

Butibac Powder for Suspension

Ceftibuten as Ceftibuten Dihydrate INN

Composition : Each 5 ml reconstituted suspension contains Ceftibuten 90mg as Ceftibuten Dihydrate INN.

Pharmacology: Ceftibuten dihydrate is a semi-synthetic Cephalosporin antibiotic for oral administration. Ceftibuten exerts its bactericidal action by binding to essential target proteins of the bacterial cell wall.

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

Dosage and administration : Child:-9mg/kg once daily for 10 days.

CEFTIBUTEN ORAL SUSPENSION PEDIATRIC DOSAGE CHART	
CHILD'S WEIGHT	90 mg/5 mL
10 kg 22 lbs	1 tsp Once daily
20 kg 44 lbs	2 tsp Once daily
40 kg 88 lbs	4 tsp Once daily

Ceftibuten Oral Suspension must be administered at least 2 hours before or 1 hour after a meal. Safety and efficacy of Ceftibuten in infants <6 months have not been established. Or, as directed by the registered physicians.

Contraindication : 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 resistance 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.

Side effects : Common side effects include nausea, vomiting, diarrhoea, stomach upset, or headache.

Use in Pregnancy and lactation : Pregnancy category "B". There are no adequate well controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Caution should be exercised when this drug is administered to nursing women.

Use in Child : See dosage and administration.

Drug Interaction : Theophylline & Antacid : Do not alter the pharmacokinetic profile of Ceftibuten. Ranitidine : Increases the C_{max} & AUC of Ceftibuten

Overdosage : Overdosage 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.

Storage : Store below 30° C in a dry place. After reconstitution the prepared suspension should be used within 14 days and keep in a cool place preferable in a refrigerator between 2°C to 8°C. Keep all medicines out of reach of children.

Packing : Each box contains dry powder of Ceftibuten Dihydrate to reconstituted suspension of 60ml.

Manufactured by
 **DRUG INTERNATIONAL LTD.**
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