

## PACKAGE LEAFLET: INFORMATION FOR THE USER

---

### PANCEF

400mg Film-coated tablets

CEFIXIME

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

---

#### What is in this leaflet?

1. What PANCEF is and what it is used for
2. Before you take PANCEF
3. How to take PANCEF
4. Possible side effects
5. How to store PANCEF

#### 1. WHAT PANCEF IS AND WHAT IS IT USED FOR

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

Cefixime is used to treat:

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

#### 2. BEFORE YOU TAKE PANCEF

##### **Do not take PANCEF if you**

- are allergic (hypersensitive) to cefixime or any of the ingredients in the tablet. 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 PANCEF***

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. Not all people who are allergic to penicillins are also allergic to cephalosporins. However, you should not take this medicine if you ever had a severe 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 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 but you may need a lower dose.

- 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.

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.

### ***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 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 may alter the results of a blood test for antibodies called the direct Coomb's 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:

- 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.
- oral contraceptives (the birth control pill)

### ***Taking PANCEF with food and drink***

Cefixime may be taken with or without food. The tablet should be swallowed 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 does not usually affect your ability to drive or use machines. However, if you feel light-headed or dizzy, do not drive or use machines.

### ***3. HOW TO TAKE PANCEF***

#### **Dosage**

Always take cefixime exactly as your doctor has told you. You should 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 usual dose is

#### **Adults**

The usual adult dose is one tablet taken once daily. 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 well 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.

#### **Elderly**

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

#### **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 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**

It is important that you take this medicine until you finish the prescribed course. You should not stop the medicine 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 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:

**Very rare side effects (affect less than 1 in**

**10,000 patients)** include:

- 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)

**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
- abdominal (tummy) 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:

- 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 kid neys are working

**Very rare side effects (affect less than 1 in**

**10,000 patients)** include:

- 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

**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 PANCEF**

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children. Keep blister in the outer carton.

Do not take Cefixime after the expiry date which is stated on the blister and carton after "EXP".

The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.