

Package leaflet: Information for the user

[Product Name] 250 mg film-coated tablets

[Product Name] 500 mg film-coated tablets

Cefuroxime

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

1. What [Product Name] is and what it is used for

[Product Name] is an antibiotic used in adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicines called *cephalosporins*.

[Product Name] is used to treat infections of:

- the throat
- sinus
- middle ear
- the lungs or chest
- the urinary tract
- the skin and soft tissues.

This medicine can also be used to treat Lyme disease (an infection spread by parasites called ticks).

2. What you need to know before you take [Product Name]

Do not take [Product Name]

- if you are allergic to cefuroxime, any cephalosporin antibiotics or any of the other ingredients of this medicine (listed in section 6);
- if you have ever had a severe allergic reaction to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).

If you think this applies to you, don't take [Product Name] until you have checked with your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking [Product Name].

You must look out for certain symptoms, such as allergic reactions, fungal infections (such as *candida*) and severe diarrhoea (*pseudomembranous colitis*) while you are taking [Product Name]. This will reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

Children

[Product Name] is not recommended for children aged under 3 months, as the safety and effectiveness are not known in this age group.

If you need a blood test

[Product Name] can affect the results of a test for blood sugar levels, or a blood screen called the *Coombs test*. If you need a blood test tell the person taking the sample that you are taking [Product Name].

Other medicines and [Product Name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you can obtain without a prescription.

- Medicines used to reduce the amount of acid in your stomach (e.g. *antacids* used to treat heartburn) can affect how [Product Name] works.

- Probenecid (a medicine used to treat gout)
- Oral anticoagulants (medicines used to reduce the clotting ability of the blood)

Tell your doctor or pharmacist if you are taking any medicine like this.

Contraceptive pills

[Product Name] may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with [Product Name] you also need to use a barrier method of contraception (such as condoms). Ask your doctor for advice.

Pregnancy and breast-feeding

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. Your doctor will consider the benefit of treating you with [Product Name] against the risk to your baby.

Driving and using machines

[Product Name] can make you dizzy and have other side effects that make you less alert.

Don't drive or use machines if you do not feel well.

3. How to take [Product Name]

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

Take [Product Name] after food. This will help to make the treatment more effective.

Swallow [Product Name] tablets whole with some water.

Don't chew, crush or split the tablets – this may take the treatment less effective.

Adults

The recommended dose is 250 mg to 500 mg twice daily depending on the severity and type of infection.

Children

The recommended dose is 10 mg/kg (to a maximum of 125 mg) to 15 mg/kg (to a maximum of 250 mg/kg) twice daily depending on the severity and type of infection.

[Product Name] is not recommended for children aged under 3 months, as the safety and effectiveness are not known in this age group.

Depending on the illness or how you or your child responds to treatment, the initial dose may be changed or more than one course of treatment may be needed.

Patients with kidney problems

If you have a kidney problem, your doctor may change your dose.

Talk your doctor if this applies to you.

If you take more [Product name] than you should

If you take too much [Product Name] you may have neurological disorders, in particular you may be more likely to have fits (*seizures*).

Don't delay. Contact your doctor or your nearest hospital emergency department immediately. If possible, show them the [Product Name] pack.

If you forget to take [Product Name]

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop taking [Product Name]

It is important that you take the full course of [Product Name]. Don't stop unless your doctor advises you to – even if you are feeling better. If you don't complete the full course of treatment, the infection may come back.

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.

Conditions you need to look out for

A small number of people taking [Product Name] get an allergic reaction or potentially serious skin reaction.

Symptoms of these reactions include:

- Severe allergic reaction. Signs include raised and itchy rash, swelling, sometimes of the face or mouth causing difficulty in breathing.
- Skin rash, which may blister, and looks like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge).
- A widespread rash with blisters and peeling skin. (These may be signs of *Stevens-Johnson syndrome* or *toxic epidermal necrolysis*).
- Fungal infections. Medicines like [Product Name] can cause an overgrowth of yeast (*Candida*) in the body which can lead to fungal infections (such as thrush). This side effect is more likely if you take [Product Name] for a long time.

- Severe diarrhoea (*Pseudomembranous colitis*). Medicines like [Product Name] can cause inflammation of the colon (large intestine), causing severe diarrhoea, usually with blood and mucus, stomach pain, fever
- Jarisch-Herxheimer reaction. Some patients may get a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with [Product Name] for Lyme disease. This is known as the *Jarisch-Herxheimer reaction*. Symptoms usually last a few hours or up to one day.

Contact a doctor or nurse immediately if you get any of these symptoms.

Common(may affect up to 1 in 10 people)

- fungal infections (such as *Candida*)
- headache
- dizziness
- diarrhoea
- feeling sick
- stomach pain.

Common side effects that may show up in blood tests:

- an increase in a type of white blood cell (*eosinophilia*)
- an increase in liver enzymes.

Uncommon (may affect up to 1 in 100 people)

- being sick
- skin rashes.

Uncommon side effects that may show up in blood tests:

- a decrease in the number of blood platelets (cells that help blood to clot)
- a decrease in the number of white blood cells
- positive Coomb's test.

Other side effects

Other side effects have occurred in a very small number of people, but their exact frequency is unknown:

- severe diarrhoea (*pseudomembranous colitis*)
- allergic reactions
- skin reactions (including severe)

- high temperature (*fever*)
- yellowing of the whites of the eyes or skin
- inflammation of the liver (*hepatitis*).

Side effects that may show up in blood tests:

- red blood cells destroyed too quickly (*haemolytic anaemia*).

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 [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product Name]

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 blister and carton after {Exp}. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use [Product Name] if you notice the tablets are chipped or there are other visible signs of deterioration.

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 [Product Name] contains

The active substance is cefuroxime (present as cefuroxime axetil). Each tablet contains 250 mg or 500 mg of cefuroxime.

The other ingredients are:

Core:

Cellulose microcrystalline (PH101), Cellulose microcrystalline (PH112), croscarmellose sodium, sodium lauryl sulphate, hydrogenated vegetable oil, silica colloidal anhydrous.

Film Coat: Opadry White OY-S-58910 [containing hypromellose (E464), titanium dioxide (E171), macrogol (E1521), talc (E553b)].

What [Product Name] looks like and contents of the pack

[Product Name] 250 mg tablets are white to off white, film coated modified capsule shaped tablets, debossed with '250' on one side and plain on other . The tablets have a length of 15.0 mm, width of 6.5 mm and a thickness of 5.05 mm.They are packed in PVC/Aclar/Al blisters containing 6, 10, 12, 14, 20, 24, 30, 50, 100 or 120 film-coated tablets.

[Product Name] 500 mg tablets are white to off white , film coated modified capsule shaped tablets, debossed with '500' on one side and plain on other. The tablets have a length of 18.0 mm, width of 9.0 mm and a thickness of 6.95 mm.They are packed in PVC/Aclar/Al blisters containing 6, 10, 12, 14, 15, 20, 24, 30, 50, 100, 120 or 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

NL: CefuroximRanbaxy 250 mg (500 mg) filmomhulde tabletten

CZ: Znobact 250 mg (500 mg) potahované tablety

HU: Ceroxim 250 mg (500 mg) filmtabletta

DE: CEFUROX BASICS 250mg (500mg) Filmtabletten

PL: Ceroxim

SK: Cefuroxim Ranbaxy 250 mg (500 mg) filmom obalené tablety

ES: Cefuroxima Mundogen comprimidos recubiertos conpelícula EFG

This leaflet was last revised in Month YYYY