

Patient Information Leaflet
CEFAZIM 200
(Cefixime Tablet USP 200mg)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- a) What Cefazim 200 is and what it is used for
- b) Before you take Cefazim 200
- c) How to take Cefazim 200
- d) Possible side effects
- e) How to store Cefazim 200
- f) Further information

a) What Cefazim 200 is and what it is used for

Cefazim 200 belongs to a group of medicines called Cephalosporins, which are used for treating infections.

Cefazim 200 can be used to treat:

- infection of the middle ear
- sinus infection
- throat infection
- infection causing sudden worsening of long-standing bronchitis
- serious lung infections (pneumonia) acquired outside of hospital
- infections in the urinary tract

b) Before you take Cefazim 200

Do not take Cefazim 200 if you:

- are allergic (hypersensitive) to cefixime or to any of the other ingredients of this medicine (see section f).
- An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- are allergic (hypersensitive) to any other cephalosporin type of antibiotic.
- have ever had a severe allergic reaction to penicillin antibiotic or to any other beta-lactam type of antibiotic.

Take special care with Cefazim 200

Before you take Cefazim 200 you should tell your doctor if you:

- are allergic to penicillin antibiotics or to any other beta-lactam type of antibiotics. Not all people who are allergic to penicillins are also allergic to cephalosporins. However, you take special care if you ever had an allergic reaction to any penicillin. This is because you might also be allergic to this medicine.

In patients who develop severe allergic reaction or anaphylaxis (serious allergic reaction which causes difficulty in breathing or dizziness) after administration of Cefazim 200, the medicine should be withdrawn and appropriate treatment should be given.

- have ever been told that your kidneys do not work very well. Also, if you are taking any sort of treatment (like dialysis) for kidney failure. You may take Cefazim 200 but you may need a lower dose.
- have severe or persistent diarrhoea that may be bloody and that may be associated with stomach pain or cramps: these symptoms may occur during or shortly after treatment and signal a rare, but potentially life-threatening adverse reaction. Stop taking Cefazim 200 and contact your doctor immediately. Medicines which may slow or stop bowel movements must not be taken.

Having a course of Cefazim 200 can temporarily increase the chance that you can get infections caused by other sort of germs on which Cefazim 200 does not act. For example, thrush (infection caused by a yeast germ called Candida) may occur.

Effect on laboratory tests

If you are to undertake any blood or urine tests, inform your doctor that you are taking Cefazim 200, as cefixime can alter the results of some of these tests.

Cefazim 200 can alter the results of some urine tests for sugar (such as Benedict's or Fehling's tests). If you have diabetes and routinely test your urine, tell your doctor. This is because other tests may have to be used to monitor your diabetes while you are having this medicine.

Cefazim 200 may alter the results of a blood test for antibodies called the direct Coombs' test.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking:

- anticoagulant (blood thinning) therapy with medicines such as warfarin.

Taking Cefazim 200 with food and drink

Cefazim 200 may be taken with or without food. You should swallow the tablets whole with a glass of water.

Pregnancy and breast-feeding

If you are pregnant, likely to become pregnant or breast-feeding, you must tell your doctor before taking this medicine. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Cefixime do not usually affect your ability to drive or use machines. However, if you feel light-headed or dizzy, do not drive or operate machinery.

c) How to take Cefazim 200

Dosage:

Your doctor will decide the right dose of Cefazim 200 and will tell you how long to take your medicine. The number of Cefazim 200 tablets you need to take will depend on your condition.

Follow your doctor's instructions exactly and never change the dose yourself. Ask your doctor or pharmacist if you are unsure about how much medicine to take or when to take it.

The usual course of treatment is 7 days. This may be continued for up to 14 days if required.

Adults and Children over 10 Years or weighing more than 50kg:

The recommended adult dosage is 200-400mg daily according to the severity of infection, given either as a single dose or in two divided doses.

Elderly:

Elderly patients may be given the same dose as recommended for adults. Renal function should be assessed and dosage should be adjusted in severe renal impairment.

Children under 10 years:

Cefaxime Tablets 200mg are not recommended for use in children under 10 years old.

The safety and efficacy of cefixime has not been established in children less than 6 months.

Renal Impairment:

Cefixime may be administered in the presence of impaired renal function. Normal dose and schedule may be given in patients with creatinine clearances of 20 ml/min or greater. In patients whose creatinine clearance is less than 20ml/min, it is recommended that a dose of 200 mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis or haemodialysis should follow the same recommendation as that for patients with creatinine clearances of less than 20ml/min.

If you take more Cefazim 200 than you should

If you accidentally take too many tablets or a child swallows any Cefazime 200 tablets, contact your nearest hospital casualty department or your doctor immediately.

If you forget to take Cefazim 200

If you forget to take a tablet, take one as soon as you remember. However, if the next dose is due in less than 6 hours, skip the missed dose and go back to your regular dosing schedule. Do not take double doses.

If you stop taking Cefazim 200

Do not stop treatment early because it is important that you complete the FULL course of this medicine in order to reduce the chance of the infection returning.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

d) Possible Side Effects

Like all medicines, Cefixime can cause side effects, although not everybody gets them.

The following side effects are important and will require immediate action if you experience them. You should stop taking Cefixime and see your doctor immediately if the following symptoms occur:

Rare side effects (affect less than 1 in 1,000 patients) include:

- swelling of the face, tongue and windpipe which can cause great difficulty in breathing

Very rare side effects (affect less than 1 in 10,000 patients) include:

- watery and severe diarrhoea that may also be bloody

- a sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure
- severe, extensive, blistering skin rash

The following side-effects have also been reported:

Common side effects (affect less than 1 in 10 patients) include:

- diarrhoea

Uncommon side effects (affect less than 1 in 100 patients) include:

- headache
- nausea
- vomiting
- stomach (abdominal) pain
- changes in blood tests that check how your liver is working
- skin rash

Rare side effects (affect less than 1 in 1000 patients) include:

- infections caused by germs that Cefixime does not act on. For example, thrush
- loss of appetite
- flatulence (wind)
- changes in blood tests that check how your kidney is working
- fever
- allergy reaction
- dizziness
- itchy skin
- inflammation of the lining of the mouth and / or other internal surfaces

Very rare side effects (affect less than 1 in 10000 patients) include:

- fall in the number of different cells in the blood (symptoms can include tiredness, new infections and easy bruising or bleeding)
- Restlessness and increased activity
- Liver problems including jaundice (yellowing of the skin or whites of the eyes)
- inflammation of the kidney

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

e) How to Store Cefazim 200

- Keep out of the reach and sight of children.
- Store at temperature not exceeding 30°C, protect from moisture.

f) Further Information

What Cefazim 200 contains

The active ingredient is cefixime. Each film coated tablet contains Cefixime USP as Trihydrate equivalent to Anhydrous cefixime 200mg.

The tablet also contains: Colloidal Anhydrous Silica, Maize starch, Magnesium Stearate, Purified talc, Microcrystalline cellulose, Croscarmellose Sodium, Propylene Glycol, Titanium Dioxide, Hypromellose, Isopropyl alcohol, Dichloromethane.

What Cefazim 200 looks like and contents of the pack

Cefazim 200 is white, circular, slightly biconvex, film coated tablets, plain on both sides.

The product is available in:

1×10 Alu-Alu Blister Pack enclosed in a carton.

Marketing Authorization Holder: ZIM LABORATORIES LIMITED

Manufacturing site:

ZIM LABORATORIES LIMITED

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Kalmeshwar, Nagpur 441501,

Maharashtra State, India.

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