## Butibac -

Composition: Each Capsule Contains Ceftibuten 400mg as Ceftibuten Dihvdrate 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: The usual dose of Ceftibuten is 400 mg once daily.Or, as directed by the registered physician.

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

Side effects: Common side effects include nausea, vomiting, diarrhea, 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.

Drug Interaction: Theophyline & Antacid: Concomitant administration may do not alter the pharmacokinetic profile of Ceftibuten. Ranitidine: Concomitant administration may increases the Cmax & 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. Away from light. Keep all medicines away from children.

Packing: Each box contains 1 x 7's capsules in blister pack.

Manufactured by

DRUG INTERNATIONAL LTD.