Package Leaflet: Information for the user





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 ame 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
- What you need to know before you take Zinnať
- How to take Zinnat
- Possible side effects How to store Zinnat
- 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 bacter are sensitive to Zinnat during your treatment. whether the bacteria

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 think this applies to you, **don't take Zinnat** until you have checked with your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking

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.

Contraceptive pills

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

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.

Zinnat suspension also contains aspartame, which is a source of phenylalanine. If you have an intolerance to aspartame or have a condition called **phenylketonuria** (PKU):

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

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

Children

The recommended dose of Zinnat 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

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 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. 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?
- (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 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.
- tests:

Common side effects that may show up in blood 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

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine. medicine.

5. How to store Zinnat

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 pack after EXP. The expiry date refers to the last day of that month.

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.

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

- The active substance is 125 mg per 5 ml of cefuroxime (present as cefuroxime axetil). The other ingredients are aspartame (E951),
- ranthan gum, acesulfame potassium, Povidone K30, stearic acid, sucrose, tutti fruitti flavour 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 is supplied in an amber, glass, multidose bottle. The bottle contains 70 ml of suspension. Your pharmacist will have made this up with water using the original granules that were supplied in the bottle. The bottle is contained within a carton. Marketing authorisation holder and manufacturer

Marketing Authorisation Holder: Glaxo Wellcome UK Limited, Stockley Park West,

Uxbridge, Middlesex UB11 1BT
Manufacturer: Glaxo Operations UK Ltd,
Harmire Road, Barnard Castle,
Co. Durham DL12 8DT

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Zinnat Suspension

125 mg/5 ml 10949/0094 Reference number

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Instructions for reconstitution

Directions for making up the suspension



Shake the bottle to loosen the content. All the granules should be free-flowing in the bottle. Remove the 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 Add the total amount of cold water as stated on the label or up to the volume line on the cup provided (if supplied). 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 to prevent the suspension becoming too thick.



Pour the total amount of cold water into the bottle. Replace the 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 immediately at between 2 and 8°C (do not freeze) and let it rest for at least one hour before taking the first dose.