Ceftoril®

Ceftibuten
Capsule/Suspension

Description
Ceftibuten is a semisynthetic 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.

Indications
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 daily for 10 days.
Pediatric Patients: Children 6 months & above: 9 mg/kg once daily for 10 days.

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

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. 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. 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.

Drug Interactions
Theophylline
The effect of ceftibuten on the pharmacokinetics of theophylline administered orally has not been investigated.
Antacids or H2-receptor antagonists
The effect of increased gastric pH on the bioavailability of ceftibuten was evaluated in 18 healthy adult volunteers. Each volunteer was administered one 400 mg ceftibuten capsule. A single dose of liquid antacid did not affect the Cmax or AUC of ceftibuten; however, 150 mg of ranitidine every 12 hours for 3 days increased the ceftibuten Cmax by 23% and ceftibuten AUC by 16%. The clinical relevance of these increases is not known.

Adverse Effects
Nausea, vomiting, diarrhea, stomach upset or headache may occur.

Use in Special Population
Pregnancy: *Pregnancy Category B*
There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.
Nursing Mothers
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.
Pediatric Use
The safety and efficacy of ceftibuten in infants less than 6 months of age has not been established.
Geriatric Patients
Geriatric patients should be monitored closely, particularly their renal function, as dosage adjustment may be required.

Pharmaceutical Precaution
Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

Commercial Pack
Ceftoril® Casule: Box contains 8 capsules in 2X4's Alu-Alu blister strips. Each blister strip is packed within a pouch. Each capsule contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 400 mg.
Ceftoril® Suspension: Bottle contains 60 ml of suspension. Each 5 ml contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 90 mg.

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