Package leaflet: Information for the patient

Cefuroximaxetil 125, omhulde tabletten 125 mg
Cefuroximaxetil 250, omhulde tabletten 250 mg
Cefuroximaxetil 500, omhulde tabletten 500 mg

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 [Nationally completed name] is and what it is used for

[Nationally completed 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*.
[Nationally completed name] is used to treat infections of:
- the throat
- sinus
- middle ear
- the lungs or chest
- the urinary tract
- the skin and soft tissues.

[Nationally completed name] can also be used:
- to treat Lyme disease (an infection spread by parasites called ticks).

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]:

- **if you are allergic** to cefuroxime, to **any cephalosporin antibiotics** or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had a severe allergic (hypersensitive) reaction to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after treatment with cefuroxime or any other cephalosporin antibiotics.

➔ If you think this applies to you, **don't take** [**Nationally completed name]** until you have checked with your doctor.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using [Nationally completed name].
[**Nationally completed name] is not recommended for children aged under 3 months**, as the safety and effectiveness are not known in this age group.

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

Take special care with [Nationally completed name]

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with cefuroxime treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you need a blood test
[Nationally completed 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 [Nationally completed name].

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.
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 [Nationally completed name] works.
Probenecid
Oral anticoagulants

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

Pregnancy, breast-feeding and fertility
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 [Nationally completed name] against the risk to your baby.

Driving and using machines
[Nationally completed 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.

[Nationally completed name] coated tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per coated tablet, that is to say essentially 'sodium-free'.

[Nationally completed name] 125 mg coated tablets contain aspartame
This medicine contains 0.2 mg aspartame in each coated tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take [Nationally completed 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 [Nationally completed name] after food. This will help to make the treatment more effective.

Swallow [Nationally completed name] tablets with some water.

Don't chew, crush or split the tablets — this may make the tablets difficult to swallow and the treatment less effective.

The recommended dose is:
Adults
The usual dose of [Nationally completed name] is 250 mg to 500 mg twice daily depending on the severity and type of infection.

Use in children and adolescents
The usual dose of [Nationally completed name] is 10 mg/kg (to a maximum of 125 mg) to 15 mg/kg (to a maximum of 250 mg) twice daily depending on:

- the severity and type of infection

[Nationally completed 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 to your doctor** if this applies to you.

If you take more [Nationally completed name] than you should
If you take too much [Nationally completed 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 [Nationally completed name] pack.

If you forget to take [Nationally completed name]
Don't take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop taking [Nationally completed name]
Don't stop [Nationally completed name] without advice.

It is important that you take the full course of [Nationally completed 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.

Stop using cefuroxime and seek medical attention immediately if you notice any of the following symptoms:
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Conditions you need to look out for
A small number of people taking [Nationally completed 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**.
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

Other conditions you need to look out for while taking [Nationally completed name] **include:**
- **fungal infections.** Medicines like [Nationally completed 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 [Nationally completed name] for a long time.
- **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like [Nationally completed 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 [Nationally completed 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 side effects
These 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 side effects
These 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, pharmacist or nurse. 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 [Nationally completed 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 label and carton after EXP. The expiry date refers to the last day of that month.

Store in the original packaging in order to protect from moisture.

This medicine does not require any special temperature storage conditions.

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 [Nationally completed name] 125 mg contains

- The active substance is cefuroxime.
  [Nationally completed name] 125 mg contains 150.36 mg of cefuroxime axetil per coated tablet, equivalent to 125 mg of cefuroxime.
  The other ingredients (excipients) are sodium laurylsulfate, copovidone, croscarmellose sodium (E468), magnesium stearate (E470B), anhydrous colloidal silicon dioxide (E551), granulated mannitol (E421), microcrystalline cellulose (E 460), crospovidone (E1202) and talc (E553B), mannitol (E421), soluble (potato) starch, titanium dioxide (E171), and aspartame (E951).

What [Nationally completed name] 250 mg and 500 mg contain
- The active substance is cefuroxime.

  [Nationally completed name] 250 mg contains 300.72 mg of cefuroxime axetil per coated tablet equivalent to 250 mg of cefuroxime.
  [Nationally completed name] 500 mg contains 601.44 mg of cefuroxime axetil per coated tablet (equivalent to 500 mg of cefuroxime).
- The other ingredients (excipients) are sodium laurylsulfate, copovidone, croscarmellose sodium (E 468), magnesium stearate (E 470B), anhydrous colloidal silicon dioxide (E 551), granulated mannitol (E 421), microcrystalline cellulose (E 460), crospovidone (E 1202) and talc (E 553B), hypromellose, polyethylene glycol, polysorbate 80, and titanium dioxide (E 171).

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] tablets are coated.

[Nationally completed name] 125 mg coated tablets are white to slightly yellowish, biconvex, oblong tablets.

[Nationally completed name] 250 mg coated tablets are white to slightly yellowish, biconvex, oblong tablets scored on both sides.

[Nationally completed name] 500 mg coated tablets are white to slightly yellowish, biconvex, oblong tablets.

[Nationally completed name] 125 mg coated tablets are available in carton boxes with blister(s) tear-off or strips containing 8, 10, 12, 14, 15, 20, 24 and 500 coated tablets.

[Nationally completed name] 250 mg coated tablets are available in carton boxes with blister(s) tear-off or strips containing 8, 10, 12, 14, 15, 16, 20, 24 and 500 coated tablets.

[Nationally completed name] 500 mg coated tablets are available in carton boxes with blister(s) tear-off or strips containing 8, 10, 12, 14, 15, 16, 20, 24 and 500 coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikant
Sandoz GmbH
Biochemiestraße 10
6250 Kundl
Oostenrijk

Dit medicijn is in het register ingeschreven onder:
Cefuroximaxetil 125, omhulde tabletten 125 mg - RVG 26702
Cefuroximaxetil 250, omhulde tabletten 250 mg - RVG 26703
Cefuroximaxetil 500, omhulde tabletten 500 mg - RVG 26704

Dit geneesmiddel is geregistreerd in de lidstaten van de Europese Economische Ruimte en in het Verenigd Koninkrijk (Noord-Ierland) onder de volgende namen:

Oostenrijk	Cefuroxim Sandoz 250 mg, 500 mg – Filmtabletten
België	Cefuroxim Sandoz 250 mg, 500 mg omhulde tabletten
Tsjechië	Xorimax 250 mg, 500 mg potahované tablety
Hongarije	Xorimax 250 mg, 500 mg bevont tabletta
Litouwen	Xorimax 500 mg dengtos tabletės
Letland	Xorimax 500 mg apvalkotās tabletes
Nederland	Cefuroximaxetil 125, omhulde tabletten 125 mg, 250, omhulde tabletten 250 mg, 500, omhulde tabletten 500 mg
Polen	Xorimax 250, 500
Slowakije	Xorimax 125 mg. 250 mg, 500 mg
Spanje	Cefuroxima Sandoz 500 mg comprimidos recubiertos EFG

Verenigd Koninkrijk (Noord-Ierland) Cefuroxim 250 mg Tablets

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2023