Buticef

Ceftibuten INN

Composition:
Buticef powder for suspension: Each 5 ml contains Ceftibuten 90 mg as Ceftibuten Dihydrate INN.
Butacef 400 mg capsule: Each film coated tablet contains Ceftibuten 400 mg as Ceftibuten Dihydrate INN.

Description: Ceftibuten is a third-generation Cephalosporin antibiotic. Ceftibuten exerts its bactericidal action by binding to essential target proteins of the bacterial cell wall. This binding leads to inhibition of cell-wall synthesis.
Pharmacokinetics: Ceftibuten is very well absorbed after oral administration Apparent plasma clearance (CL/F), is approximately 40-75 ml/min, and the renal clearance is approximately 30-50 ml/min, corresponding to the fraction excreted unchanged in the urine of approximately 60%-70% of the dose. The apparent volume of distribution after oral dosing (Vd/F) was approximately 0.2 L/kg.

Indication: Acute Bacterial Exacerbations of Chronic Bronchitis due to Haemophilus influenzae(including β-lactamase-producing strains), Moraxella catarrhalis (including β-lactamase-producing strains), or Streptococcus pneumoniae (penicillin-susceptible strains only). **Acute Bacterial Otitis Media** due to Haemophilus influenzae (including β-lactamase-producing strains), Moraxella catarrhalis (including β-lactamase-producing strains), or Streptococcus pyogenes. **Pharyngitis and Tonsillitis** due to Streptococcus pyogenes.

Dosage and administration:
Adults: 400 mg once a day for 10 days.
Children 6 months up to 12 years of age- Usually 9 mg/kg of body weight a day for 10 days.

Renal Impairment: Cetibuten Capsules may be administered at normal doses in the presence of impaired renal function with Creatinine Clearance (CrCl) of 50 mL/min or greater. **CrCl:** 30-49 mL/min recommended dose is 4.5 mg/kg or 200 mg Q24h; **CrCl**: 5-29 mg/kg recommended dose is 2.25g/kg or 100 mg Q24h.

Direction for reconstitution of powder for suspension:

- One bottle contains the powder and another bottle contains the diluent.
- Shake the powder filled bottle to loosen the powder . Then pour the diluent completely into the powder filled bottle.
- Tighten the cap of the bottle and shake vigorously until it is properly mixed.
- Reconstituted suspension should be used within 14 days.

Drug Interaction: Ceftibuten with Antacids or H_2-receptor antagonists may increase the Ceftibuten Cmax.

Overdose: Overdosage of Cephalosporins can cause cerebral irritation leading to convulsions. Ceftibuten is readily dialyzable and significant quantities (65% of plasma concentrations) can be removed from the circulation by a single hemodialysis session. Information does not exist with regard to removal of Ceftibuten by peritoneal dialysis.

Contraindication: Ceftibuten is contraindicated in patients with known allergy to the Cephalosporin group of antibiotics.

Precaution: Ceftibuten is readily dialyzable. Dialysis patients should be monitored carefully, and administration of Ceftibuten should occur immediately following dialysis. Ceftibuten should be prescribed with caution to individuals with a history of gastrointestinal disease, particularly colitis.

Side effect: Nausea, Diarrhea, Headache, Increased eosinophils, Decreased hemoglobin, Dyspepsia, Thrombocytosis, Abdominal pain, Dizziness, Increased bilirubin, vomiting.

Use in pregnancy and lactation: Pregnancy Category B There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Lactation:** It is not known whether Ceftibuten (at recommended dosages) is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ceftibuten is administered to a nursing woman.

Storage: Store the capsules between 2° to 25°C. Protect from light and moisture.

Presentation:
Buticef 400 mg capsule: Each box contains 10 capsuls in blister pack.
Buticef powder for suspension: Bottle contains dry powder to make 60 ml suspension.

Manufactured by:
The **IBN SINA** Pharmaceutical Industry Ltd.
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