

TOCEF

Cefixime Capsule/Powder for Suspension

Presentation

TOCEF 200 : Each capsule contains Cefixime USP 200 mg (as Trihydrate).

TOCEF 400 : Each capsule contains Cefixime USP 400 mg (as Trihydrate).

TOCEF powder for suspension 50ml : Each 5ml reconstituted suspension contains Cefixime USP 100 mg (as Trihydrate).

TOCEF powder for suspension 37.5ml : Each 5ml reconstituted suspension contains Cefixime USP 100 mg (as Trihydrate).

Pharmacodynamic properties

Cefixime like other cephalosporins kills bacteria by interfering the synthesis of bacterial cell wall. Cefixime binds with transpeptidase enzyme which is responsible for the synthesis of bacterial cell wall & thus interfere with peptidoglycan synthesis. Cefixime shows bactericidal activity against a wide variety of Gram-positive & gram-negative bacteria at easily achievable plasma concentration.

Pharmacokinetic properties

Cefixime is absorbed slowly after oral administration, the time taken to reach maximum plasma concentration increase with increasing dose. Whether taken with meal or not, 40-50% of an oral dose is absorbed from gastro-intestinal tract. The absolute oral bioavailability of Cefixime is in the range of 22-54% & plasma protein binding is about 65%. The plasma half-life is usually 3-4 hours that may prolong when there is renal impairment. Cefixime is predominantly eliminated as unchanged in urine.

Indication

Upper & lower respiratory tract infections

Urinary tract infections

Gonococcal urethritis

Acute otitis media

Enteric fever

Dosage and administration

TOCEF 200 : 1 or 2 capsule as a single dose or in 2 divided doses daily for 7-14 days, according to the severity of infection.

TOCEF 400 : 1 capsule as a single dose daily for 7-14 days, according to the severity of infection.

TOCEF Suspension : Child dose : 8-10 mg/kg daily as a single dose or in two divided doses for 7-14 days according to the severity of infection or for children of age

1/2-1 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

above 12 Years : adult dose.

Side effects

TOCEF is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature.

Gastro-intestinal disturbances : Diarrhoea (if severe diarrhoea occurs TOCEF should be discontinued), changes in the colour of stool, nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported.

Central nervous system disturbances : Headache, dizziness.

Others : Hypersensitivity reactions which usually subsided upon discontinuation of therapy; infrequent and reversible haematological changes; elevation of serum amylase.

Contraindication

Patients with known hypersensitivity to cephalosporin group of drugs.

Precaution

TOCEF should be prescribed with caution in individuals with a history of gastrointestinal diseases, particularly colitis. Dosage adjustment is only necessary in severe renal failure (creatinine clearance <20 ml. min⁻¹).

Interactions

Patients receiving anticoagulants and Cefixime concomitantly increase prothrombin time.

Use in pregnancy and lactation

No data are available, so it is probably best to avoid using the drug during pregnancy and by the nursing mothers.

Storage

Capsule : Store at room temperature and away from direct sunlight.

Suspension : Prior to reconstitution, store at room temperature. After reconstitution, the suspension may be kept for 14 days under refrigeration or at room temperature, without significant loss of potency.

Directions for reconstitution of suspension

TOCEF 50ml : Shake the bottle well before mixing water to loosen the powder. Add 35ml (7 measuring spoonfuls) boiled and cooled water in the bottle and shake well to make 50ml suspension.

TOCEF 37.5ml : Shake the bottle well before mixing water to loosen the powder. Add 25ml (5 measuring spoonfuls) boiled and cooled water in the bottle and shake well to make 37.5ml suspension

Information for the patient

- 1) Shake well before using the suspension.
- 2) Do not discontinue the therapy suddenly, without consulting your doctor.
- 3) Discard unused portion of reconstituted suspension after the above mentioned time.
- 4) Keep away from the reach of the children.

Commercial pack

TOCEF 200 : Each box contains 2 Alu-Alu blister packs of 4 capsules.

TOCEF 400 : Each box contains 2 Alu-Alu blister packs of 4 capsules.

TOCEF 50ml powder for suspension : Each bottle contains dry powder for the preparation of 50ml suspension.

TOCEF 37.5ml powder for suspension : Each bottle contains dry powder for the preparation of 37.5ml suspension.

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.
Gazipur, Bangladesh

