

Cefix[®]

(Cefixime trihydrate)

Composition

Cefix[®] 200 mg capsule: Each capsule contains 200 mg Cefixime (trihydrate).

Cefix[®] 400 mg capsule: Each capsule contains 400 mg Cefixime (trihydrate).

Cefix[®] 100 mg suspension: Each 5 ml contains 100 mg Cefixime (trihydrate).

Pharmacological Properties

Cefix[®] is a broad spectrum semi-synthetic third generation cephalosporin for oral administration. The bactericidal action results from inhibition of cell wall synthesis. Cefix[®] is highly beta-lactamase stable, which makes it effective against many organisms resistant to penicillins and some cephalosporins.

Indications

Cefix[®] is active against the following Gram-positive and Gram-negative organisms:

Streptococcus pneumoniae, *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella* (Branhamella) *catarrhalis*, *Escherichia coli*, *Proteus mirabilis*, *Proteus vulgaris*, *Neisseria gonorrhoeae*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, *Pasteurella multocida*, *Providencia* species, *Shigella* species, *Citrobacter diversus*, *Serratia marcescens*.

Cefix[®] is indicated in the treatment of the following infections:

-Pharyngitis, tonsillitis and sinusitis.

-Acute bronchitis and acute exacerbation of chronic bronchitis.

-Otitis media.

-Uncomplicated urinary tract infection

-Uncomplicated cervical or urethral gonorrhoea.

Dosage and Administration

Usual adult dose: 400 mg daily, this may be given as 400 mg once daily or 200 mg every 12 hours.

For the treatment of uncomplicated urethral or cervical gonococcal infections, 400mg as single dose is recommended.

Usual pediatric dose: 8mg/kg/day of suspension. This may be given as single dose or in two divided doses as 4mg/kg/12 hours.

The following table shows children dose:

Patient weight (kg)	Dose / day (mg)	Dose / day (ml)
6.25	50	2.5
12.5	100	5.0
18.75	150	7.5
25	200	10.0

Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose.

Dosage in renal impairment

In cases of renal impairment, the dosage should be adjusted according to the creatinine clearance.

If the creatinine clearance more than or equals 60 ml / min., the standard dose of 400 mg can be given, if it ranges from 21- 60 ml/min., 75% of the standard dose can be given and in cases where it is less than 20ml / min., half the standard dose can be given.

Contraindications

Cefixime is contraindicated in patients who had previous hypersensitivity reactions to any of cephalosporins antibiotics

Adverse Effects

Cefix[®] has mild and transient side effects such as diarrhea, nausea, vomiting, abdominal pain, skin rashes, urticaria and transient elevation in liver enzymes.

Some of these adverse effects may occur:

- Hypersensitivity Reactions:
 - Anaphylactic/Anaphylactoid Reactions
 - Angioedema
 - Facial Edema
- Hepatic:
 - Hepatitis
 - Jaundice
- Renal:
 - Acute Renal Failure
- Central Nervous System
 - Seizures
- Hemic and Lymphatic Systems:
 - Neutropenia
- Abnormal Laboratory Tests:
 - Hyperbilirubinemia
- Other
 - Toxic Epidermal Necrolysis

Warnings and Precautions

As with other antibiotics, prolonged use may result in overgrowth of non-susceptible organisms.

Drug interaction with warfarin and anticoagulant may occur.

Overdose

Although no specific antidote exists, gastric lavage may be indicated.

Use in pregnancy and lactation

Pregnancy category B: this drug should be used during pregnancy only if clearly needed.

It is not known whether cefixime is excreted in breast milk, yet no problems in humans have been reported to date.

Presentations

Cefix[®] 200 mg capsule: 8 capsules per pack.

Cefix[®] 400 mg capsule: 5 capsules per pack.

Cefix[®] 100 mg suspension: 30, 60 ml bottle.



(This is a medication - keep medications out of reach of children)

- Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, method for use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.