

# Velofix

Cefixime USP

## Composition

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

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

**Velofix PFS:** After reconstitution each 5 ml suspension contains Cefixime Trihydrate equivalent to Cefixime USP 100 mg.

**Velofix DS PFS:** After reconstitution each 5 ml suspension contains Cefixime Trihydrate equivalent to Cefixime USP 200 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

Cefixime is indicated in the following infectious diseases-

Respiratory Tract Infections: Pneumonia, Sinusitis, Otitis Media, Pharyngitis and Tonsillitis, Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis (AECB).

Typhoid

Urinary Tract Infections

Uncomplicated gonorrhoea (cervical/urethral)

## Dosage & Administration

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

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

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

Child 6 months - 1 year: 3.75 ml or 75 mg daily.

1-4 Years: 100 mg daily.

4-10 Years: 200 mg daily.

10-12 Years: 300 mg daily.

Children >50 kg or >12 years and Adults: 400 mg/day divided every 12-24 hours.

Uncomplicated cervical/urethral gonorrhoea due to *N. gonorrhoeae*: 400 mg as a single dose.

For *S. pyogenes* infections, treat for 10 days; use suspension for otitis media due to increased peak serum levels as compared to capsule form.

Dosing adjustment in renal impairment: Clr 21-60 mL/minute or with renal hemodialysis: Administer 75% of the standard dose; Clr<20 mL/minute or with CAPE); Administer 50% of the standard dose;

Moderately dialyzable (10%).

## Contraindications

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

## Use in Pregnancy

Pregnancy Risk Factor: 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.

## Use in 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.

Pediatric Use

Safety and effectiveness of Cefixime in children aged less than six months old have not been established.

## Warning & Precaution

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), prolonged use may result in superinfection; use with caution in patients with a history of penicillin allergy especially IgE-mediated reactions (eg.: anaphylaxis, urticaria). May cause antibiotic-associated colitis or colitis secondary to *C. difficile*.

## 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.

## Drug Interaction

Aminoglycosides: May be a possible additive to nephrotoxicity;

Carbamazepine: Cefixime may increase serum levels of carbamazepine;

Furosemide: May be a possible additive to nephrotoxicity;

Probenecid: May decrease cephalosporin elimination;

Warfarin: Cefixime may increase prothrombin time when administered with warfarin; Food: Delays cefixime absorption.

## Overdosage

Symptoms of overdose include neuromuscular hypersensitivity and convulsions. Many beta-lactam containing antibiotics have the potential to cause neuromuscular hyperirritability or convulsive seizures. Hemodialysis may be helpful to aid in the removal of drug from blood; otherwise, treatment is supportive or symptom-directed.

## Storage

Store in a cool & dry place, protected from light. Keep out of reach of children.

## How Supplied

**Velofix 200 Capsule:** Box containing 2x6 capsules in alu-alu blister pack.

**Velofix 400 Capsule:** Box containing 2x4 capsules in alu-alu blister pack.

**Velofix PFS:** Bottle containing powder to reconstitute 50 ml suspension with a measuring cup.

**Velofix DS PFS:** Bottle containing powder to reconstitute 50 ml suspension with a measuring cup.



Manufactured by  
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