

Package leaflet: Information for the patient

Ceftal 250 mg coated tablets

Ceftal 500 mg 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 Ceftal is and what it is used for
2. What you need to know before you take Ceftal
3. How to take Ceftal
4. Possible side effects
5. How to store Ceftal
6. Contents of the pack and other information

1. What Ceftal is and what it is used for

Ceftal 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*.

Ceftal is used to treat infections of:

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

Ceftal can also be used:

- to treat Lyme disease (an infection spread by parasites called ticks).

2. What you need to know before you take Ceftal

Do not take Ceftal:

- **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 beta-lactam antibiotic (penicillins, monobactams and carbapenems).
- ➔ If you think this applies to you, **don't take Ceftal** until you have checked with your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ceftal.

Ceftal 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 diarrhoea (*pseudomembranous colitis*) while you are taking Ceftal. This will reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

If you need a blood test

Ceftal 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 Ceftal.

Other medicines and Ceftal

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 Ceftal 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 Ceftal against the risk to your baby.

Driving and using machines

Ceftal **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.

Ceftal coated tablets contain aspartame and sodium.

250 mg: This medicine contains 0.3 mg aspartame in each coated tablet.

500 mg: This medicine contains 0.4 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.

This medicine contains less than 1 mmol sodium (23 mg) per coated tablet, that is to say essentially 'sodium-free'.

3. How to take Ceftal

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 Ceftal after food. This will help to make the treatment more effective.

Swallow Ceftal 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 Ceftal 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 Ceftal 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.

Ceftal 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 Ceftal than you should

If you take too much Ceftal 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 Ceftal pack.

If you forget to take Ceftal

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 Ceftal

Don't stop Ceftal without advice.

It is important that you take the full course of Ceftal. 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).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- 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 Cefal 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**.

Other conditions you need to look out for while taking Cefal include:

- **fungal infections.** Medicines like Cefal 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 Cefal for a long time.
 - **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like Cefal 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 Cefal 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: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ceftal

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 Ceftal contains

- The active substance is cefuroxime.
Ceftal 250 mg contains 300.72 mg of cefuroxime axetil per coated tablet equivalent to 250 mg of cefuroxime.
Ceftal 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 (E468), magnesium stearate (E470B), anhydrous colloidal silicon dioxide (E551), mannitol (E421), microcrystalline cellulose (E 460), crospovidone (E1202) and talc (E553B), mannitol (E421), soluble (potato) starch, titanium dioxide (E171) and aspartame (E951).

What Ceftal looks like and contents of the pack

Ceftal tablets are coated.

Ceftal 250 mg coated tablets are white to slightly yellowish, biconvex, oblong tablets scored on both sides.

Ceftal 500 mg coated tablets are white to slightly yellowish, biconvex, oblong tablets.

Ceftal 250 mg coated tablets are available in carton boxes with blister(s) tear-off or strips containing 8, 10, 12, 14 and 24 coated tablets.

Ceftal 500 mg coated tablets are available in carton boxes with blister(s) tear-off or strips containing 6, 8, 10, 12, 14 and 24 coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer

Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria.

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

Austria	Ceforoxim Hexal 250 mg – Filmtabletten Ceforoxim Hexal 500 mg – Filmtabletten
Ireland	Ceftal 250 mg coated tablets Ceftal 500 mg coated tablets
Italy	CEFUROXIMA SANDOZ CEFUROXIMA SANDOZ
Netherlands	Cefuroximaxetil 250, omhulde tabletten 250 mg Cefuroximaxetil 500, omhulde tabletten 500 mg
Poland	Cefuroxime-1A Pharma Cefuroxime-1A Pharma

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