

Ceftibuten Dihydrate INN

# Ceftiben™

**COMPOSITION:** **Ceftiben™** Capsule: Each capsule contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 400 mg. **Ceftiben™** Powder for Suspension: Each 5 ml reconstituted suspension contains Ceftibuten Dihydrate INN equivalent to Ceftibuten 90 mg.

**PHARMACOLOGY:** 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.

**INDICATION:** Ceftibuten is indicated for the treatment of individuals with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

- Acute Bacterial Exacerbations of Chronic Bronchitis
- Acute Bacterial Otitis Media
- Pharyngitis
- Tonsillitis
- Pneumonia
- Urinary Tract Infections
- Enteritis
- Gastroenteritis

**DOSAGE & ADMINISTRATION:** Adults: 400 mg once daily for 10 days. Paediatric Patients: Children 6 months & above: 9 mg/kg/day once daily for 10 days.

**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 resistant organisms. Careful observations of the patient are essential. The dose of Ceftibuten may require adjustment for 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 should be monitored carefully and administration of Ceftibuten should occur immediately following dialysis. Ceftibuten should be prescribed with caution to individuals with a history of gastrointestinal disease, particularly colitis.

**SIDE EFFECT:** Nausea, vomiting, diarrhea, stomach upset, or headache may occur.

**USE IN PREGNANCY & LACTATION:** Pregnancy Category B. It is not known whether Ceftibuten (at recommended dose) 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.

**DRUG INTERACTION:** Theophylline & Antacid: Do not alter the pharmacokinetic profile of Ceftibuten. Ranitidine: Increase the  $C_{max}$  & AUC of Ceftibuten.

**STORAGE CONDITION:** Store below 25° C, protected from light & moisture. Keep out of reach of children.

**HOW SUPPLIED:** **Ceftiben™** Capsule: Each box contains 6 capsules in blister pack. **Ceftiben™** Powder for Suspension: Each bottle contains Powder for Suspension for 60 ml Suspension.

Manufactured by



**SQUARE**  
**PHARMACEUTICALS LTD.**

Kaliakoir, Bangladesh

TM- Trade Mark

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