Orbuten

Ceftibuten

Composition:

Orbuten Powder for Suspension: After reconstitution each 5 ml suspension contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 90 mg.

Pharmacology:

Microbiology: 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. Ceftibuten is stable in the presence of most plasmid-mediated beta-lactamases. Ceftibuten has been shown to be active against most strains of the following organisms- Gram-positive aerobes: *Streptococcus pneumoniae* (penicillin-susceptible strains), *Streptococcus pyogenes*. Gram-negative aerobes: *Haemophilus influenzae* (including beta-lactamase-producing strains) *Moraxella catarrhalis* (including beta-lactamase-producing strains).

Indications:

Ceftibuten is indicated for infections caused by susceptible microorganisms: 1) Acute Bacterial Exacerbations of Chronic Bronchitis 2) Pharyngitis and Tonsillitis 3) Acute Bacterial Otitis Media. Ceftibuten is also effective in treating urinary tract infection, pneumonia, enteric fever, gastroenteritis etc.

Dosage and administration:

For children: The dose is 9 mg/kg body weight once daily for 10 days. The suspension must be administered at least 2 hours before or 1 hour after a meal.

For renal impairment: For the patients with creatinine clearance of 50 mL/min or greater normal dose should be administered. The recommended dose for renal insufficiency patients is given in the following table.

Creatinine Clearance (mL/min)	Recommended Dosing Schedules
>50	9 mg/kg or 400 mg once daily (Normal dose)
30-49	4.5 mg/kg or 200 mg once daily
5-29	2.25 mg/kg or 100 mg once daily

Hemodialysis Patients: Single dose of 400 mg Orbuten capsule or 9 mg/kg suspension (maximum of 400 mg of ceftibuten) may be administered at the end of each hemodialysis session to patients undergoing hemodialysis two or three times weekly.

Contraindications:

Ceftibuten is contraindicated to patients with the history of hypersensitivity reactions to ceftibuten, other cephalosporins & penicillins.

Direction for reconstitution:

1. Shake the bottle to loosen powder 
2. Open the bottle cap safely 
3. Add 35 ml of boiled & cooled water slowly into the bottle with the oral dispenser 
4. Shake well to get a homogenous suspension 

Administration of suspension:

1. Shake the bottle well before use. 
2. Insert the tip of the oral dispenser in the outlet of the attached bottle adapter. 
3. Invert the bottle and pull the plunger to get the required amount of suspension. 
4. Put the tip of the dispenser in the child's mouth, inside the cheek & press the plunger gently to squirt the medicine into the mouth. 
5. After each use close the bottle with the cap & wash the oral dispenser. 

Manufactured by:
ARISTOPHARMA LTD.
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Side-effects:

Nausea, headache, diarrhea, abdominal pain, dyspepsia etc. may occur.

Use in special groups:

Use in pregnancy: Pregnancy category B. This drug should be used during pregnancy only if clearly needed. ***Use in 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. ***Use in pediatric patients:*** The safety and efficacy of ceftibuten in infants less than 6 months of age have not been established. ***Use in geriatric patients:*** The usual adult dosage is recommended. However if renal function is hampered, dosage adjustment may be required.

Precautions:

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

Drug Interactions:

Theophylline: The pharmacokinetics of theophylline was not altered during co-administration with ceftibuten. Antacids or H_2-receptor antagonists: A single dose of liquid antacid did not affect the C_{max} or AUC of ceftibuten; however, 150 mg of ranitidine $q_{12}h$ for 3 days increased the C_{max} of ceftibuten by 23% and AUC by 16%.

Storage:

Orbuten Powder for Suspension: Store below 25^{o} C in dry place & protect from light. After reconstitution, the suspension may be used for 14 days when stored in refrigerator between 2^{o}-8^{o} C.

Packing:

Orbuten Powder for Suspension: Bottle containing dry powder for preparation of 60 ml suspension.

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