

Zoventa[®]

Ceftibuten INN



Presentation

Zoventa[®] 200: Each capsule contains Ceftibuten (Dihydrate) INN 217.54 mg equivalent to Ceftibuten 200 mg.
Zoventa[®] 400: Each capsule contains Ceftibuten (Dihydrate) INN 435.08 mg equivalent to Ceftibuten 400 mg.
Zoventa[®] Powder for Suspension: After reconstitution each 5 ml suspension contains Ceftibuten (Dihydrate) INN 97.89 mg equivalent to Ceftibuten 90 mg.
Zoventa[®] DS Powder for Suspension: After reconstitution each 5 ml suspension contains Ceftibuten (Dihydrate) INN 195.78 mg equivalent to Ceftibuten 180 mg.

Description

Ceftibuten Dihydrate is a semisynthetic cephalosporin antibiotic for oral administration.

Indication, Dosage & Administration

Indication	Adult Dosage	Pediatric Dosage
Otitis Media	400 mg orally every 24 hours for 10 days	> 6 months: 9 mg/kg/day (maximum 400 mg) every 24 hours for 10 days
Tonsillitis/Pharyngitis	400 mg orally every 24 hours for 10 days	> 6 months: 9 mg/kg/day (maximum 400 mg) every 24 hours for 10 days
Bronchitis	400 mg orally every 24 hours for 10 days	>12 years: 400 mg orally every 24 hours for 10 days
Cystitis	400 mg orally every 24 hours for 7 days	>12 years: 400 mg orally every 24 hours for 7 days
Pneumonia	200 mg orally every 12 hours for 7 to 14 days	>12 years: 200 mg orally every 12 hours for 7 to 14 days
Sinusitis	400 mg orally every 24 hours for 10 to 14 days	>12 years: 400 mg orally every 24 hours for 10 to 14 days
Urinary tract Infection	400 mg orally every 24 hours for 10 days	> 6 months: 9 mg/kg/day (maximum 400 mg) every 24 hours for 10 days

Dose Adjustment in special cases

Renal Impairment

CrCl 5 to 29 ml/min: 2.25 mg/kg or 100 mg orally once a day
CrCl 30 to 49 ml/min: 4.5 mg/kg or 200 mg orally once a day

Hepatic Impairment

Dose adjustment is not necessary.

Reconstitution of suspension

- Shake bottle to loosen powder.
- Open the bottle cap carefully.
- Withdraw 5ml of boiled & cooled water with oral dispenser.
- Slowly add 5ml water into the bottle.
- Repeat 3 & 4 procedures 8 times to add 40 ml water. 5ml x 8 times = 40 ml.
- Shake well for 1 to 2 minutes to obtain a homogenous suspension.

Side effects

Aphasia, jaundice, melena, psychosis, stridor, toxic epidermal necrolysis, serum sickness-like reactions and Stevens-Johnson syndrome reported.

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. Dialysis patients should be monitored carefully and administration of Ceftibuten should occur immediately following dialysis.

Use in pregnancy and lactation

Pregnancy: Pregnancy Category B. There are no controlled data on the use of Ceftibuten in pregnant women. Ceftibuten should be used in pregnancy only when the benefit clearly outweighs the risk.

Lactation: It is not known whether Ceftibuten (recommended dosage) is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ceftibuten is administered to nursing women.

Contraindications

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

Drug Interactions

Theophylline & Antacids: Do not alter the pharmacokinetics of Ceftibuten.
H2-receptor antagonists: Ranitidine increase the Cmax & AUC of Ceftibuten.

Overdose

Overdose 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.

Commercial pack

Zoventa[®] 200: Each box contains 2 x 6's capsules in Alu-Alu blister pack.
Zoventa[®] 400: Each box contains 1 x 6's capsules in Alu-Alu blister pack.
Zoventa[®] Powder for Suspension: Each bottle contains Ceftibuten dry powder to reconstitute 60 ml suspension.
Zoventa[®] DS Powder for Suspension: Each bottle contains Ceftibuten dry powder to reconstitute 60 ml suspension.

Storage

Store at temperature not exceeding 30°C in a dry place. Protect from light and moisture.

Medicine: Keep out of reach of children



Healthcare

Manufactured by
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