

## Cefixime 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Cefixime is and what it is used for
2. What you need to know before you take Cefixime
3. How to take Cefixime
4. Possible side effects
5. How to store Cefixime
6. Contents of the pack and other information

### 1. What Cefixime is and what it is used for

Cefixime contains a medicine called cefixime. This belongs to a group of antibiotics called "cephalosporins", which are used for treating infections caused by bacteria. Cefixime is 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. What you need to know before you take Cefixime

#### Do not take Cefixime:

- If you are allergic to cefixime or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to any other cephalosporin type of antibiotic.
- If you have ever had a severe allergic reaction to penicillin antibiotic or to any other beta-lactam type of antibiotic.

Do not take this medicine if the above applies to you. Talk to your doctor or pharmacist before taking Cefixime film-coated tablets.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Cefixime if:

- You have ever had colitis;
- You have kidney problems;
- The person taking this medicine is a child under the age of 12.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Cefixime is not suitable for everyone.

Before you take Cefixime you should tell your doctor if you:

- Are allergic to penicillin antibiotics or to any other beta-lactam type of antibiotics.

An allergic reaction may include rash, itching, difficulty in swallowing or breathing or swelling of the face, lips, throat and tongue. Not all people who are allergic to penicillins are also allergic to cephalosporins. However, you should 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, the medicine should be discontinued and appropriate treatment should be given.

- Are taking other medicines which are known to be harmful to your kidneys. Also inform your doctor if you have any kidney problems. Your doctor may perform certain test regularly to measure how well your kidneys are working during the treatment.
- Have severe or persistent diarrhoea with stomach pain or cramps during or shortly after treatment with Cefixime, stop taking this medicine and contact your doctor immediately. Medicines which may slow or stop bowel movements must not be taken.

If you develop syndrome known as DRESS syndrome or Stevens-Johnson syndrome or skin reaction known as toxic epidermal necrolysis (see section 4. Possible side effects) while you are taking Cefixime, stop taking this medicine and contact your doctor immediately.

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

### Other medicines and Cefixime

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 are taking:

- Medicines which are known to be harmful to your kidneys like:
  - antibiotics include aminoglycoside antibiotics, colistin, polymyxin and viomycin;
  - medicines that increase the amount of urine your body produces (diuretics) such as ethacrynic acid or furosemide;
- Nifedipine, a medicine used for the treatment of high blood pressure or heart problems;
- Anticoagulants (blood thinning medicines) such as warfarin in some patients. Cefixime causes problems with blood clotting and may increase the time taken for the blood to clot.

### Effect on laboratory tests

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

Cefixime 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 for 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 can alter the results of some urine tests for ketones. Tell your doctor that you are taking Cefixime because other tests may have to be used.

Cefixime can alter the results of a blood test for antibodies called the direct Coomb's test.

### Cefixime with food and drink

Cefixime may be taken with or without food. The tablet should be swallowed with a glass of water.

### Pregnancy, breast-feeding and fertility

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

### Driving and using machines

Cefixime does not usually affect your ability to drive and use machines.

### 3. How to take Cefixime

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The dose your doctor prescribes depends on the type of infection and how bad the infection is. It also depends on how well the kidneys are working. Your doctor or pharmacist will explain this to you.

The recommended dose is:

#### Adults

The usual adult dose is 400 mg (1 tablet) daily as single oral dose or divided in two equal oral doses of 200 mg (1/2 tablet) every 12 hours. The medicine should always be taken at the same time each day.

#### Patients with kidney problems

In patients with kidney problems, the dosage of Cefixime 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 your kidneys are working.

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

#### Older people

No change in dose is needed for elderly patients, provided the kidneys are normal.

#### Adolescents 12 years of age and older

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

#### Children under 12 years of age

The pharmaceutical form tablet is not suitable for children younger than 12 years.

#### If you take more Cefixime than you should

If you or your child have taken more of this medicine than you should, talk to your doctor or contact your nearest hospital emergency department immediately.

#### If you forget to take Cefixime

If you forget to take a tablet, take it 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 a double dose to make up for a forgotten dose.

### If you stop taking Cefixime

It is important that you take this medicine until you finish the prescribed course. You should not stop taking Cefixime just because you feel better. If you stop too soon, the infection may start up again. If the person being treated still feels unwell at the end of the prescribed course of treatment or feels worse during treatment, tell your doctor.

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 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:

Very rare (may affect up to 1 in 10,000 people):

- Watery and severe diarrhoea that may also be bloody;
- Sudden severe allergic reactions (anaphylactic shock) such as skin rash or hives, itchiness, swelling of the face, lips, tongue or other parts of the body, tightness of the chest, wheezing and collapse;
- Severe skin illness with blistering of the skin, mouth, eyes and genitals (Stevens Johnson syndrome, toxic epidermal necrolysis) (see section 2. What you need to know before you take Cefixime - Warnings and Precautions).

Not known (frequency cannot be estimated from the available data):

- Severe skin eruption, fever, enlarged lymph nodes, increase in the numbers of white blood cells called eosinophils (DRESS syndrome) (see section 2. What you need to know before you take Cefixime - Warnings and precautions).

The following side-effects have also been reported:

**Common** (may affect up to 1 in 10 people):

- Diarrhoea.

**Uncommon** (may affect up to 1 in 100 people):

- Headache;
- Nausea;
- Vomiting;
- Abdominal (tummy) pain;
- Changes in blood tests that check how your liver is working;
- Skin rash.

**Rare** (may affect up to 1 in 1000 people):

- An increased chance that you can get infections caused by germs that cefixime does not act on. For example, thrush;
- Increase in the numbers of white blood cells called eosinophils;
- Allergic reaction;
- Loss of appetite;
- Dizziness;
- Flatulence (wind);
- Itchy skin;
- Inflammation of mucus (moist) linings such as the mouth and/or other internal surfaces;
- Fever;
- Changes in blood tests that check how your kidneys are working.

**Very rare** (may affect up to 1 in 10,000 people):

- Fall in the number of different cells in the blood (symptoms can include tiredness, new infections and easy bruising or bleeding);
- Allergic reaction characterised by skin rashes, fever, joint pains and enlarged organs;
- Restlessness and increased activity;
- Liver problems including jaundice (yellowing of the skin or whites of the eyes);
- Inflammation of the kidney.

**Not known** (frequency cannot be estimated from the available data):

- Rise in the number of blood platelets (thrombocytosis);
- Fall in the number of a type of white blood cells (neutropenia);
- Dyspepsia;
- Skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Cefixime

Store below 25°C.

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

Do not use this medicine after the expiry date which is stated on the carton after {EXP}. The expiry date refers to the last day of that month.

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 contains

- The active substance is cefixime.

Each film coated tablet contains 400 mg cefixime (as cefixime trihydrate).

- The other ingredients are: *Tablet core*: Microcrystalline Cellulose; Calcium hydrogen phosphate dihydrate; Starch, pregelatinized; Magnesium stearate. *Film-coating*: Hypromellose 5 cP E464; Macrogol 400; Titanium dioxide E171.

#### What Cefixime looks like and contents of the pack

Cefixime film-coated tablets are white to slightly cream, oblong, biconvex film-coated tablets with bisection line on one side of the tablet.

The film coated tablets are blister-packed in transparent PVC/PVDC/Al foil. Each blister contains 5 tablets or 7 tablets. The lithographed cardboard carton contains 1 blister with 5 tablets (5 tablets) or 1 blister with 7 tablets (7 tablets) or 2 blisters with 5 tablets (10 tablets) and a leaflet inside.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

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#### Manufacturer

ALKALOID-INT d.o.o., Šlandrova ulica 4, 1231 Ljubljana – Črnuče, Slovenia  
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#### This medicinal product is authorised in the Member states of the EEA under the following names:

UK	Cefixime 400 mg film-coated tablets
Austria	Cefixim InnFarm 400 mg Filmtabletten
Czech Republic	Cefixime InnFarm 400 mg, potahované tablety
Spain	XIFIA 400 mg comprimidos recubiertos con película EFG
Hungary	Suffixin Forte 400 mg filmtabletta
Poland	Cetix
Portugal	Cefixima InnFarm
Romania	XIFIA 400 mg comprimate filmate
Slovak Republic	Cefixime InnFarm 400 mg

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#### Advice/medical education

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections.

If your doctor has prescribed antibiotics, you need them precisely for your current illness.

Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.

Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosage;
- schedules;
- duration of treatment.

#### Consequently, to preserve the efficacy of this drug:

- 1 - Use antibiotics only when prescribed.
- 2 - Strictly follow the prescription.
- 3 - Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
- 4 - Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
- 5 - After completion of treatment, return all unused drugs to your chemist's shop to ensure they will be disposed of correctly.

