

PACKAGE LEAFLET: INFORMATION FOR THE USER

PANCEF

100 mg/5 ml granules for oral suspension

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

PANCEF contains an active substance called cefixime. This belongs to a group of antibiotics called “cephalosporins”, which are used for treating infections caused by bacteria.

PANCEF is used in children above 6 months, adolescents and adults to treat:

- infection of the middle ear,
- infection causing sudden worsening of long-standing bronchitis,
- uncomplicated acute infection of the bladder,
- uncomplicated infection of the kidneys.

2. BEFORE YOU TAKE PANCEF

Do not take PANCEF:

- if you are allergic to cefixime or to any of the other ingredients

of this medicine,

- if you are allergic (hypersensitive) 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.

This medicine should not be administered to preterm new-borns and new-borns.

Do not take this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking PANCEF oral suspension.

Warnings and Precautions

Talk to your doctor or pharmacist before taking PANCEF if:

- you have ever had colitis,
- you have kidney problems,
- your child is under the age of 6 months.

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

Before you take PANCEF 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 (serous allergic reaction which causes difficulty in breathing or dizziness) after administration of PANCEF, the medicine should be discontinued and appropriate treatment should be given.

- are taking other medicines which are known to be harmful to you 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 PANCEF, 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 PANCEF, stop taking this medicine and contact your doctor immediately.

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

This medicine may cause vomiting and diarrhea (see section 4. Possible side effects). In such case, the efficacy of PANCEF and/ or other medicinal products taken by you (as the birth control pill) may be impaired.

Other medicines and PANCEF

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. PANCEF 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 PANCEF, as cefixime can alter the results of some of these tests.

PANCEF 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.

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

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

PANCEF with food and drink

PANCEF may be taken with or without food.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

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

PANCEF contains sucrose

This medicine contains 2.52 g of sucrose per 5 ml reconstituted suspension. This should be taken into account by patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars (fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency), contact your doctor before taking this medicinal product.

3. HOW TO TAKE PANCEF

Always take this medicine exactly as your doctor or pharmacist 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 reconstituted suspension should be administered undiluted before or during a meal. The usual dose is:

Adults

400 mg once daily (= 20 ml of the reconstituted suspension) as a single dose or 2 times daily 200 mg (= 10 ml) at intervals of 12 hours.

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 under 12 years

PANCEF 8 mg / kg body weight / day, either as a single dose or two divided doses 12 hourly.

The dosing recommendations are given in the following table:

Body weight	Daily dose (ml) Once daily	Daily dose (ml) Twice	daily dose (mg)
6.0 kg-9 kg (for infants above 6 months)	1 x 2.5 ml	2 x 1.25 ml	50 mg
10.0 kg	4 ml	2 x 2 ml	80 mg
12.5 kg	5 ml	2 x 2.5 ml	100 mg
15.0 kg	6 ml	2 x 3 ml	120 mg
17.5 kg	7 ml	2 x 3.5 ml	140 mg
20.0 kg	8 ml	2 x 4 ml	160 mg
22.5 kg	9 ml	2 x 4.5 ml	180 mg
25.0 kg	10 ml	2 x 5 ml	200 mg
27.5 kg	11 ml	2 x 5.5 ml	220 mg
30.0 kg	12 ml	2 x 6 ml	240 mg
37.5 kg	15 ml	2 x 7.5 ml	300 mg
>37.5 kg	20 ml	2 x 10 ml	400 mg

For adolescents and adults without swallowing problems, the use of cefixime tablets is recommended.

Renal insufficiency

PANCEF 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

20 ml/min/1.73 m², it is recommended that a dose of 200 mg once daily should not be exceeded.

In children under 12 years with a creatinine clearance of <20 ml/min/1.73 m², a dose of 4 mg cefixime/kg body weight should be given only once a day.

Preparation of the suspension

100 ml oral suspension: To reconstitute add 66 ml of water in two portions shaking after each addition.

Shake the medicine bottle well before each use.

Duration of treatment

The usual course of treatment is 7 days. This may be continued for up to 14 days according to the severity of the infection.

For acute uncomplicated cystitis in women, the treatment period is 1-3 days.

If you take more PANCEF 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 PANCEF

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.

If you stop taking PANCEF

It is important that you take this medicine until you finish the prescribed course. You should not stop taking PANCEF 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 PANCEF 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 PANCEF - 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 PANCEF - 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,
- skin rash.

Rare (may affect up to 1 in 1,000 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PANCEF

Keep this medicine out of the sight and reach of children. Unreconstituted product should be stored below 25°C. Reconstituted suspension: The reconstituted suspension may be stored for 14 days at ambient conditions (below 25°C) or refrigerated conditions.

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.