

Package leaflet: Information for the patient

Cefixime ABR 400 mg film-coated tablets

Cefixime

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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1. What Cefixime ABR 400 is and what it is used for

Cefixime ABR 400 belongs to a group of medicines, called cephalosporins, which are used for the treatment of infections in adults and children.

Cefixime ABR 400 is indicated for the treatment of:

- infection of the middle ear
- infection of the sinuses
- infection of the throat
- infection that causes sudden worsening of a persistent bronchitis
- severe lung infections (pneumonia), acquired out of the hospital
- infections of the urinary tract.

2. What you need to know before you take Cefixime ABR 400

Do not take Cefixime ABR 400

- if you are allergic to cefixime or any of the other ingredients of this medicine (listed in section 6). The allergic reaction may include rash, itching, difficulty in breathing or swelling of the face, throat or tongue;
- if you are allergic to other cephalosporin antibiotics;
- if you have ever had a severe allergic reaction to a penicillin antibiotic or any other beta-lactam antibiotic.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cefixime ABR 400.

Before taking Cefixime ABR 400, you should tell your doctor:

- if you are allergic to penicillin antibiotics or any other antibiotic of the beta-lactam group. Not all people, allergic to penicillin, are allergic to cephalosporins. However, take special measures, if you have ever had an allergic reaction to any antibiotic of the penicillin group. This is needed because you might be allergic to this medicine, as well.

In patients developing severe allergic reactions or anaphylaxis (a severe allergic reaction, which causes difficulty in breathing or dizziness) after the administration of Cefixime ABR 400, the medicine should be stopped and adequate treatment should be instituted.

- if you have ever been told that your kidneys do not work properly; also, if you are undergoing some treatment (such as dialysis) for renal insufficiency. You may still receive Cefixime ABR 400, but you may need a lower dose.
- if you have severe or persistent diarrhoea, which may contain traces of blood and is combined with abdominal pain or spasms: these symptoms may present during or shortly after the treatment and give warning of a rare, but potentially life-threatening undesirable effect. Stop taking Cefixime ABR 400 and contact your doctor immediately. Medicines that slow down or stop intestinal peristalsis should not be taken.

During the therapeutic course with Cefixime ABR 400, the likelihood of catching infections, caused by microbes irresponsive to the action of Cefixime ABR 400, may temporarily increase. Thrush (an infection caused by a fungus, called *Candida*) may occur.

Interference with laboratory tests

If you are going to have some blood or urine testing, tell your doctor that you receive Cefixime ABR 400, since cefixime may interfere with some of these test results.

Cefixime ABR 400 may interfere with the results of some tests for detecting glucose in the urine (such as Benedict's test or Fehling's test). If you have diabetes and test your urine regularly, tell your doctor. This is needed because other tests for controlling your diabetes are to be used, whilst you are taking this medicine.

Cefixime ABR 400 may interfere with the results of a blood test for antibodies, called the Coombs' test.

Other medicines and Cefixime ABR 400

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if:

- you have been on anticoagulant (for thinning the blood) treatment with medicines, such as warfarin.

Cefixime ABR 400 with food, drink and alcohol

Cefixime ABR 400 can be taken before or after meals. The tablets should be swallowed whole with a glass of water.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Usually, Cefixime ABR 400 has no influence on the ability to drive or use machines. However, if you experience dizziness or vertigo, do not drive and do not operate machines.

3. How to take Cefixime ABR 400

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide the correct dose of Cefixime ABR 400 and will tell you how long to take your medicine. The number of Cefixime ABR 400 tablets, which you need to receive, will depend on your condition. Follow exactly the instructions of your doctor and never change your dose on your own. Ask your doctor or pharmacist if you are not sure about the amount of the medicine you have to receive or when you should receive it.

Adults

The recommended dose is one or two tablets Cefixime ABR 400 daily. If you have been prescribed two Cefixime ABR 400 tablets daily, these can be received in one intake as a single dose or as two individual doses.

If your doctor has prescribed to you one dose daily, it should be taken every 24 hours. If your doctor has prescribed to you two doses daily, each dose should be taken every 12 hours (it may turn more convenient to take the one dose in the morning and the other in the evening). This medicine should be taken at the same time each day.

Elderly (over 64 years of age)

In the elderly, the dosage is the same as in adults with normal renal function.

Patients with kidney problems

In elderly patients with kidney problems, the dose of Cefixime ABR 400 may need to be reduced. Your doctor will calculate your correct dose, depending on the blood or urine test results, which are indicative of how properly your kidneys are functioning, as well as on the severity of your infection.

Data on the use of Cefixime ABR 400 in children and adolescents with kidney problems are insufficient. Therefore, Cefixime ABR 400 is not recommended for use in these patients.

Use in children and adolescents

Adolescents over 12 years of age

In adolescents over 12 years of age, a dosage the same as that in adults may be administered.

Children over 6 months to 11 years of age

In children over 6 months to 11 years of age, cefixime should be given rather as an oral suspension (liquid which is taken orally) than as a tablet.

Children under 6 months of age

Cefixime ABR 400 is not recommended for use in children under 6 months of age.

If you take more Cefixime ABR 400 than you should

If you have accidentally taken more tablets or a child has swallowed Cefixime ABR 400 tablets, contact the emergency centre at the nearest hospital or your doctor immediately.

If you forget to take Cefixime ABR 400

If you forget to take a tablet, take it as soon as you remember. However, if the intake of your next dose is in less than 6 hours, skip the forgotten dose and follow your regular dosing schedule. Do not take a double dose.

If you stop taking Cefixime ABR 400

Do not stop the treatment earlier, because it is important to complete the full course of treatment with this medicine, in order to reduce the likelihood of an infection re-occurrence.

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

4. Possible side effects

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

The following side effects are serious and requiring immediate action, if you experience them. You should stop taking cefixime and go to the doctor immediately upon occurrence of the following symptoms:

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

- swelling of the face, tongue and air tube, which may cause severe difficulty in breathing

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

- watery and severe diarrhoea, which may contain traces of blood
- a sudden allergic reaction with difficulty in breathing, rash, wheezing and a drop of the arterial pressure
- severe, extensive rash with blistering

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 (feeling sick)
- vomiting (being sick)
- stomach (abdominal) pain
- changes in the laboratory test results indicative for the functioning of the liver
- skin rash

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

- infections, caused by microbes irresponsive to the action of cefixime, e.g. thrush
- loss of appetite

- flatulence (wind)
- changes in the laboratory test results indicative for the functioning of the kidneys
- fever
- allergic reaction
- dizziness
- itching of the skin
- inflammation of the mucosa lining the mouth and/or other internal surfaces

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

- reduction of the various blood cell counts (the symptoms may include fatigue, newly occurred infections and bruising or bleeding after a minor trauma)
- agitation and overactivity
- liver problems, including jaundice (yellowing of the skin or white of the eyes)
- inflammation of the kidneys

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 ABR 400

Keep this medicine out of the sight and reach of children.

Do not use Cefixime ABR 400 after the expiry date (EXP) which is stated on the pack. The expiry date refers to the last day of that month.

Store below 25°C.

Store the blister in the cardboard carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cefixime ABR 400 contains

- The active substance is cefixime. Each film-coated tablet contains 447.63 mg cefixime trihydrate, equivalent to 400 mg cefixime.
- The other ingredients are cellulose, microcrystalline; starch, pregelatinised; silica, colloidal anhydrous; magnesium stearate; calcium hydrogen phosphate, anhydrous; opadry white Y-1-7000

Opadry white Y-1-7000 contains: hypromellose (E 464), macrogol 400 (E 1520), titanium dioxide (E 171)

What Cefixime ABR 400 looks like and contents of the pack

White to off-white, rectangular-shaped film-coated tablets with rounded edges and a score line on both sides.

Blister of PVC/ PVdC / Al foil or PVC/Aclar/ Al foil: 10 film-coated tablets in a blister. One blister with a patient leaflet is inserted in a cardboard carton.

Marketing Authorisation Holder

Antibiotic-Razgrad AD

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Razgrad 7200

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This leaflet was last revised in 10/2011.