Tibucef

Ceftibuten Dihydrate INN

Presentation

Tibucef 400 Capsule: Each capsule contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 400 mg.
Tibucef Powder for Suspension: After reconstitution each 5 ml suspension contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 90 mg.

Description

Ceftibuten dihydrate is a third-generation semisynthetic cephalosporin antibiotic for oral administration used to treat certain infections caused by bacteria. Ceftibuten exerts its bactericidal action by binding to essential target proteins of the bacterial cell wall. Ceftibuten was found to be very stable in the presence of five commonly occurring beta-lactamases of both the chromosomal-mediated (P99, K1) and plasmid-mediated (CARB-2, OXA-1, TEM-1) types.

Pharmacokinetics

Ceftibuten is rapidly and almost completely absorbed following oral administration where food decreases rate and extent of absorption of Ceftibuten. Oral bioavailability is 75–90%. Ceftibuten is distributed into blister fluid, bronchial secretions, nasal secretions, sputum, middle ear fluid, tracheal secretions, and tonsillar tissue. The drug is 65% bound to plasma proteins. The half-life of Ceftibuten in adults with normal renal function is 2–2.6 hours & children 6 months to 16 years of age is 1.9–2.5 hours. But in renal impaired patients the average plasma half-life is 7.1–22.3 hours depending on creatinine clearance. Ceftibuten is present in plasma and urine principally as cis-Ceftibuten; about 10% of a dose is converted in vivo to trans-Ceftibuten. Approximately 56% of a dose eliminated in urine and 39% excreted in feces within 24 hours.

Indications

Tibucef is indicated for the treatment of following conditions-

- ***Acute Bacterial Exacerbations of Chronic Bronchitis*** due to *Haemophilus influenzae* & *Moraxella catarrhalis* (including β-lactamase-producing strains) or *Streptococcus pneumoniae* (penicillin-susceptible strains only).
- ***Acute Bacterial Otitis Media*** due to *Haemophilus influenzae* & *Moraxella catarrhalis* (including β-lactamase-producing strains) or *Streptococcus pyogenes*.
- ***Pharyngitis and Tonsillitis*** due to *Streptococcus pyogenes.*
- ***Pneumonia & Sinusitis***
- ***Typhoid***
  Gastroenteritis
- ***Uncomplicated UTIs*** caused by susceptible *Escherichia coli,* Klebsiella, *Proteus mirabilis*, Enterobacter, or Staphylococci.
- ***Complicated or recurrent UTIs*** caused by susceptible *E. coli,* Klebsiella, *P. mirabilis,* Enterobacter, or Staphylococci.

Dosage & Administration

Adolescents & adults (12 years and older):

Infection	Dose	Frequency	Duration
Acute Exacerbations of Chronic Bronchitis	400 mg	once daily	10 days
Pneumonia	400 mg	once daily	07-14 days
Acute Otitis Media	400 mg	once daily	10 days
Sinusitis	400 mg	once daily	10-14 days
Pharyngitis and Tonsillitis	400 mg	once daily	10 days
Uncomplicated UTIs	400 mg	once daily	07 days

Pediatric patients (6 months to 12 years):
9 mg/kg once daily for 10 days.

Hepatic Impairment

Dosage adjustment is not required.

Renal Impairment

Patient with impaired renal function the dosage adjustment is required as following-

CrCl (mL/min)	Daily Dosage
>50	9 mg/kg or 400 mg once daily
30–49	4.5 mg/kg or 200 mg once daily
5–29	2.25 mg/kg or 100 mg once daily

Preparation of Suspension

Shake the bottle well to loosen the powder. To prepare 60 ml suspension, add 35 ml of boiled and cooled water (by given measuring cup) to the dry powder of the bottle. For ease of preparation, add water to the bottle in two proportions. Shake the bottle well after each addition until all the powder is in suspension.
Reconstituted suspension should be kept tightly closed and to be consumed within 14 days of preparation while store in a refrigerator (2°C- 8° C temperature). Shake the suspension well before each use.

Side Effect

Ceftibuten may causes nausea, vomiting, headache, diarrhea, dyspepsia, abdominal pain. In less than 1% or greater than 0.1% case Ceftibuten may causes anorexia, constipation, dry mouth, dyspnea, fatigue, flatulence, nasal congestion, paresthesia, rash, somnolence, urticaria, vaginitis.

Precaution

Ceftibuten should be used with caution to individuals with a history of gastrointestinal disease, particularly colitis.

Contraindication

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

Use in Pregnancy & Lactation

Pregnancy: Ceftibuten was not teratogenic in the pregnant rat at oral doses up to 400 mg/kg/day (approximately 8.6 times the human dose based on mg/m^2/day). ***Lactation:*** It is not known whether Ceftibuten (at recommended dosages) is excreted in human milk. Caution should be exercised when Ceftibuten is administered to a nursing woman.

Drug Interaction

Theophylline & Antacids: Theophylline & Antacids does not affect the C_{max} or AUC of Ceftibuten.
H2-receptor antagonists: Ranitidine increased the Ceftibuten C_{max} by 23%.

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.

Storage

Ceftibuten should be kept in a cool (below 25° C) and dry place and protected from light & children.

Commercial Pack

Tibucef 400 Capsule: Each box containing 1x6 capsules in Alu-Alu Strip.
Tibucef Powder for Suspension: Each box contain a bottle containing powder for 60 ml suspension, a measuring cup and a dropper.

Manufactured by

GLOBE PHARMACEUTICALS LTD.
Noakhali, Bangladesh