Cebuten®

Ceftibuten Dihydrate INN

PRESENTATION:
Cebuten 400mg capsule:
Each capsule contains Ceftibuten dihydrate INN equivalent to Ceftibuten 400mg.

DESCRIPTION:
Ceftibuten is the dihydrate salt of Ceftibuten, is a semi synthetic Cephalosporin antibiotic for oral administration.

PHARMACOKINETICS:
Absorption:
Cebuten is rapidly absorbed after oral administration. When Ceftibuten capsules were administered once daily for 7 days, the average Cmax was 17.9 µg/mL on day 7. Therefore, Ceftibuten accumulation in plasma is about 20% at steady state.
Distribution: The average apparent volume of distribution (V/F) of Ceftibuten in 6 adult subjects is 0.21 L/kg (1 SD = 0.03 L/kg).

Protein Binding:
Ceftibuten is 65% bound to plasma proteins. The protein binding is independent of plasma Ceftibuten concentration.

Tissue Penetration:
Bronchial secretions:
In a study of 15 adults administered a single 400-mg dose of Ceftibuten and scheduled to undergo bronchoscopy, the mean concentrations in epithelial lining fluid and bronchial mucosa were 15% and 37%, respectively, of the plasma concentrations.

Sputum:
Ceftibuten sputum levels average approximately 7% of the concomitant plasma Ceftibuten level. In a study of 24 adults administered Ceftibuten 200 mg bid or 400 mg qd, the average Cmax in sputum (1.5µg/mL) occurred at 2 hours post dose and the average Cmax in plasma (17µg/mL) occurred at 2 hours.

Middle-ear fluid (MEF):
In a study of 12 pediatric patients administered 9 mg/kg, Ceftibuten MEF area under the curve (AUC) averaged approximately 70% of the plasma AUC. In the same study, Cmax values were 14.3±2.7 µg/mL in MEF at 4 hours post dose and 14.5±3.7 µg/mL in plasma at 2 hours post dose.

Tonsillar tissue:
Data on Ceftibuten penetration into tonsillar tissue are not available.
Cerebrospinal fluid: Data on Ceftibuten penetration into cerebrospinal fluid are not available.

METABOLISM AND EXCRETION:
Ceftibuten is excreted in the urine; 95% of the administered radioactivity was recovered either in urine or feces.

INDICATIONS:
Cebuten is used to treat acute bacterial exacerbations of chronic bronchitis (ABECB), acute bacterial otitis media, pharyngitis, and tonsilitis. It is also indicated for pneumonia, infections of the urinary tract, enteritis and gastroenteritis.

DOSAGE AND ADMINISTRATION:
The usual dose of Cebuten is 400mg once daily.

SPECIAL POPULATIONS:
Geriatric patients:
Ceftibuten pharmacokinetics have been investigated in elderly (65 years of age and older) men (n = 8) and women (n = 4). Each volunteer received Ceftibuten 200-mg capsules twice daily for 3.5 days. The average Cmax was 17.5 (3.7) µg/mL after 3.5 days of dosing compared to 12.9 (2.1) µg/mL after the first dose; Ceftibuten accumulation in plasma was 40% at steady state. Information regarding the renal function of these volunteers was not available; therefore, the significance of this finding for clinical use of CEFTIBUTEN Capsules in elderly patients is not clear. Ceftibuten dosage adjustment in elderly patients may be necessary.

Patients with renal insufficiency:
Ceftibuten pharmacokinetics has been investigated in adult patients with renal dysfunction. The Ceftibuten plasma half-life increased and apparent total clearance (Cl/F) decreased proportionately with increasing degree of renal dysfunction. In 6 patients with moderate renal dysfunction (creatinine clearance 30 to 49 mL/min), the plasma half-life of Ceftibuten increased to 7.1 hours and Cl/F decreased to 30 mL/min. In 6 patients with severe renal dysfunction (creatinine clearance 5 to 29 mL/min), the half-life increased to 13.4 hours and Cl/F decreased to16 mL/min. In 6 functionally anephric patients (creatinine clearance <5 mL/min), the half-life increased to 22.3 hours and Cl/F decreased to 11 mL/min (a 7- to 8-fold change compared to healthy volunteers). Hemodialysis removed 65% of the drug from the blood in 2 to 4 hours. These changes serve as the basis for dosage adjustment recommendations in adult patients with mild to severe renal dysfunction.

CONTRAINDICATIONS:
Cebuten is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS:
Before therapy with the Cebuten product is instituted, careful inquiry Should be made to determine whether the patient has had previous Hypersensitivity reactions to ceftibuten, other cephalosporin, penicillin, or other drugs. If this product is to be given to penicillin sensitive Patients, caution should be exercised because cross Hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to the Ceftibuten product occurs, discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures.

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.

STORAGE:
Store in a cool (below 30ºC) dry place, away from light and children.

PACK SIZE:
Each box of Cebuten 400 contains 2 X 7's capsules.

®TRADE MARK
Manufactured by
RENATA LIMITED
Rajendrapur, Gazipur, Bangladesh
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