

# ROXIM<sup>®</sup>

Cefixime Trihydrate USP  
Capsule / Powder for Suspension

## DESCRIPTION

**ROXIM<sup>®</sup>** is a preparation of cefixime, a third generation cephalosporin antibiotic for oral administration. Cefixime has marked in-vitro bactericidal activity against a wide variety of Gram-positive & Gram-negative organisms. Cefixime is also stable to hydrolysis by many beta-lactamases. Cefixime has a longer duration of action than the other cephalosporins that are active by mouth.

## INDICATIONS

**ROXIM<sup>®</sup>** is indicated for the treatment of following acute infections, when caused by susceptible microorganisms.

### Upper respiratory tract infections

Otitis Media & other URTIs where the causative organism is known or suspected to be resistant to other commonly used antibiotics, or where treatment failure may carry significant risk.

### Lower respiratory tract infections

e.g. Bronchitis.

### Urinary tract infections

e.g. Cystitis, Cystourethritis, Pyelonephritis.

Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *E. coli*, *Proteus mirabilis*, *Klebsiella* species, *Haemophilus influenzae* (beta-lactamases positive & negative), *Moraxella catarrhalis* (beta-lactamases positive & negative) & *Enterobacter* species. Cefixime is highly stable in the presence of beta-lactamase enzymes.

Most strains of Enterococci (*Streptococcus faecalis*, group D *Streptococci*) & *Staphylococci* (including coagulase positive & negative strains & methicillin resistant strains) are resistant to Cefixime. In addition, most strains of *Pseudomonas*, *Clostridium*, *Bacteroids fragilis* & *Listeria monocytogenes* are resistant to Cefixime.

## DOSAGE & ADMINISTRATION

The usual treatment of Cefixime is 7 days. This may be continued for up to 14 days.

Adult & children over 10 years : 200-400 mg daily as a single dose  
or in 2 divided doses.

Children over 6 months : 8 mg/kg/daily as a single dose or in  
2 divided doses.

Children 6 months-1 year : 75 mg daily

Children 1-4 years : 100 mg daily

Children 5-10 years : 200 mg daily

## CONTRAINDICATIONS

Patients with known hypersensitivity to cephalosporin antibiotics; porphyria.

## PRECAUTIONS

Cefixime should be prescribed with cautions in individuals with history of gastrointestinal diseases, particularly colitis. Dosage adjustment is only necessary in severe renal failure (creatinine clearance < 20 mL/min).

#### USE IN PREGNANCY & LACTATION

Sufficient information is not available, so it is probably best to avoid using the drug during pregnancy & lactating period.

#### SIDE-EFFECTS

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild & self-limiting in nature.

Gastrointestinal disturbances: Diarrhoea (If severe diarrhoea occurs, cefixime should be discontinued), changes in the color of stool, nausea, abdominal pain, dyspepsia, vomiting and flatulence have been reported.

Central nervous system disturbances: Headache, dizziness.

Others: Hypersensitivity reactions, which usually subsided upon discontinuation of therapy; infrequent & reversible haematological changes, elevation of serum amylase.

#### PHARMACEUTICAL PRECAUTION

Do not store above 30 °C. Protect from moisture & light. Keep out of the reach of children.

#### PACKAGING

**ROXIM®** 200 capsule : Box containing 2 strips of 8 capsules or 25 strips of 8 capsules each. Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg in HPMC capsule shell.

**ROXIM®** 400 capsule : Box containing 1 strip of 8 capsules or 25 strips of 8 capsules each. Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 400 mg in HPMC capsule shell.

**ROXIM®** S powder for : Bottle containing powder for the preparation of 30 mL suspension. After reconstitution each 5 mL contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

**ROXIM®** M powder for : Bottle containing powder for the preparation of 50 mL suspension. After reconstitution each 5 mL contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

**ROXIM®** L powder for : Bottle containing powder for the preparation of 75 mL suspension. After reconstitution each 5 mL contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

**ROXIM®** XL powder for: Bottle containing powder for the preparation of 60 mL suspension. After reconstitution each 5 mL contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

**ROXIM®** powder for : Bottle containing powder for the preparation of 15 mL paediatric drops suspension. After reconstitution each mL contains Cefixime Trihydrate USP equivalent to Cefixime 25 mg.

## SK+F

Manufactured by

**ESKAYEF BANGLADESH LIMITED**

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