

Module 3

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cefixime 200 mg Film-coated tablets

Cefixime

The name of your medicine is Cefixime 200 mg Film-coated tablets and will be referred to as Cefixime 200 throughout the rest of this document.

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, Please 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:

1. What Cefixime 200 is and what it is used for
2. Before you take Cefixime 200
3. How to take Cefixime 200
4. Possible side effects
5. How to store Cefixime 200
6. Further information

1. WHAT CEFIXIME 200 IS AND WHAT IT IS USED FOR

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

Cefixime 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

2. BEFORE YOU TAKE CEFIXIME 200

Do not take Cefixime 200 if you

- are allergic (hypersensitive) to cefixime or to any of the other ingredients of this medicine (see section 6).
- 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 Cefixime 200

Before you take Cefixime 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which causes difficulty in breathing or dizziness) after administration of Cefixime 200, the medicine should be withdrawn and appropriate treatment should be given.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 Cefixime 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 Cefixime 200 and contact your doctor immediately. Medicines which may slow or stop bowel movements must not be taken.

Having a course of Cefixime 200 can temporarily increase the chance that you can get infections caused by other sort of germs on which Cefixime 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 Cefixime 200, as cefixime can alter the results of some of these tests.

Cefixime 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.

Cefixime 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 Cefixime 200 with food and drink

Cefixime 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.

3. HOW TO TAKE CEFIXIME 200

Dosage

Your doctor will decide the right dose of Cefixime 200 and will tell you how long to take your medicine. The number of Cefixime 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.

Usual dose for adults

The usual adult dosage is one to two Cefixime 200 tablets daily. If two cefixime 200mg tablets per day are prescribed then these can be taken either as a single dose or in two divided doses. If your doctor has prescribed one dose a day, it should be taken every 24 hours. If your doctor has prescribed two doses a day, each dose should be taken every 12 hours (you may find it convenient to take one dose in the morning and the other in the evening). The medicine should always be taken at the same time each day.

Elderly

For elderly patients, the doses are the same as adults provided the kidney functions are normal.

Patients with kidney problems

In adult patients with kidney problems, the dosage of Cefixime 200 may need to be reduced. Your doctor will calculate the right dose for you according to the results of blood or urine tests that measure how well your kidneys are working and also according to the severity of your infection.

There are insufficient data regarding the use of Cefixime 200 in children and adolescents with kidney problems. Cefixime 200 is therefore not recommended for use in these patients.

Adolescents 12 years of age and older

Adolescents 12 years of age and older may be given the same dose as adults.

Children older than 6 months and up to 11 years of age

Children older than 6 months and up to 11 years should be given cefixime as an oral suspension (liquid to be taken by mouth) rather than as a tablet.

Children less than 6 months of age

Cefixime 200 is not recommended for use in children less than 6 months of age.

If you take more Cefixime 200 than you should

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

If you forget to take Cefixime 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 Cefixime 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.

4. 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.

5. HOW TO STORE CEFIXIME 200

Keep out of the reach and sight of children.

- Do not use Cefixime 200 after the end of the expiry month (use by date) shown on the product packaging. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep blister in the outer carton.
- Medicines should not be disposed off via waste water or household waste. Ask your pharmacist how to dispose off medicines not longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What Cefixime 200 contains**

The active ingredient is cefixime. Each film coated tablet contains 223.81 mg Cefixime trihydrate equivalent to 200 mg Anhydrous Cefixime.

The tablet also contains: calcium hydrogen phosphate, starch pregelatinised, cellulose microcrystalline, colloidal silica anhydrous, magnesium stearate and Opadry white (Y-1-7000).

The Opadry White (Y-1-7000) contains Hypromellose (E 464), Macrogol (E 1520) and Titanium Dioxide (E 171).

What Cefixime 200 looks like and contents of the pack

White, circular, biconvex film coated tablets debossed with 'C' on one side and plain on the other side.

The product is available in:

PVC/ PVdC/ Al blister pack: 6s, 7s, 10s – One blister packed in a carton along with a PIL
 12s, 14s, 20s – Two blisters packed in a carton along with a PIL
 30s – Three blisters packed in a carton along with a PIL
 40s – Four blisters packed in a carton along with a PIL
 100s – Ten blisters packed in a carton along with a PIL

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Orchid Europe Ltd
 Building 3, Chiswick Park, 566, Chiswick High Road,
 Chiswick, London, W4 5YA, United Kingdom

This medicinal product is authorized in the member states of the EEA under the following names

Bulgaria	Cefixime Orchid Europe
Germany	Cefixime Orchid Europe Ltd 200mg Filmtabletten
Ireland	Cefixime 200mg Film-coated tablets
Italy	Cefixime 200mg Film-coated tablets
Poland	Cefiksym Orchid Europe Ltd
United Kingdom	Cefixime 200mg Film-coated tablets

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