

Cefim-3[®]

Cefixime

Description

Cefim-3[®] (Cefixime) is a broad spectrum Cephalosporin antibiotic of third generation for oral administration. It is a bacterial antibiotic and is stable to hydrolysis by many β -lactamases. 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. Cefim-3[®] is mainly excreted unchanged in bile and urine.

Indication and usage

Cefim-3[®] is indicated for the treatment of upper and lower respiratory tract infections. Urinary tract infections, gonococcal urethritis, typhoid fever & acute otitis media.

Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Escherichia coli*, *Proteus mirabilis*, *Klebsiella species*, *Hemophilus influenzae* (β -lactamase positive and negative), *Moraxella catarrhalis* (β -lactamase positive and negative), and *Enterobacter species*. Cefixime is highly stable in the presence of β -lactamase enzymes.

Dosage and administration

The usual duration of treatment of Cefixime is 7 days. This may be continued for up to 14 days.

Adult and children over 10 years	:	200-400mg daily as a single dose or in 2 divided doses
Child over 6 months	:	8 mg/ kg daily as a single dose or in 2 divided doses
Child 6 months – 1 year	:	75 mg daily or 3.75ml
Child 5-10 years	:	200 mg daily

Pregnancy and Lactation

Reproduction studies was performed in mice and rats at doses up to 400 times the human dose and revealed no evidence of impaired fertility or harm to the foetus due to Cefixime.

There are no adequate and well controlled studies in pregnant women. Therefore, Cefixime should not be used in pregnancy or in nursing mothers unless considered essential by the physicians.

Side effects

Cefixime generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self limiting in nature. Among them diarrhoea, dyspepsia, headache, dizziness, elevation of serum amylase may occur.

Contraindications

Patients with known hypersensitivity to Cephalosporin group drugs.

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.

Drug interactions

In common with other Cephalosporins, increases in prothrombin times have been noted in a few patients. Care should therefore be taken in patients receiving anticoagulant therapy. A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with test based on enzymatic glucose oxidase reactions.

Directions of reconstitution for suspension

Shake the bottle well before mixing the water.

Cefixim-3[®] suspension (30 ml): To prepare 30 ml suspension, add 20 ml of boiled and cooled water in two portions and shake till powder is completely mixed with water.

Cefixim-3[®] suspension (50 ml): To prepare 50 ml suspension, add 35 ml of boiled and cooled water in two portions and shake till powder is completely mixed with water.

Cefixim-3[®] suspension (75 ml): To prepare 75 ml suspension, add 52.5 ml of boiled and cooled water in two portions and shake till powder is completely mixed with water.

Keep the prepared suspension in a cool place, and consume within 14 days of preparation.

Used the supplied dropper for water measurement.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

- Cefim-3[®] capsule : Each capsule contains Cefixime 200 mg as Trihydrate USP.
Cefim-3[®] DS capsule : Each capsule contains Cefixime 400 mg as Trihydrate USP.
Cefim-3[®] suspension : After reconstitution, each 5 ml contains Cefixime 100 mg as Trihydrate USP.

Package quantities

- Cefim-3[®] capsule : Carton of 12 capsules in blister pack.
Cefim-3[®] DS capsule : Carton of 6 capsules in blister pack.
Cefim-3[®] suspension : Bottle of 30 ml, 50 ml & 75 ml with Food Grade Dropper.

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