INSTRUCTIONS FOR USE

PANCEF400 mg film-coated tablets
cefiximum

Please, read the instructions before use!
-Save the instructions – you may wish to read it later again.
-If after reading you have any questions, ask your doctor or pharmacist.
-This medicine was prescribed personally to you and cannot be given to any other person for whom it could be harmful, although they have disease blemishes, similar to yours.
-If any adverse reaction becomes serious or if you notice any adverse reaction, not mentioned in these instructions, inform your doctor or pharmacist.

Instructions include:

1. WHAT IS MEDICINE PANCEF, FILM-COATED TABLETS, AND FOR WHICH PURPOSE IT IS USED?

The medicine contains the active substance cefixime, i.e. the cephalosporin of the third generation for oral use. It works by inhibiting the bacterial wall formation. It is stable against the hydrolytic activity of a great number of bacterial beta-lactamases. It is effective against many Gram-negative aerobic bacteria and *Streptococcus spp.*

The medicine is used to treat infections caused by microorganisms, sensitive to cefixime:
- upper and lower respiratory tract acute infections (oropharyngeal mucosal inflammation, tonsillitis, acute inflammation in the bronchial mucosa, acute exacerbation of bronchial mucosa chronic inflammation, pneumonia, acute and chronic sinusitis),
- acute infection of the middle ear,
- urinary tract infections,
- uncomplicated cervical or urethral gonorrhoea.

2. WHAT YOU SHOULD KNOW BEFORE TAKING PANCEF

Do not take this medicine if:

- you are allergic (hypersensitive to) to cefixime or to any cephalosporin antibiotics or to any other ingredients of the medicine Pancef.

Be especially careful when taking the medicine Pancef

- if you are hypersensitive to penicillins and/or other medicines,
- if you suffer from any other form of hypersensitivity,
- if you have severe renal failure,
- if you have any gastrointestinal disease, especially colitis (inflammation of the large intestine).

If any hypersensitive reaction occurs in the form of a rash, hives, drug-induced fever, itching, treatment with cefixime should be stopped.

As during use of other antimicrobial medicines also during prolong treatment with cefixime an infection caused by microorganisms, insensitive to cefixime (*C. difficile*, *Staphylococcus spp.*, *Enterococcus spp.*, *Candida spp.*), may occur.

Administration of other medicines

If you take or you have been taking any medicine recently, also obtained without prescription, inform your doctor or pharmacist.

This is especially important at concomitant administration of Pancef with other medicines:

- probenecid (medicine used for treatment of gout) which prolongs the time of cefixime elimination and thus increases the cefixime serum concentration,
- carbamazepine (medicine for treatment of epilepsy), since the cerbamazepine serum concentration increases,
- aminoglycosides (antibiotics), since the risk of nephrotoxicity increases,
- medicines preventing blood clotting (e.g. warfarin) since their effect may increase.

The medicine Pancef may cause false positive results in some laboratory testing.

Administration of Pancef with food and drink:

Take the medicine Pancef either when your stomach is empty or with a glass of water during a meal.

Pregnancy and breast feeding:

Consult a doctor or a pharmacist before taking any medicine.

Pregnancy

It is not recommended to take the medicine Pancef during pregnancy. Its administration is justified only in individual emergency cases where the expected benefit for the mother justifies a potential risk for the foetus.

Breast feeding

It is not recommended for mothers who breastfeed to take the medicine. Its administration is justified only in individual emergency cases where the expected benefit for the mother justifies a potential risk for the baby.

Effects on the ability to drive and use machines

The medicine Pancef has no influence on the ability to drive and use machines.

3. HOW TO TAKE THE MEDICINE PANCEF

When taking Pancef, strictly take in consideration the instructions given by your doctor. If in doubt, consult a doctor or a pharmacist.
The doctor will told you the frequency and way of administration of the medicine and how long the treatment will last. You may not change the doses or stop the treatment without first consulting your doctor.
Follow these instructions, unless your doctor tells you differently!
The tablets are designed only for oral use. You may take the tablets either when your stomach is empty or with a glass of water during meal.

Dosing:

Adults

The usual daily dose is 400 mg (one tablet), either as a single dose every 24 hours, or divided in two equal doses of 200 mg (a half tablet) every 12 hours.
The recommended single-dose for treatment of lower urinary tract infections at women is 400 mg (one tablet) or three-day lasting treatment with 400 mg (one tablet) dose per day.
Recommended single dose for the treatment of uncomplicated gonococcal infections of the cervix/urethra is 400 mg (one tablet).

Children and adolescents aged 12 years and more

Children and adolescents aged 12 years and more may receive an equal dose as recommended for adults.

Children aged from 6 months to 12 years

It is recommended that to children aged from 6 months to 12 years should be given cefixime in the form of oral suspension, since with the tablets adequate dosing for this age group could not be achived.
The recommended daily dose for children in this age group is 8 mg/kg of body weight/day, either as a single dose every 24 hours or divided in two equal doses every 12 hours.

Children under 6 months

The efficacy and safety of the use of medicine in babies, under 6 months, has not been established.

Elderly

Elderly patients may receive the same dose as recommended for adults (see above). Before the start of treatment of elderly patients an evaluation of renal function is needed and adaptation of the dose in case of severe renal impairment (creatinine clearance is less than 0.33 ml/s, see »dosing in patients with renal impairment«).

Dosing in patients with renal impairment

In adult patients with impaired renal function, cefixime may be used. At creatinine clearance amounting to 0.33 ml/s or higher, adaptation of a dose and an interval between doses is not needed. At patients with creatinine which is lower than 0.33 ml/s, a dose 200 mg per day is recommended.
In patients treated with the chronic ambulatory peritoneal dialysis or haemodialysis, as regards a dose or an interval between doses, apply the same recommendations as in patients with creatinine clearance lower than 0.33 ml/s.
Data regarding the use of cefixime in children and adolescents with renal insufficiency are limited, thus the use of cefixime in children and adolescents with renal insufficiency is not recommended.

Duration of treatment:
The treatment usually lasts from 7 to 14 days, depending on the fact how severe is the infection. Streptococcal pharyngeal infections must be treated for 10 days.

If you consider the effect of the medicine is too strong or too weak, consult your doctor or pharmacist.

If you have taken higher dose of medicine Pancef than allowed
If you have taken higher dose of medicine Pancef than allowed, immediately consult your doctor or pharmacist. Show the doctor the rest of tablets in the box.

If you have forgotten to take the medicine Pancef
If you have forgotten to take the dose, do not be alarmed at this. Take the dose as soon as you remember and then you continue with taking it as before.
Do not take a double dose, if you have forgotten to take a previous dose.

If you have stopped taking the medicine Pancef
It is very important that you take the medicine for so long as prescribed by the doctor.
Do not stop to take the medicine Pancef on your own, since your medical condition can get worse.
If you have any additional questions on medicine administration, consult a doctor or a pharmacist.

4. POSSIBLE UNDESIRABLE EFFECTS

As in administration of other medicines also in administration of Pancef undesired effects can occur, but not at all patients.

The majority of undesirable effects are mild and temporary.

Undesirable effects are hereinafter ranked according to their incidence.

Evaluation of undesired effects is based on the following incidences:

Very frequent	they occur at more than 1 to 10 patients
Common	they occur at 1 to 10 patients among 100 patients
Uncommon	they occur at 1 to 10 patients among 1.000 patients
Rare	they occur at 1 to 10 patients among 10.000 patients
Very rare	they occur at less than 1 patient among 10.000 patients
Unknown incidence	unknown (cannot be estimated from the available data.

Uncommon undesired effects (they occur at 1 to 10 patients among 1.000 patients):
Headache, vertigo, stomach ache, dyspepsia (a disorder of digestive function with the upper abdominal pain after meal), wind (flatulence), nausea and vomiting.

Rare undesired effects (they occur at 1 to 10 patients among 10.000 patients):

Hypersensitive reactions in the form of a rash, hives, drug-induced fever and itching, temporary elevated liver enzymes in the blood (AST, ALT and alkaline phosphatises), genital itching, vaginal inflammation and vaginal yeast infection.

Very rare undesired effects (they occur at less than 1 patient among 10.000 patients): temporary thrombocytopenia (decreased number of platelets in peripheral blood), eosinophilia (increased number of eosinophils (a type of white blood cells) in peripheral blood), prolongation of prothrombin time (where the blood clotting time prolongs), skin rash (Erythema multiforme, Stevens-Johnson syndrome), serum sickness-like reactions, such as a risk of rash, joint inflammation and pains with or without fever, pseudomembranous colitis (suppurative inflammation of large intestines which may occur also during treatment itself or after end of treatment with antibiotics) and temporary high level of urea or creatinine in the blood.

If any undesirable effects become serious or you notice any undesirable effect, not mentioned in these instructions, inform your doctor or pharmacist!

5. STORAGE OF PANCEF

Medicine must be stored out of reach of children!

Pancef should not be used after the expiry date indicated on the packaging beside the label EXP (abbreviation for expiry date). The expiry date relates to the last day of the given month.

No special instructions are needed for storage of the medicine.

The medicine should not be disposed in waste waters or in domestic waste. Consult your pharmacist about the way of disposal of medicinal product that you do not need any more. Such actions help to protect the environment.

6. ADDITIONAL INFORMATION

What does Pancef contain
The active substance is cefixime.
One film-coated tablet contains 400 mg of cefixime, corresponding to 447.63 mg of cefixime trihydrate.

The excipients are: microcrystalline cellulose (E460), pregelatinized starch, calcium hydrogen phosphate, gelatine (E441), maise starch, magnesium stearate (E572), and sodium lauryl sulphate in the tablet core and hypromellose (E464), macrogol 4000 and titanium dioxide (E171) in the film coating of the tablets.

Nature and contents of the package of the medicine Pancef
The medicine Pancef are elongated tablets of white to mildly blurring yellow colour, normal convex and with a scoring on one side. The tablet can be divided into equal halves.

The medicine is available in the box with 10 film-coated tablets of 400 mg. In each box there are 2 blisters made of PVC/TE/PVdC/Al foil with 5 film-coated tablets.

General classification for supply of the medicine:
The medicine is available on prescription only.

Marketing authorization holder and manufacturer:
ALKALOID-INT d.o.o.,
Šlandrova ulica 4,
1231 Ljubljana- Črnuče,
R Slovenija
Tel.: 01 - 300 42 90
Faks: 01 - 300 42 91
E-pošta: info@alkaloid.si

For any further information about this medicine you may refer to the representation office of the marketing authorization holder.

Instructions were approved on: