

Tgocef

Cefixime

Capsule and Powder for Suspension

PHARMACOLOGY

Tgocef (Cefixime) is a broad spectrum semisynthetic third generation Cephalosporin antibiotic for oral administration. It is a bactericidal antibiotic and is stable to hydrolysis by many beta lactamases.

Tgocef (Cefixime) kills bacteria by interfering in the synthesis of the bacterial cell wall. 40-50% of an oral dose is absorbed from gastrointestinal tract whether taken with meals or not. The plasma half-life is usually about 3 to 4 hours and may be prolonged when there is renal impairment. **Tgocef** is mainly excreted unchanged in bile and urine.

COMPOSITION

Tgocef 200 Capsule □ Each Capsule contains Cefixime Trihydrate USP □ equivalent to Cefixime 200 mg.

Tgocef 400 Capsule □ Each Capsule contains Cefixime Trihydrate USP □ equivalent to Cefixime 400 mg.

Tgocef Powder for □ : □ When reconstituted each 5 ml Suspension Suspension □ □ contains Cefixime Trihydrate USP equivalent to □ □ Cefixime 100 mg.

Tgocef DS Powder for □ : □ When reconstituted each 5 ml Suspension Suspension □ □ contains Cefixime Trihydrate USP equivalent to □ □ Cefixime 200 mg.

INDICATION

- Upper Respiratory Tract Infections e.g. Sinusitis, Tonsillitis, □ Pharyngitis, Laryngitis.
- Lower Respiratory Tract Infections e.g. Pneumonia, Acute bronchitis □ and Acute Exacerbations of Chronic Bronchitis, Bronchiectasis.
- Acute Otitis Media.
- Typhoid & Paratyphoid fever.
- Urinary Tract Infections e.g. Cystitis, Cystourethritis, Uncomplicated □ Pyelonephritis, Glomerulonephritis.
- Gonococcal Infections.

DOSAGE AND ADMINISTRATION

Adult & child over 10 years: 200 - 400 mg daily in 1-2 divided doses for 7-14 days according to severity of infection

Child over 6 months □ : 8 mg/kg in 1-2 divided doses

Or 6 months-1 year □ : 3.75 ml or 75 mg daily

1-4 years □ : 5 ml or 100 mg daily

5-10 years □ : 10 ml or 200 mg daily

Typhoid and Paratyphoid

Adult □ : 200 mg 12 hourly

Child □ : 10 mg/kg 12 hourly

Gonorrhoea □ : 400-800 mg as a single dose

USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy category B.

This drug should be used during pregnancy only if clearly needed.

Lactation: It is not known whether Cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

CONTRAINDICATION

Tgocef (Cefixime) is contraindicated in patients with known hypersensitivity to cephalosporin group of drugs.

SIDE EFFECT

Tgocef (Cefixime) is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature. Among them diarrhoea, changes in the color of stool, nausea, abdominal pain, dyspepsia, headache, dizziness, elevation of serum amylase may occur.

PRECAUTION

Tgocef (Cefixime) should be prescribed with caution in individual with a history of gastrointestinal diseases, particularly colitis. Dosage adjustment is only necessary in severe renal failure (creatinine clearance < 20ml/min).

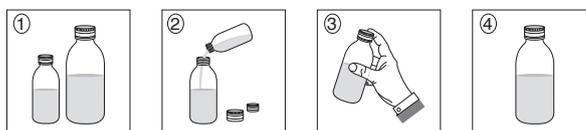
DRUG INTERACTION

Carbamazepine: Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly.

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

Direction for Preparation

For 30 ml, 50 ml & DS 50 ml PFS



1. One bottle contains Cefixime powder for suspension and another bottle contains the diluent.
2. Shake the bottle to loosen the powder. Open the cap of both bottles. Pour the diluent into the powder containing bottle.
3. Tight the cap of bottle completely and shake vigorously until it is properly mixed.
4. The suspension is ready for use. Prepared suspension may be □ consumed for 14 days of preparation if kept in room temperature or in a refrigerator.

STORAGE

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

Powder for 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.

PACKAGING

Tgocef 200 Capsule : Each box contains 3x4 capsules in alu-alu pack.

Tgocef 400 Capsule : Each box contains 2x4 capsules in alu-alu pack.

Tgocef Powder for Suspension: Each box contains two bottles. One bottle contains Cefixime powder and another bottle contains diluent for suspension. After reconstitution as per direction bottle containing 30 & 50 ml suspension.

Tgocef DS Powder for Suspension: Each box contains two bottles. One bottle contains Cefixime powder and another bottle contains diluent for suspension. After reconstitution as per direction bottle containing 50 ml suspension.



Manufactured by
SOMATEC PHARMACEUTICALS LTD.
SARULIA, DEMRA, DHAKA, BANGLADESH