Cebumax™

Ceftibuten Capsule & Powder for Suspension

Presentation
Cebumax™ 400 mg Capsule: Each capsule contains Ceftibuten 400 mg (as Ceftibuten Dihydrate INN).
Cebumax™ 60 ml Powder for Suspension: Each 5 ml contains Ceftibuten 90 mg (as Ceftibuten Dihydrate INN).

Properties and effects
Ceftibuten is a semisynthetic oral cephalosporin. It exerts its bactericidal action by binding to essential target proteins of the bacterial cell wall. This binding leads to inhibition of cell-wall synthesis.

Pharmacokinetic Properties
Ceftibuten is rapidly absorbed after oral administration. Ceftibuten accumulation in plasma is about 20% at steady state. The average apparent volume of distribution (V/F) of ceftibuten capsule and powder for suspension is 0.21 L/kg and 0.5 L/kg. Ceftibuten is 65% bound to plasma proteins. About 10% of ceftibuten is converted to the trans-isomer. The trans-isomer is approximately ⅛ as antimicrobially potent as the cis-isomer. Ceftibuten is excreted in the urine.

Indications
- Acute Bacterial Exacerbations of Chronic Bronchitis
- Pharyngitis
- Tonsillitis
- Acute Bacterial Otitis Media

Dosage and Administration
For adult:
400 mg once daily for 10 days
For children:
Standard dose for pediatric patient is 9 mg/kg once daily for 10 days. Oral Suspension must be administered at least 2 hours before or 1 hour after a meal. Pediatric dosage chart is as follows:

CHILD'S WEIGHT	90 mg/5 mL	180 mg/5 mL
10 kg/22 lbs	1 tsp QD	1/2 tsp QD
20 kg/44 lbs	2 tsp QD	1 tsp QD
40 kg/88 lbs	4 tsp QD	2 tsp QD

Pediatric patients weighing more than 45 kg should receive the maximum daily dose of 400 mg.

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

Side Effects
The following adverse experiences have been reported during worldwide post-marketing surveillance: aphasia, jaundice, melena, psychosis, stridor, Stevens-Johnson syndrome, and toxic epidermal necrolysis.

Precautions
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. If superinfection occurs during therapy, appropriate measures should be taken. The dose of ceftibuten may require adjustment in patients with varying degrees of renal insufficiency, particularly in patients with creatinine clearance less than 50 mL/min or undergoing hemodialysis. 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.

Over Dose
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.

Drug Interactions
Theophylline and antacid do not alter the pharmacokinetic profile of Ceftibuten. Ranitidine increases the Cmax and AUC of Ceftibuten.

Use in Pregnancy & Lactation
Pregnancy category B. It is not known whether Ceftibuten is excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when it is administrated to a nursing mother.

Storage Conditions
Store in a cool (below 25˚C) & dry place; away from light. Keep out of reach of children. After reconstitution suspension may be used for 14 days while stored at 2˚–8˚C.

Commercial Pack
Cebumax™ 400 mg Capsule: Each box contains 2 Alu-Alu pouch of 4 capsules.
Cebumax™ 60 ml Powder for Suspension: Each box contains 2 bottles one having dry powder and other contain 45 ml diluents to reconstitute 60 ml suspension.

Manufactured by:
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