixime is a broad spectrum Cephalosporin antibiotic of third generation for oral administration. It is a bactericidal antibiotic and is stable to hydrolysis by many beta-lactamases. Cefixime kills bacteria by interfering the synthesis of the bacterial cell wall. Cefixime is highly active against *Neisseria gonorrhoeae, Haemophilus influenzae, Morexella catarrhalis* including beta-lactamase producers. Most of them are Enterobacteriaceae, beta-haemolytic Streptococci (Group A & B) and *Streptococcus pneumoniae.* Cefixime is more active than other oral Cephalosporins against *Escherichia coli, Klebsiella spp, Proteus mirabilis* and *Serratia marcescens.* Cefixime is also active against *Streptococcus pyogenes*. 40-50% of an oral dose is absorbed from gastro-intestinal tract, whether taken with meals or not. The plasma half-life is usually about 3 to 4 hours and may be prolonged when there is renal impairment. About 65% is bound to plasma protein. Cefixime is mainly excreted unchanged in bile and urine.

Indications
Treatment of the following infections caused by susceptible strains of the designated microorganisms:
Middle Ear: Otitis media caused by *S. pneumoniae, H. influenzae* (beta-lactamase positive and negative strains), *B. catarrhalis* (beta-lactamase positive and negative strains) and *S. pyogenes. Paranasal Sinuses*: Sinusitis caused by *S. pneumoniae*, *H. influenzae* (beta-lactamase positive and negative strains), and *B. catarrhalis* (beta-lactamase positive and negative strains). *Urinary Tract:* Acute uncomplicated cystitis and urethritis caused by *E. coli, P. mirabilis,* and *Klebsiella species*. *Upper Respiratory Tract:* Pharyngitis and tonsillitis caused by *S. pyogenes*. *Lower Respiratory Tract*: Acute bronchitis caused by *S. pneumoniae*, *B. catarrhalis* (beta-lactamase positive and negative strains) and *H. influenzae* (beta-lactamase positive and negative strains). *Uncomplicated Gonorrhea:* Uncomplicated gonorrhea (cervical/urethral and rectal) caused by *N. gonorrhoeae*, including penicillinase (beta-lactamase-positive) and nonpenicillinase (beta-lactamase-negative) producing strains.

Dosage and Administrations
Adult: 1 or 2 capsules (200-400 mg) as once or in 2 divided doses daily for 7-14 days, according to the severity of the infection.
Children above 6 months: 8 mg per kg body weight as a single dose or in two divided doses for 7-14 days according to the severity of the infection or as following:
6 months-1 year: 75 mg/day
1-4 years: 100 mg/day
5-10 years: 200 mg/day
11-12 years: 300 mg/day
Above 12 years: Adult dose may be administered.
Efficacy and safety in infants aged less than six months have not been established.

Side Effects
Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials was mild and self-limiting in nature. *Gastro-intestinal disturbances:* such as Diarrhoea (if severe diarrhoea occurs, Cefixime should be discontinued), changes in the color of stool, nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported. *Central nervous system disturbances:* Headache, dizziness, etc. *Others:* Hypersensitivity reactions which usually subsided upon discontinuation of therapy; infrequent and reversible haematological changes; elevation of serum amylase, etc.

Contraindications
Cefixime is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Precautions
Cefixime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. Dosage adjustment is only necessary in severe renal failure (creatinine clearance < 20 ml/min). *Use in pregnancy and lactation:* No data is available, so it is probably the best to avoid using the drug during pregnancy and by the nursing mothers.

Drug Interactions
Carbamazepine: Elevated carbamazepine levels have been reported in postmarketing experience when Cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations. *Warfarin and Anticoagulants:* Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.

Overdosage
Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of Cefixime did not differ from the profile seen in patients treated at the recommended doses.

Direction for Reconstitution
Zemicef™ 30 ml, 40 ml & 50 ml and Zemicef™DS 50 ml suspension: One bottle contains the powder; another bottle contains the diluent. Shake the bottle to loosen the powder. Now pour the diluent completely into the bottle of powder. For ease of preparation, pour the diluent in two portions. Do not add extra water to the suspension. Close the bottle tightly & shake the bottle gently until the powder is dissolved properly. Now the suspension is ready for use. Shake the bottle well before each use.

Pharmaceutical Precautions
Store in a cool dry place protected from light. Keep out of reach of children.

Commercial Packs
Zemicef™ 200 Capsule: Each box contains 2X7's capsules in Alu-Alu blister pack.
Zemicef™ 400 Capsule: Each box contains 2X4's capsules in Alu-Alu blister pack.
Zemicef™ 30 ml Powder for Suspension: Box containing two bottles. One bottle contains Cefixime powder to reconstitute suspension & another bottle contains diluent for preparing suspension. After reconstitution as per direction the bottle of powder contains 30 ml suspension.
Zemicef™ 40 ml Powder for Suspension: Box containing two bottles. One bottle contains Cefixime powder to reconstitute suspension & another bottle contains diluent for preparing suspension. After reconstitution as per direction the bottle of powder contains 40 ml suspension.
Zemicef™ 50 ml Powder for Suspension: Box containing two bottles. One bottle contains Cefixime powder to reconstitute suspension & another bottle contains diluent for preparing suspension. After reconstitution as per direction the bottle of powder contains 50 ml suspension.
Zemicef™DS 50 ml Powder for Suspension: Box containing two bottles. One bottle contains Cefixime powder to reconstitute suspension & another bottle contains diluent for preparing suspension. After reconstitution as per direction the bottle of powder contains 50 ml suspension.

Manufactured by :

POPULAR

POPULAR PHARMACEUTICALS LTD.
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