Logibac

Capsule/ Powder for Suspension

Ceftibuten

COMPOSITION

Logibac 400 mg Capsule: Each capsule contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 400 mg.

Logibac 60 ml Powder for Suspension: When reconstituted each 5 ml suspension contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 90 mg.

PHARMACOLOGY

Ceftibuten is a semisynthetic oral cephalosporin. It is stable in the presence of most plasmid mediated β-lactamases and is found highly effective against both gram (+ve) and gram (-ve) agents including S. pneumoniae, S. pyogenes, H. influenzae, M. catarrhalis etc.

MODE OF ACTION

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 capsule and suspension are rapidly absorbed after oral administration Ceftibuten accumulation is about 20% at steady state. The average apparent volume of distribution of Ceftibuten capsule is 0.21 L/kg (±1SD=0.03L/kg) and suspension is 0.5L/kg (±1SD=0.2L/kg). 10% of Ceftibuten is converted to the trans-isomer. The trans-isomer is approximately ½ as antimicrobially potent as the cis-isomer. Ceftibuten is excreted in the urine.

INDICATIONS

Ceftibuten (Logibac) is indicated for the treatment of individuals with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

• 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 & ADMINISTRATION

Route of administration: Oral.

Adults: 400 mg once daily for 10 days.

Child: 9 mg/kg once daily for 10 days.

OR AS DIRECTED BY PHYSICIAN.

CONTRAINDICATIONS

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

WARNING & PRECAUTION

As with other broad-spectrum antibiotics, prolonged treatment may result in the possible emergence and overgrowth of resistant organisms. Careful observation of the patient is essential. The dose of Ceftibuten may require adjustment to patients with varying degrees of renal insufficiency, particularly in patients with Creatinine clearance less than 50 mL/min or undergoing hemodialysis. Ceftibuten is readily dialyzable. Dialysis 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 EFFECTS

Common side effects: The following adverse experiences have been reported during worldwide post-marketing surveillance: aphasia, jaundice, melena, psychosis, serum sickness-like reactions, stridor, and toxic epidermal necrolysis.

Rare side effects: Anorexia, Constipation, Dry mouth, Dyspnea, Dysuria, Eructation, Fatigue, Flatulence, Loose stools, Moniliasis, Nasal congestion, Paresthesia, Pruritus, Rash, Somnolence, Taste perversion, Urticaria, Vaginitis

USE IN PREGNANCY & LACTATION

Ceftibuten has revealed no evidence of harm to the fetus. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction is not always predictive of human response, this drug should be used during pregnancy only if clearly needed. It is not known whether Ceftibuten (recommended dosages) is excreted in human milk. Though many drugs are excreted in human milk, caution should be exercised when Ceftibuten is administered to nursing women.

USE IN CHILDREN & ADOLESCENTS

The safety and efficacy of Ceftibuten in infants less than 6 months of age has not been established. The usual adult dosage recommendation may be followed for patients in this age group

DRUG INTERACTION

With medicine: Theophylline & Antacid: Do not alter the pharmacokinetic profile of Ceftibuten.

Ranitidine: Increases the Cmax & AUC of Ceftibuten.

With food & others: Food affects the bioavailability of ceftibuten capsules and oral suspension

OVERDOSAGE

Overdosage of Ceftibuten 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

Store below 30°C & dry place, protect from light.

Keep all medicines out of reach of children.

PACKING

Logibac 400 mg Capsule: Each box contains 2x4 capsules in blister pack.

Logibac 60 ml Powder for Suspension: Each bottle contains Dry Powder for 60 ml Suspension with an oral dispenser.

*** Further information is available on request.**

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Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness