

Onefix

Cefixime USP

Composition

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

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

Onefix PD 21 ml: After reconstitution according to direction each ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 25 mg.

Onefix PFS 30 ml: After reconstitution according to direction each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

Onefix PFS 50 ml: After reconstitution according to direction each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

Onefix DS PFS 50 ml: After reconstitution according to direction each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

Pharmacology

Cefixime is a broad-spectrum 3rd generation oral Cephalosporin antibiotic. It is a bactericidal antibiotic and is stable to many beta-lactamases. Cefixime kills bacteria by interfering with the synthesis of the bacterial cell wall. Cefixime is highly active against *Neisseria gonorrhoeae*, *Haemophilus influenzae*, *Moraxella catarrhalis* including beta-lactamase producers, most of the Enterobacteriaceae, beta haemolytic *Streptococcus* (group A & B) and *Streptococcus pneumoniae*. Cefixime is more active than other oral cephalosporins against *Escherichia coli*, *klebsiella spp*, *Proteus mirabilis* and *Serratia marcescens*. Cefixime is also active against *Streptococcus pyogenes*. 40-50% of an oral dose is absorbed from gastrointestinal tract whether taken with meals or not. Peak plasma concentration attained within 2-6 hrs, plasma half-life is usually 3-4 hours and about 65% is bound to plasma protein. Cefixime is mainly excreted unchanged through bile and urine.

Indication

Cefixime is indicated for the treatment of following infections:

- Uncomplicated urinary tract infections
- Upper and lower respiratory tract infections
- Acute otitis media
- Acute exacerbation of chronic bronchitis
- Uncomplicated gonorrhoea (Cervical & Urethral)
- Multi-drug resistant (MDR) enteric fever

Dosage and Administration

a) *Route of administration:* Oral

Capsule: Adult & age over 12 Years dosage:

1 or 2 capsules (200 mg -400 mg) as a single dose or in two divided doses daily for 7-14 days, according to the severity of infections.

Suspension: Child dose: 8 mg/kg daily as a single dose or in two divided doses for 7-14 days according to the severity of infection or age.

6 month -1 years : 3 ml or 75 mg daily

1-4 years : 5 ml or 100 mg daily

5-10 years : 10 ml or 200 mg daily

11-12 years : 15 ml or 300 mg daily

Contra-indication

Cefixime is contraindicated in known hypersensitivity to Cefixime or other antibiotics of Cephalosporin group.

Warning & Precaution

Cefixime should be administered with caution in renal impairment, a history of colitis and on anticoagulant therapy. Like other antibiotics, pseudomembranous colitis has been reported with Cefixime. Dosage adjustment is only necessary in severe renal failure (creatinine clearance <20 ml/min)

Side effects

a) *Common:* Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature. Gastrointestinal disturbances: Diarrhea, abdominal pain, dyspepsia, nausea and vomiting. Hypersensitivity Reactions: Skin rashes, urticaria, pruritus, angioedema and facial edema.

b) *Rare:* Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.

Use in Pregnancy and Lactation

a) *Use in Pregnancy:* Pregnancy category B. Although the use of Cefixime in pregnancy is not known to be harmful, this drug should be used during pregnancy only if clearly needed.

b) *Use in Lactation:* Since Cefixime is excreted in breast milk in low concentration, caution should be exercised when Cefixime is administered to a nursing woman.

Use In children & adolescent

Children: Efficacy and safety in infants aged less than six months have not been established.

Geriatric Use: Clinical studies did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Drug Interaction

a) *With Medicine:* Carbamazepine: Elevates Carbamazepine blood level. Warfarin: Increase prothrombin-time.

b) *With Food & Others:* Cefixime is usually taken with or without food.

Direction for reconstitution of suspension

Reconstituted volume of Onefix dry powder for suspension	Required amount of boiled & cooled water	Reconstitutions process
Onefix PFS 30 ml	20 ml	First, shake the bottle to loosen granules. Then add the water in two approximately equal portions. Shake vigorously after each addition of water.
Onefix PFS 50 ml	30 ml	
Onefix DS PFS 50 ml	35 ml	
Onefix PD 21 ml	13 ml	

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 upto 2 gm of cefixime did not differ from the profile seen in patients treated at the recommended doses.

Storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

Reconstituted Suspension: After reconstitution the suspension can be used within 7 days if be kept at room temperature and within 14 days if be kept in refrigerator. Shake well before using the suspension. Always keep the bottle tightly closed.

Packing

Onefix 200 Capsule: Each box contains 14 (2x7's) capsules in Alu-Alu blister pack.

Onefix 400 Capsule: Each box contains 14 (2x7's) capsules in Alu-Alu blister pack.

Onefix PD 21 ml: Each amber glass bottle contains dry powder to make 21 ml suspension with a measuring spoon and a dropper.

Onefix PFS 30 ml: Each amber glass bottle contains dry powder to make 30 ml suspension with a measuring cup.

Onefix PFS 50 ml: Each amber glass bottle contains dry powder to make 50 ml suspension with a measuring cup.

Onefix DS PFS 50 ml: Each amber glass bottle contains dry powder to make 50 ml suspension with a measuring cup.

Manufactured by

Apex Pharma Ltd.

Shafipur, Kaliakair, Gazipur, Bangladesh

for

ONE PHARMA LTD.

C-23-24, BSCIC I/A

Bogura, Bangladesh



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