

Orgaxim™

Cefixime

COMPOSITION:

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

Orgaxim™ 400 capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 400 mg.

Orgaxim™ 50 ml Powder For Suspension: Each 5 ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

Orgaxim™ 75 ml Powder For Suspension: Each 5 ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

PHARMACOLOGY:

Orgaxim™ (Cefixime) is a cephalosporin antibiotic with broad spectrum bactericidal activity against both gram-positive and gram-negative bacteria. Cefixime interferes with the synthesis of bacterial cell wall by attaching to Penicillin Binding Protein (PBP) and inhibiting peptidoglycan synthesis, thus causing change to the bacterial cell wall.

INDICATIONS:

Orgaxim™ is indicated for the treatment of the following infections caused by the susceptible micro-organisms:-

- Upper respiratory tract infections
- Lower respiratory tract infections
- Uncomplicated gonorrhea
- Skin and soft tissue infections
- Bone and joint infections
- Septicemia endocarditis
- Acute otitis media
- Typhoid fever

DOSAGE & ADMINISTRATION:

Route of administration: **Orgaxim™** Capsule and PFS should be administered orally according to dosage guidelines.

Adults:

1 or 2 capsule as single dose daily or in two divided doses for 7-14 days according to the severity of infections.

Children dose:

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

½ -1 year : 3.75 ml or 75 mg

1- 4 years : 5 ml or 100 mg

5 -10 years : 10 ml or 200 mg

11-12 years: 15 ml or 300 mg

CONTRAINDICATIONS:

Patients with known hypersensitivity to cephalosporin group of antibiotics.

WARNINGS & 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.

SIDE-EFFECTS:

Common side effects: The drug is generally well tolerated. The most frequent side effects observed are diarrhoea and stool changes. That has more commonly associated with higher doses. The drug should be discontinued if marked diarrhoea occurred.

Rare side effects: Nausea, abdominal pain, dyspepsia, vomiting, flatulence, headache and dizziness

USE IN PREGNANCY & LACTATION:

It is probably best to avoid using the drug during pregnancy and by the nursing mother.

DRUG INTERACTIONS:

Care should be exercised in patients receiving anticoagulant and cefixime concomitantly due to the possibility that cefixime may increase prothrombin times.

OVERDOSE:

Gastric lavage may be indicated; otherwise, no specific antidote exists.

STORAGE:

Capsule: Protect from light exposure. Store in cool & dry place at a temperature not exceeding 30°C. Keep out of the reach of children.

Powder for Suspension: Prior to reconstitution, store below 30°C. After reconstitution, the suspension may be kept for 14 days under refrigeration or at room temperature.

PACKING:

Orgaxim™ 200 capsule: Each box contains 12's/14's capsules in Alu-Alu blister strip.

Orgaxim™ 400 capsule: Each box contains 7's/8's capsules in Alu-Alu blister strip.

Orgaxim™ Powder For Suspension: 50 ml/75 ml bottle contains dry powder to reconstitute suspension.

Manufactured by:

Apex Pharma Ltd. for

Organic Health Care Ltd.

Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur, Bangladesh.

