ROXIM®

Cefixime Trihydrate USP
Capsule / Powder for Suspension

DESCRIPTION

ROXIM® 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® 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/day 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

Capsule: Do not store above 30 °C temperature. Protect from moisture & light.
Powder for Suspension: Do not store above 25 °C temperature. Protect from moisture & light.
Keep out of the reach of children.

For accurate dosing of the suspension, please check the direction for reconstitution and also the direction for administration of suspension on the opposite of this page.

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 10 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 Suspension :	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 Suspension :	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 Suspension :	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: Suspension	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 Paediatric Drops :	Bottle containing powder for the preparation of 15 mL suspension. After reconstitution each mL contains Cefixime Trihydrate USP equivalent to Cefixime 25 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH
® REGD. TRADEMARK
PM06054 V02

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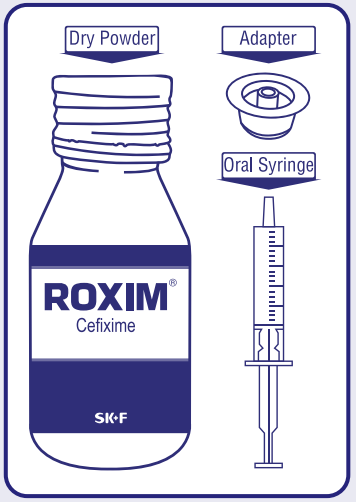
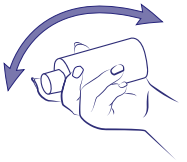
ROXIM®

Cefixime Powder for Suspension USP



Direction for Reconstitution of Suspension (সাসপেনশন প্রস্তুতির নিয়মাবলী)

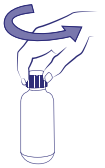
1



1. Before use, shake the bottle to loosen the powder.

১. ব্যবহারের পূর্বে বোতল ঝাঁকিয়ে নিন, যেন পাউডার জমাট বেঁধে না থাকে।

2



2. Open the bottle cap safely. Set the adapter (given inside) onto the bottle replacing the poly plug.

২. বোতল ক্যাপটি সাবধানে খুলুন। ছিপি সরিয়ে ভেতরে দেয়া অ্যাডাপটারটি বোতলের সাথে সংযুক্ত করুন।

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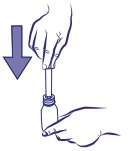
3



3. Using the oral syringe, add the required quantity of boiled and cooled water into the bottle as per the direction mentioned in the carton.

৩. ওরাল সিরিঞ্জের সাহায্যে মোড়কে উল্লেখিত নির্দেশনা অনুযায়ী নির্ধারিত পরিমাণ ফুটানো ঠান্ডা পানি বোতলের মধ্যে যোগ করুন।

4

4. Shake well to obtain a homogenous suspension.

৪. ভালভাবে ঝাঁকিয়ে সম্পূর্ণরূপে মিশ্রিত সাসপেনশন তৈরি করুন।

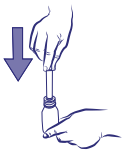
Direction for Administration of Suspension (সাসপেনশন সেবন প্রক্রিয়া)

1

1. Shake the bottle well before each use.

১. প্রতিবার ব্যবহারের পূর্বে বোতল ভাল করে ঝাঁকিয়ে নিন।

2



2. Insert the tip of the oral syringe in the outlet of the attached bottle adapter.

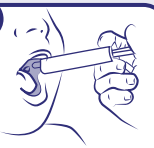
২. ওরাল সিরিঞ্জটি বোতলের মুখে থাকা অ্যাডাপটারের ছিদ্রের সাথে সংযুক্ত করুন।

3

3. Invert the bottle and pull the plunger to get the required amount of suspension.

৩. ওরাল সিরিঞ্জ সংযুক্ত বোতলটি উল্টিয়ে পরিমাণ মত সাসপেনশন টেনে নিন।

4



4. Put the tip of the oral syringe into mouth & press the plunger gently to squirt the medicine into the mouth.

৪. ওরাল সিরিঞ্জের অগ্রভাগ মুখের ভিতরে রেখে প্লানজারে চাপ প্রয়োগের মাধ্যমে ধীরে ধীরে সাসপেনশন সেবন করান।

5

5. Close the bottle with the cap and wash the oral syringe after each use.

৫. ক্যাপ দিয়ে বোতলের মুখ বন্ধ রাখুন এবং প্রতিবার ব্যবহারের পর ওরাল সিরিঞ্জটি ধুয়ে রাখুন।