

Package leaflet: Information for the user

Zinnat 125 mg film-coated tablets

Zinnat 250 mg film-coated tablets

Zinnat 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Zinnat is and what it is used for

Zinnat 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*.

Zinnat is used to treat infections of:

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

Zinnat can also be used:

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

Your doctor may test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to Zinnat during your treatment.

2. What you need to know before you take Zinnat

Do not take Zinnat:

- **if you are allergic** to cefuroxime axetil or **any cephalosporin antibiotics** or any of the other ingredients of Zinnat (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 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 Zinnat** until you have checked with your doctor.

Take special care with Zinnat:

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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zinnat.

Children

Zinnat 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 Zinnat. 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

Zinnat 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 Zinnat.

Other medicines and Zinnat

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Probenecid

Oral anticoagulants

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

Pregnancy and 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.

Driving and using machines

Zinnat **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.

Important information about some of the ingredients of Zinnat

- Zinnat tablets contain parabens (methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)) which may cause allergic reactions (possibly delayed).
- This medicine contains 0.00152 mg sodium benzoate in each 125 mg tablet.
- This medicine contains 0.00203 mg sodium benzoate in each 250 mg tablet.
- This medicine contains 0.00506 mg sodium benzoate in each 500 mg tablet.
- This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium free'.

→ **Check with your doctor** that Zinnat is suitable for you.

3. How to take Zinnat

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

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

Swallow Zinnat tablets whole with some water.

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

The recommended dose

Adults and children weighing 40 kg and over

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

Children weighing less than 40 kg

Children weighing less than 40 kg should preferably be treated with Zinnat oral suspension or sachets. The recommended dose of Zinnat is 10 mg/kg (to a maximum of 250 mg) to 15 mg/kg (to a maximum of 250 mg) twice daily depending on:

- the severity and type of infection.

Zinnat 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 Zinnat than you should

If you take too much Zinnat 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 Zinnat pack.

If you forget to take Zinnat

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 Zinnat

Don't stop Zinnat without advice

It is important that you take the full course of Zinnat. 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 Zinnat 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).
- **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*).

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

- **fungal infections**. Medicines like Zinnat 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 Zinnat for a long time.
- **severe diarrhoea (*Pseudomembranous colitis*)**. Medicines like Zinnat 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 Zinnat 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Ireland: HPRa Pharmacovigilance, Website www.hpra.ie. Malta: the ADR reporting website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zinnat

Keep this medicine out of the sight and reach of children.

Store in the original pack at or below 30°C.

Do not use Zinnat if the tablets are chipped or there are other visible signs of deterioration.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Don't 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 to protect the environment.

6. Contents of the pack and other further information

What Zinnat contains

- The active substance in each tablet is 125 mg, 250 mg or 500 mg cefuroxime (present as cefuroxime axetil).
- The other ingredients are microcrystalline cellulose, croscarmellose sodium type A, sodium lauryl sulphate, hydrogenated vegetable oil, silica colloidal anhydrous, hypromellose, propylene glycol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and Opaspray white M-1-7120J [containing titanium dioxide (E171) and sodium benzoate (E211)].

What Zinnat looks like and contents of the pack

Zinnat Tablets 125 mg are white, film-coated, capsule-shaped tablets plain on one side and engraved with 'GX ES5' on the other. They are packaged in aluminium foil blister packs, enclosed in a carton. Each pack contains 6, 10, 12, 14, 16, 20, 24 and 50 tablets.

Zinnat Tablets 250 mg are white, film-coated, capsule-shaped tablets plain on one side and engraved with 'GX ES7' on the other. They are packaged in aluminium foil blister packs, enclosed in a carton. Each pack contains 6, 10, 12, 14, 16, 20, 24 and 50 tablets.

Zinnat Tablets 500 mg are white, film-coated, capsule-shaped tablets plain on one side and engraved with 'GX EG2' on the other. They are packaged in aluminium foil blister packs, enclosed in a carton. Each pack contains 6, 10, 12, 14, 16, 20, 24 and 50 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Sandoz Pharmaceuticals d.d.,
Verovškova ulica 57,
SI-1000 Ljubljana,
Slovenia.

Manufacturers

Sandoz GmbH,
Kundl (AICO FDF Kundl),
Biochemiestraße 10,
6250 Kundl,
Austria.

Or

Lek Pharmaceuticals d. d.,
Verovškova ulica 57,
Ljubljana, 1526
Slovenia.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

125 mg film-coated tablets

Czech Republic, Denmark, France, Hungary, Ireland, Lithuania, Netherlands, Poland, Romania, Slovakia, United Kingdom (Northern Ireland) – Zinnat
Germany – Elobact

250 mg film-coated tablets

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland) – Zinnat

Germany – Elobact

Greece – Zinadol

Italy – Oraxim

Portugal – Zipos

Portugal – Zoref

500 mg film-coated tablets

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, United Kingdom (Northern Ireland) – Zinnat

Germany – Elobact

Greece – Zinadol

Italy – Oraxim

Portugal – Zipos

Portugal – Zoref

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