Only for the use of Medical Professionals

Cefteria®

Ceftibuten

Description

Cefteria® is a preparation of Ceftibuten Dihydrate which is a semisynthetic oral cephalosporin. Ceftibuten exerts its bactericidal action by binding to essential target proteins of bacterial cell wall. This binding leads to inhibition of cell wall synthesis.

Indications

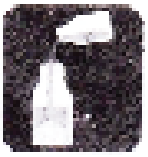
Cefteria® is indicated for the treatment of individuals with mild to moderate infection caused by strains of the designated microorganism in the specific condition listed below-

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

Dosage & administration

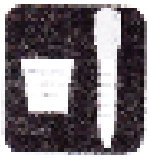
Adults: 400 mg once daily for 10 days
Children: 9 mg/kg once daily for 10 days.
Pediatric patients weighing more than 45 kg should receive the maximum daily dose of 400 mg.

1. Small bottle contains diluent and large bottle contains powder for suspension.



2. Pour the diluent slowly into large bottle.

3. Tighten the cap of large bottle and shake the bottle vigorously.



4. Use measuring cup or dropper to consume reconstituted suspension.

Directions for preparation of suspension

Small bottle contains diluent and large bottle contains powder for suspension. Pour the diluent slowly into large bottle. Tighten the cap of large bottle and shake vigorously. Use measuring cup or dropper to consume reconstituted suspension. The reconstituted suspension is stable for 14 days when stored in the refrigerator at 2°C-8°C.
60 ml suspension: Add 40 ml diluent for 60 ml.
120 ml suspension: Add 80 ml diluent for 120 ml.

Use in pregnancy & lactation

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.

Lactation

It is not known whether Ceftibuten is excreted into milk. Caution should be exercised when Ceftibuten is administered to a nursing mother, if necessary breastfeeding must be discontinued.

Side effects
The most common side effects include aphasia, jaundice, melena, psychosis, serum sickness-like reactions, stridor, and toxic epidermal necrolysis.

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

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 super infection 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.

Warnings
Ceftibuten should be prescribed with caution in individuals with a history of gastrointestinal diseases, particularly colitis. 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. Before therapy with the Ceftibuten is instituted, Careful inquiry should be made to determine whether the patient has had record of hypersensitivity reactions to Ceftibuten, other cephalosporin, penicillin or other drugs.

Drug interaction
Antacids or H2 receptor antagonists: The effect of increased gastric pH on the bioavailability of Ceftibuten was evaluated. A single dose of antacid did not affect the C_{max} or AUC of the Ceftibuten. However, 150 mg of ranitidine q12h for 3 days increased the Ceftibuten C_{max} by 23% and Ceftibuten AUC by 16%.

Overdose
Overdosage of cephalosporin can cause cerebral irritation leading to convulsions. Ceftibuten is readily dialyzable and significant quantities can be removed from the circulation by a single hemodialysis session.

Pharmaceutical precautions
Store in a cool (below 25°C) and dry place protected from light.

Presentation
Cefteria® capsule: Each capsule contains Ceftibuten 400 mg as Dihydrate INN.
Cefteria® powder for suspension: After reconstitution each 5 ml contains Ceftibuten 90 mg as Dihydrate INN.

Package quantities
Cefteria® capsule: Carton of 10 capsules in blister pack in sachet.
Cefteria® powder for suspension: Bottle of 60 ml & 120 ml with diluent.

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