

# Prexim

Cefixime Trihydrate USP



## Composition:

**Prexim 200 Capsule:** Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

**Prexim 400 Capsule:** Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 400 mg.

**Prexim Powder for Suspension:** Each 5 ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

**Prexim DS Powder for Suspension:** Each 5 ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

**Prexim Powder for Pediatric Drops:** Each ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 25 mg.

## Description:

Cefixime is a semi-synthetic, broad spectrum cephalosporin antibiotic of third generation for oral administration. It is a bactericidal antibiotic & kills bacteria by interfering in the synthesis of the bacterial cell wall. Cefixime is highly stable in the presence of beta-lactamase enzymes. Cefixime has marked in-vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms including beta lactamase producers. Clinical efficacy of Cefixime has been demonstrated in infections caused by commonly occurring pathogens including Gram-positive organism: Streptococcus pneumoniae, Streptococcus pyogenes, Gram-negative organism: Escherichia coli, Proteus mirabilis, Klebsiella spp., Haemophilus influenzae (beta-lactamase positive and negative), Moraxella catarrhalis (beta-lactamase positive and negative), Salmonella typhi and Enterobacter species.

## Indications:

Prexim is indicated for the treatment of following acute infections: Urinary tract infections: cystitis, cystourethritis, pyelonephritis, gonococcal urethritis. Upper respiratory tract infections, otitis media. Lower respiratory tract infections: bronchitis, pneumonia etc. Skin & soft tissue infections, Typhoid fever.

## Dosage and Administration:

The usual treatment of Prexim is 7 days. This may be continued for up to 14 days according to the severity of infection.

### Prexim Capsule:

Adult and child over 10 years: 200-400 mg daily as a single dose or in two divided doses.

Prexim Powder for Suspension, DS Powder for Suspension & Powder for Pediatric Drops:

Child above 6 months: 8 mg/kg daily as a single dose or in 2 divided doses in the

or: Child 6 months-1 year: 75 mg daily. 1-4 Years: 100 mg daily. 5-10 Years: 200 mg daily. 11-12 Years: 300 mg daily. Above 12 years: adult dose.

Typhoid Fever: 20 mg/kg daily into divided dosage for 10 days.

## Direction for reconstitution:

To reconstitute Prexim 30 ml powder for suspension, add 20 ml supplied diluent to the content of the bottle and shake well to mix uniformly. To reconstitute Prexim 50 ml powder for suspension, add 35 ml supplied diluent to the content of the bottle and shake well to mix uniformly. To reconstitute Prexim DS 50 ml powder for suspension, add 35 ml supplied diluent to the content of the bottle and shake well to mix uniformly. To reconstitute Prexim 21 ml powder for pediatric drops, add 16 ml supplied diluent to the content of the bottle and shake well to mix uniformly.

## Side Effects:

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials are mild and self limiting in nature.

**Gastro-intestinal disturbance:** Diarrhea (if severe diarrhea occurs, Cefixime should be discontinued), changes in the color of stool, nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported.

**CNS disturbances:** Headache, dizziness.

**Others:** Hypersensitivity reactions which usually subsided upon discontinuation of therapy; infrequent and reversible hematological changes; elevation of serum amylase.

## Contraindications:

Patients with known hypersensitivity to Cefixime or Cephalosporin group of drugs.

## Precautions:

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

## Use in Pregnancy & Lactation:

**Pregnancy:** Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Lactation:** It is not known whether Cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

**Use in elderly:**

No special precautions are necessary. No dosage adjustment is required for elderly.

## Overdose:

Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of Cefixime did not differ from the profile seen in patients treated at the recommended doses.

## Storage:

Do not store above 25°C. Protected from light. Keep out of the reach of children.

## Packaging:

**Prexim 200 Capsule:** Each Carton contains 2x7's capsules in blister pack.

**Prexim 400 Capsule:** Each Carton contains 2x7's capsules in blister pack.

**Prexim 30 ml Powder for Suspension:** Each Carton contains a bottle of dry powder & a bottle of 20 ml diluent for preparation of 30 ml suspension with a 5 ml measuring spoon & a measuring cup.

**Prexim 50 ml Powder for Suspension:** Each Carton contains a bottle of dry powder & a bottle of 35 ml diluent for preparation of 50 ml suspension with a 5 ml measuring spoon & a measuring cup.

**Prexim DS Powder for Suspension:** Each Carton contains a bottle of dry powder & a bottle of 35 ml diluent for preparation of 50 ml suspension with a 5 ml measuring spoon & a measuring cup.

**Prexim 21 ml Powder for Pediatric Drops:** Each Carton contains a bottle of dry powder & a bottle of 16 ml diluent for preparation of 21 ml suspension with a 5 ml dropper & a 5 ml measuring spoon.

Manufactured by

**ZISKA** Ziska Pharmaceuticals Ltd.  
**PHARMA** Kaliakoir, Gazipur, Bangladesh

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