

# Fixpro

Cefixime

## COMPOSITION

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

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

**Fixpro Powder for Suspension** : After reconstitution, each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

**Fixpro DS Powder for Suspension** : After reconstitution, each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

## PHARMACOLOGY

**Fixpro** (Cefixime) is a third generation semisynthetic cephalosporin antibiotic for oral administration. It is bactericidal against a broad spectrum of gram positive and gram negative bacteria at easily achievable plasma concentrations. It kills bacteria by interfering in the synthesis of bacterial cell wall. It is highly stable in the presence of Beta-lactamase enzyme. As a result, many organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases, may be susceptible to Cefixime. Absorption of it is about 40% to 50% whether administered with or without food.

## INDICATION

**Fixpro** (Cefixime) is indicated in the treatment of the following infections when caused by the susceptible strains of the designated microorganisms:

**Uncomplicated urinary tract infections** caused by *Escherichia coli* and *Proteus mirabilis*.

**Otitis Media** caused by *Haemophilus influenzae*, *Moraxella catarrhalis* and *Streptococcus pyogenes*.

**Pharyngitis and tonsillitis** caused by *Streptococcus pyogenes*.

**Acute bronchitis and acute exacerbations of chronic bronchitis** caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*.

**Uncomplicated gonorrhoea** (cervical/urethral) caused by *Neisseria gonorrhoeae*.

## DOSAGE AND ADMINISTRATION

The usual course of treatment is 7 days. This may be continued for up to 14 days depending on the severity of the infection.

**Adult and children over 12 years:** The recommended adult dose is 200-400 mg (1 to 2 capsules) daily, given either as a single dose or in two divided doses. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of Cefixime 400 mg is recommended.

**Children (6 month or older):** Usually 8mg/kg/day given as a single dose or in two divided doses or may be given as following :

½-1 year : 75 mg daily.

1-4 years : 100 mg daily.

5-10 years : 200 mg daily.

11-12 years : 300 mg daily.

In typhoid fever, dosage should be 10mg/kg/day for 14 days.

**Reconstitution Procedure of Suspension** : Before mixing the water, shake the bottle well to loosen the powder. Then, for **Fixpro PFS** (100 mg / 5 ml) add 35 ml (7 tea-spoonfuls) boiled and cooled water in the bottle in two equal steps of 17.5 ml and for **Fixpro DS PFS** (200 mg / 5 ml) add 30 ml (6 tea-spoonfuls) boiled and cooled water in the bottle in two equal steps of 15 ml (3 tea-spoonfuls) and shake until powder is completely mixed with water in both steps.

## CONTRAINDICATION

It is contraindicated in patient with known hypersensitivity to Cefixime or other cephalosporins.

## WARNING AND PRECAUTION

The drug should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. The drug should be given with caution in patients with marked impaired renal function as well as those undergoing continuous ambulatory peritoneal dialysis and hemodialysis. Dosage adjustment is only necessary in severe renal failure (creatinine clearance < 20 ml/min), in that case a dose of 200 mg once daily should not be exceeded.

## SIDE EFFECTS

The drug is generally well tolerated. The most frequent side effects are diarrhoea and stool changes; that have been more commonly associated with higher doses. Other side effects are nausea, abdominal pain, dyspepsia, vomiting, flatulence, headache and dizziness. Allergies in the form of rash, pruritus, urticaria, drug fever and arthralgia have been reported. These reactions usually subsided upon discontinuation of therapy.

## USE IN PREGNANCY AND LACTATION

There are, however, 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. It is not known that Cefixime is excreted in human milk. So, caution should be exercised when Cefixime is administered to a nursing woman.

## USE IN CHILDREN

The safety and efficacy of Cefixime has not been established in children aged less than 6 months.

## DRUG INTERACTION

Carbamazepine: Concomitant use elevates the Carbamazepine level.

Warfarin and other anticoagulants: Concomitant use increases prothrombin time.

## 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

**Capsule** : Keep below 30°C temperature, protected from light & moisture.

**Powder for Suspension** : Keep below 25°C temperature, protected from light & moisture.

Keep out of the reach of children.

## PACKING

**Fixpro 200 Capsule** : Each box contains 12 capsules in Alu-Alu blister pack.

**Fixpro 400 Capsule** : Each box contains 8 capsules in Alu-Alu blister pack.

**Fixpro Powder for Suspension** : Each amber glass bottle contains dry powder for 50 ml suspension.

**Fixpro DS Powder for Suspension** : Each amber glass bottle contains dry powder for 50 ml suspension.