

CEFIXIM

CEFIXIME TRIHYDRATE USP

Compositions:

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 21 ml pediatric drops: After reconstitution, each 5 ml Suspension Contains Cefixime 125 mg as Cefixime Trihydrate USP. Cefixim Suspension 30 ml: After reconstitution, each 5 ml suspension contains Cefixime 100 mg as Cefixime Trihydrate USP. Cefixim Suspension 40 ml: After reconstitution, each 5 ml suspension contains Cefixime 100 mg as Cefixime Trihydrate USP. Cefixim Suspension 50 ml: After reconstitution, each 5 ml suspension contains Cefixime 100 mg as Cefixime Trihydrate USP. Cefixim Suspension 75 ml: After reconstitution, each 5 ml suspension contains Cefixime 100 mg as Cefixime Trihydrate USP. Cefixim DS 50 ml Suspension: After reconstitution, each 5 ml suspension contains Cefixime 200 mg as Cefixime Trihydrate USP.

Pharmacology:

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 influenza, Neisseria Gonorrhoeae, beta-hemolytic Streptococcus and Streptococcus pneumoniae. Cefixime is absorbed slowly and incompletely (60% of oral dose). Cefixim is mainly excreted unchanged in bile and urine.

Dosage And Administration:

Depending on the severity of infection, the usual treatment duration of Cefixime is 7-14 days. Adults & Children over 10 years old: The recommended adult dosage is 200-400 mg daily according to the severity of infections given either as a single dose or in two divided doses. For uncomplicated gonorrhoea, a single oral dose of 400 mg may be given. 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 guideline, daily suggested doses are - 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. Dosage in Renal impairment: Dose of Cefixime should be reduced in patients with moderate to severe renal impairment. A dose of 200 mg daily should not be exceeded in patients with a creatinine clearance of less than 20 mL/minute.

Contraindications:

Cefixime 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.

Warning And Precaution:

Cefixime 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 Effects:

Cefixime 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.

Use in Pregnancy and Lactation:

Cefixime may be used in pregnancy or nursing mother consulting with the physicians.

Drug Interaction:

Carbamazepine: Concomitant use elevates the carbamazepine level. Warfarin and other anticoagulants: Concomitant use increases prothrombin time.

Overdosage:

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:

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

Packing:

Each box contains 20 (2x10) capsules in alu-alu blister pack. Cefixim 400 Capsule: Each box contains 20 (2x10) capsules in alu- alu blister pack. Cefixim 21 ml pediatric drops: Each bottle contains powder for 21 ml oral suspension. Cefixim 30 ml Suspension: Each bottle contains powder for 30 ml oral suspension. Cefixim 40 ml Suspension: Each bottle contains powder for 40 ml oral suspension. Cefixim 50 ml Suspension: Each bottle contains powder for 50 ml oral suspension. Cefixim 75 ml Suspension: Each bottle contains powder for 75 ml oral suspension. Cefixim DS 50 ml Suspension: Each bottle contains powder for 50 ml DS oral suspension

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.