

COMPOSITION

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

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

Powder for suspension : Each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg after reconstitution.

DS Powder for suspension : Each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg after reconstitution.

Powder for Paediatric Drops : Each ml contains Cefixime Trihydrate USP equivalent to Cefixime 25 mg after reconstitution.

PHARMACOLOGY

FIX-A[®] (Cefixime) is a third generation semisynthetic cephalosporin antibiotic for oral administration. **FIX-A[®]** (Cefixime) is bactericidal against a broad spectrum of gram positive and gram-negative bacteria at easily achievable plasma concentrations. **FIX-A[®]** (Cefixime) is also highly stable in the presence of beta-lactamase enzyme. As a result, many organism resistant to penicillins and some cephalosporins due to the presence of beta-lactamases, may be susceptible to **FIX-A[®]** (Cefixime). **FIX-A[®]** (Cefixime) exhibits very good activity against most of the Enterobacteriaceae, Haemophilus influenzae and Neisseria gonorrhoeae (including β -lactamase producing strains), β -hemolytic streptococci of groups A and B and Streptococcus pneumoniae. Absorption is about 40% to 50% whether administered with or without food.

INDICATIONS

FIX-A[®] (Cefixime) is indicated for the treatment of the following acute infections caused by the susceptible microorganisms. 1) Upper respiratory tract infections e.g. otitis media and other URTI where the causative organism is known or suspected to be resistant to other commonly used antibiotics, or where treatment failure may carry significant risk. 2) Lower respiratory tract infections e.g. bronchitis. 3) Urinary tract infections e.g. cystitis, cystourethritis, uncomplicated pyelonephritis. 4) Uncomplicated gonorrhea (cervical/ urethral).

DOSAGE AND ADMINISTRATION

Route of administration : Oral.

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 7-14 days depending on the severity of the infection.

For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of Cefixime 400 mg (**FIX-A[®] DS**) is recommended. Single 800 mg may be given if essential.

Children upto 12 years : Usually 8mg/kg/day given as a single dose or in two divided doses or for children of age :

1/2 - 1 Years	: 75 mg
1 - 4 Years	: 100 mg
5 - 10 Years	: 200 mg
11-12 Years	: 300 mg

Above 12 Years: adult dose should be given.

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Hypersensitivity to cephalosporin antibiotics.

PRECAUTIONS

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⁻¹), in that case a dose of 200 mg once daily should not be exceeded.

SIDE EFFECTS

Common side effects : The drug is generally well tolerated. The most frequent side effects observed are diarrhea and stool changes; that has been more commonly associated with higher doses. The drug should be discontinued if marked diarrhea occur. Other side effects seen less frequently are nausea, abdominal pain, dyspepsia, vomiting, flatulence, headache and dizziness.

Rare side effects : 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 no adequate and well controlled studies in pregnant women. **FIX-A[®]** (Cefixime) should therefore not be used in pregnancy or in nursing mothers unless considered essential by the physician.

USE IN CHILDREN & ADOLESCENTS

Efficacy and safety in infants aged less than 6 months have not been established.

DRUG INTERACTIONS

With medicine : Carbamazepine: Elevated carbamazepine levels have been reported.

Warfarin and Anticoagulants: Increased prothrombin time with or without clinical bleeding has been reported when cefixime is administered concomitantly.

With food & others : Absorption may be decreased when taken with food.

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.

STORAGE

Store below 30° C and in dry place, protected from light.

Keep all medicines out of reach of children.

PACKING

FIX-A[®] Capsule : Each box contains 2x7 capsules in Alu-Alu blister strips.

FIX-A[®] DS Capsule : Each box contains 2x7 capsules in Alu-Alu blister strips.

FIX-A[®] Powder for 37.5 ml suspension : Each bottle contains dry powder for the preparation of 37.5 ml suspension. A 5 ml spoon and a 10 ml measuring cup is given.

FIX-A[®] Powder for 40 ml suspension : Each bottle contains dry powder for the preparation of 40 ml suspension. A 5 ml spoon and a 10 ml measuring cup is given.

FIX-A[®] Powder for 50 ml suspension : Each bottle contains dry powder for the preparation of 50 ml suspension. A 5 ml spoon and a 10 ml measuring cup is given.

FIX-A[®] Powder for 75 ml suspension : Each bottle contains dry powder for the preparation of 75 ml suspension. A 5 ml dropper and a 10 ml measuring cup is given.

FIX-A[®] DS Powder for 50 ml suspension : Each bottle contains dry powder for the preparation of 50 ml suspension. A 5 ml spoon and a 10 ml measuring cup is given.

FIX-A[®] Powder for 21 ml Paediatric Drops : Each bottle contains dry powder for the preparation of 21 ml suspension. A 5 ml dropper and a 5 ml spoon is given.

* Further information is available on request.

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Manufactured by:

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