

Cefixim

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COMPOSITION:

Cefixim Capsule: Each capsule contains Cefixime 200 mg as Cefixime Trihydrate USP. **Cefixim 400 Capsule:** Each capsule contains Cefixime 400 mg as Cefixime Trihydrate USP. **Cefixim Suspension (30, 40 & 50 ml):** After reconstitution, each 5 ml suspension contains Cefixime 100 mg as Cefixime Trihydrate USP. **Cefixim DS Suspension (50 ml):** After reconstitution, each 5 ml suspension contains Cefixime 200 mg as Cefixime Trihydrate USP.

DESCRIPTION:

Cefixim (Cefixime Trihydrate) is a broad spectrum, third generation Cephalosporin antibiotic for oral use. Cefixime kills bacteria by interfering with the synthesis of bacterial cell wall. It is effective against most Enterobacteriaceae, *Haemophilus influenzae* and *Neisseria Gonorrhoeae*, β -hemolytic Streptococcus, *Streptococcus pneumoniae*. Cefixime is absorbed slowly and incompletely (60% of oral dose) from GIT, whether taken with food or not. About 65% of the drug in the circulation is bound to plasma protein. **Cefixim** is mainly excreted unchanged in bile and urine.

INDICATION:

Cefixim is indicated in the treatment of infections caused by susceptible microorganism - Upper Respiratory Tract Infections (URTI): Otitis media and others where causative organisms are known or suspected to be resistant to other commonly used antibiotics or where treatment failure may carry significant risk. Lower Respiratory Tract infection (LRTI): Bronchitis, Pneumonia etc. Gastro-intestinal Tract Infection (GITI): Typhoid or enteric fever. Urinary Tract Infection (UTI): Cystitis, Cystourethritis and Pyelonephritis. It is also indicated in Skin & soft tissue infection, Bone & joint infection and also most suitable for switch therapy from parenteral therapy.

DOSAGE AND ADMINISTRATION:

With **Cefixim** the usual course of treatment is 7 days. This may be continued up to 14 days. **Adults & Children over 10 years old:** The recommended adult dosage is 200-400 mg daily according to the severity of the infection given either as a single dose or in two divided doses. Elderly: Elderly patients may be given the same dose as recommended for the adults. Renal functions should be assessed and dosage should be adjusted in severe renal impairment. **Children:** The recommended dosage for children is 8 mg/kg/day administered as single dose or in two divided doses. As a general guide the following daily doses are suggested: **Children 6-12 months:** Suspension 3.75 ml daily. **Children 1-4 years:** Suspension 5 ml daily. **Children 5-10 years:** Suspension 10 ml daily. **Children weighing more than 50 kg or older than 10 years:** Adult dose of Cefixime (200-400 mg daily) is recommended.

Use in Pregnancy and Lactation:

Cefixim should not be used in pregnancy or nursing mother unless considered essential by the physicians. Dosage in Renal impairment: **Cefixim** may be administered in the presence of impaired renal function. In patient creatinine clearance less than 20 ml/min, it is recommended that a dose of 20 mg once daily should not be exceeded.

CONTRAINDICATION AND PRECAUTIONS:

Cefixim is contraindicated in patients with known hypersensitivity to Cephalosporin group of drugs. It should be administered with caution in patients with markedly impaired renal function.

SIDE EFFECT:

Cefixim is generally well tolerated. The majority of adverse reactions observed are mild and self-limiting in nature. **Gastrointestinal disturbances:** Diarrhoea and stool changes, nausea, abdominal pain, dyspepsia, vomiting and flatulence. **CNS disturbances:** Headache and dizziness. **Hypersensitivity reaction:** Rash, pruritus, urticaria, drug fever and arthralgia have been observed.

PHARMACEUTICAL PRECAUTIONS:

Store controlled temperature (15-25°C), use suspension within 14 days of reconstitution.

DIRECTIONS FOR RECONSTITUTION OF SUSPENSION:

At first knock the bottle several times (to loosen the dry powder). To prepare suspension boiled & cooled water is mentioned in the label. Add approximately half of the total amount of water required and shake well. Then add the remainder of water and shake again. Shake the bottle well before each use.

Presentation

Cefixim Capsule: Box contains 12 (3x4's) capsules in alu-alu blister pack.

Cefixim 400 Capsule: Box contains 08(2x4's) capsules in alu-alu blister pack.

Cefixim Suspension (30, 40 & 50 ml): Bottle contains dry powder for 30, 40 & 50 ml oral suspension.

Cefixim DS Suspension: Bottle contains dry powder for 50 ml oral suspension.

Manufactured by:

The IBN SINA Pharmaceutical Industry Ltd.
Shafipur, Gazipur, Bangladesh.