

# Roin

Ceftibuten INN

## Composition

**Roin 400 mg Capsule:** Each capsule contains 400 mg Ceftibuten as Ceftibuten Dihydrate INN.

**Roin 60 ml Powder for Suspension (PFS):** After reconstitution, each 5 ml contains Ceftibuten 90 mg as Ceftibuten Dihydrate INN.

## Description

Ceftibuten is the dihydrate salt of Ceftibuten, is a semi-synthetic Cephalosporin antibiotic for oral administration.

## 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.

## Indications

Ceftibuten (**Roin**) 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:** Due to *Haemophilus influenzae* (including  $\beta$ -lactamase producing strains), *Moraxella catarrhalis* (including  $\beta$ -lactamase producing strains), or *Streptococcus pneumoniae* (penicillin-susceptible strains only).
- **Acute Bacterial Otitis Media:** Due to *Haemophilus influenzae* (including  $\beta$ -lactamase producing strains), *Moraxella catarrhalis* (including  $\beta$ -lactamase producing strains) or *Streptococcus pyogenes*.
- **Pharyngitis and Tonsillitis:** Due to *Streptococcus pyogenes*.

## Dosage and administration

**Adults:** 400 mg once daily for 10 days.

**Children of 6 months & above:** 9 mg/kg once daily for 10 days.

## Special instruction for Roin PFS:

### Direction of preparation



1. Small bottle contains purified water and large bottle contains granules



2. Pour the purified water completely into large bottle



3. Tighten the cap of large bottle and shake the bottle for at least one minute



4. Use measuring cup or dropper for reconstituted suspension

Prepared suspension to be consumed within 14 days of preparation if kept in a refrigerator. Shake the bottle well each time before use.

## Side effects

Nausea, headache, diarrhea, dyspepsia, dizziness, abdominal pain, vomiting.

## Contraindications

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

## Use in Pregnancy and Lactation

Pregnancy category B

It is not known whether Ceftibuten is excreted in human milk, caution should be exercised when Ceftibuten is administered to a nursing woman.

## 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. The dose of Ceftibuten may require adjustment patients with varying degrees of renal insufficiency. Ceftibuten should be prescribed with caution to individuals with a history of gastrointestinal disease, particularly colitis.

## Drug Interactions

Theophylline & Antacid do not alter the pharmacokinetic profile of Ceftibuten.

Ranitidine increases the C<sub>max</sub> & AUC of Ceftibuten.

## Storage

Store below 25°C, protected from light and moisture.

For Suspension: After reconstitution, suspension may be used for 14 days while stored at 2° - 8°C.

Keep out of reach of children.

## Packaging

**Roin 400 mg Capsule:** Each carton contains 2 X 5's capsules in a blister with pouch pack.

**Roin 60 ml PFS:** Each carton contains two bottle, one having dry powder and other contain 45 ml diluent to reconstitute 60 ml suspension along with a measuring cup, a spoon and a dropper.

Manufactured by



**Ziska Pharmaceuticals Ltd.**

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