

Package leaflet: Information for the user

Zinnat 125 mg/5 ml granules for oral suspension Zinnat 250 mg/5 ml granules for oral suspension

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 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 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 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 suspension contains sugar (sucrose). If you are diabetic you need to take this into account for your diet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Zinnat suspension also contains **aspartame**, which 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.

Zinnat suspension also contains benzyl alcohol (E1519) which may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease, are pregnant or are breast-feeding (also see section above – Pregnancy and breast-feeding and fertility). This is because large amounts of benzyl alcohol can build-up in your body and may cause side-effects (called metabolic acidosis). Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Zinnat 125 mg/5 ml granules for oral suspension

This medicine contains 0.021 g aspartame in each 5 ml dose.

This medicine contains 3.1 g of sucrose in each 5 ml dose.

This medicine contains 6 mg of propylene glycol (E1520) in each 5 ml dose.

This medicine contains 4.5 mg benzyl alcohol (E1519) in each 5 ml dose.

Zinnat 250 mg/5 ml granules for oral suspension

This medicine contains 0.045 g aspartame in each 5 ml dose.

This medicine contains 2.3 g of sucrose in each 5 ml dose.

This medicine contains 4.6 mg benzyl alcohol (E1519) in each 5 ml dose.

→ **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.

Shake the bottle before use.

Zinnat suspension can be diluted in cold fruit juices, or milk drinks but should be taken immediately.

Don't mix Zinnat with hot liquids.

For step-by-step instructions on how to make up Zinnat suspension see **Instructions for reconstitution** at the end of this leaflet.

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
- the weight and age of the child, up to a maximum of 500 mg per day.

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 for Ireland via HPRAs Pharmacovigilance website: www.hpra.ie; For 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.

The suspension should be stored in a fridge at all times when not taking the medicine.

Do not allow it to freeze. It can be kept in the fridge for up to 10 days.

Do not use Zinnat if it shows any sign 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 information

What Zinnat contains

125 mg/5 ml granules for oral suspension

The active substance is 125 mg per 5 ml of cefuroxime (present as cefuroxime axetil).

The other ingredients are aspartame (E951), xanthan gum, acesulfame potassium (E950), povidone K30, stearic acid, sucrose, tutti frutti flavour (contains propylene glycol (E1520) and benzyl alcohol (E1519)) and purified water.

250 mg/5 ml granules for oral suspension

The active substance is 250 mg per 5 ml of cefuroxime (present as cefuroxime axetil).

The other ingredients are aspartame (E951), xanthan gum, acesulfame potassium (E950), povidone K30, stearic acid, sucrose, tutti frutti flavour (contains benzyl alcohol (E1519)) and purified water.

See section 2 for further important information about some of the ingredients of Zinnat.

What Zinnat looks like and contents of the pack

Zinnat Suspension 125 mg/5 ml and 250 mg/5 ml is supplied in an amber, glass, multidose bottle. The bottle contains 50 ml, 70 ml, or 100 ml of the 125 mg/5 ml suspension, or 50 ml, 70 ml or 100 ml of the 250 mg/5 ml suspension. This medicine must be made up with water using the original granules that were supplied in the bottle. The bottle is contained within a carton.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Sandoz Pharmaceuticals d.d. Verovskova ulica 57
1000, Ljubljana Slovenia.

Manufacturers:

GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus,
Dublin 24,
D24 YK11, Ireland.

Or

Lek farmacevtska družba d. d. (Lek Pharmaceuticals d. d.),
Verovškova ulica 57
Ljubljana, 1526
Slovenia.

Or

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

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/5 ml granules for oral suspension

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

Germany – Cefuroxim - 1 A Pharma 125 mg/5 ml Granulat zur Herstellung einer Suspension zum Einnehmen

Italy – Oraxim

Portugal - Zipos

Portugal – Zoref

250 mg/5 ml granules for oral suspension

Belgium, Bulgaria, Cyprus, Ireland, Italy, Luxembourg, Malta, Poland, Slovakia, Slovenia, Spain, United Kingdom (Northern Ireland) – Zinnat

Greece – Zinadol

Italy – Oraxim
Portugal - Zipos
Portugal – Zoref

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Instructions for reconstitution

Directions for making up the suspension

Please note that the time taken to prepare Zinnat suspension before administration of the first dose will take more than one hour. This includes time for the suspension to settle in the refrigerator.

Please follow the instructions given below very carefully when preparing and storing Zinnat suspension for your child.



Shake the bottle to loosen the content. Remove the bottle cap and the heat-seal membrane. If the latter is damaged or not present, the product should be returned to the pharmacist.



Add the total amount of cold water as stated on the label or up to the volume line on the measuring cup provided. If the water was previously boiled it must be allowed to cool to room temperature before adding. Do not mix Zinnat granules for oral suspension with hot or warm liquids. Cold water must be used to prevent the suspension becoming too thick.



Pour the total amount of cold water into the bottle. Replace the bottle cap. Allow the bottle to stand to allow the water to fully soak through the granules; this should take about 1 minute.



Invert the bottle and shake well (for at least 15 seconds) until all the granules have mixed with the water.



Turn the bottle into an upright position and shake well for at least 1 minute until all the granules have blended with the water. Store the Zinnat suspension in the refrigerator immediately at between 2 and 8°C (do not freeze) and let it rest for at least one hour before taking the first dose.

The reconstituted suspension should be refrigerated at all times; when refrigerated between 2 and 8°C, the reconstituted suspension can be kept for up to 10 days.

Always shake the bottle well before taking the medication.

For children who can't take Zinnat using a spoon, a dosing syringe with a 5 ml graduation may be supplied with the pack. If supplied, use the oral dosing syringe to measure your dose accurately:

1. **Remove the bottle cap.** Keep it safely.
2. Hold the bottle firmly. **Push the plastic adapter into the neck of the bottle.**
3. **Insert the syringe** firmly into the adapter.
4. Turn the bottle upside down.
5. **Pull out syringe plunger** until the syringe contains the first part of the child's full dose.
6. Turn the bottle the correct way up. **Remove the syringe** from the adapter.
7. **Put the syringe into the child's mouth**, placing the tip of the syringe against the inside of the child's cheek. **Slowly push the plunger in**, allowing time to swallow. **Don't** push too hard and squirt the liquid into the back of the child's throat or they may choke.
8. **Repeat steps 3 to 7** in the same way until the child has taken the whole dose.
9. **Take the syringe out of the bottle** and **wash** it thoroughly in clean water. Let it dry completely before you use it again.
10. **Close the bottle tightly** with the cap, leaving the adaptor in place.