

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

ZINNAT 125 MG / 5 ML FOR ORAL SUSPENSION

ZINNAT 125 MG TABLETS

ZINNAT 250 MG TABLETS

ZINNAT 500 MG TABLETS

CEFUROXIME AXETIL

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Zinnat is and what it is used for
2. Before you take Zinnat
3. How to take Zinnat
4. Possible side effects
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6. Further information

1. WHAT ZINNAT IS AND WHAT IT IS USED FOR

Zinnat belongs to a group of antibiotics called cephalosporins. It works by killing bacteria that cause infections.

Zinnat is used in adults and children to treat severe infections of the:

- ears, nose and throat
- lungs or chest
- urinary tract
- skin and soft tissues.

Zinnat is also used to treat:

- sexually transmitted infections (gonorrhoea, urethritis and cervicitis)
- Lyme disease (an infection spread by parasites called ticks).

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

2. BEFORE YOU TAKE

Do not take Zinnat

- if you are allergic (hypersensitive) to antibiotics or any of the other ingredients of Zinnat
- If you think this applies to you, don't take Zinnat until you have checked with your doctor.

Take special care with Zinnat

Zinnat is **not recommended for children aged under 3 months**, as it has not been adequately studied in this age group.

Look out for important symptoms

Zinnat can cause serious side effects such as allergic reactions, fungal infections (such as candida) and severe diarrhoea (pseudomembranous colitis). You must look out for certain symptoms while you are taking Zinnat, to reduce the risk of any problems.

While you are taking Zinnat

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 have taken Zinnat.

Taking other medicines with Zinnat

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

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

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

Contraceptive pill

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

Pregnancy and breast-feeding

There is only limited information about the safety of Zinnat in pregnant women. If you are pregnant your doctor will discuss with you if the benefits of taking Zinnat outweigh the possible risks to your baby.

The ingredients in Zinnat can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take Zinnat.

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 unless you're feeling well.

Zinnat suspension contains sugar and aspartame

Zinnat suspension contains sugar. 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

How much to take

Always take Zinnat exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

If you have kidney problems your doctor may reduce your dose.

Tablets only:

Adults

The usual dose of Zinnat is 500 mg to 1 g per day depending on the severity and type of infection.

Children

The usual starting dose of Zinnat is 250 mg to 500 mg per day depending on the severity and type of infection.

- Take Zinnat tablets 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.

Oral suspension only:

Children

Your doctor will decide on the correct dose of Zinnat for your child depending on:

- the severity and type of infection
- the weight and age of the child.

Zinnat is not recommended for children aged under 3 months, as it has not been adequately studied in this age group.

Depending on the illness or how you or your child responds to treatment, the starting dose may be changed. More than one course of treatment may be needed.

- Take Zinnat suspension 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 after mixing.
- Don't mix Zinnat suspension with hot liquids.
- For children who can't take Zinnat suspension using a spoon, a dosing syringe with a 5 ml graduation is supplied with the pack so you can measure your child's dose accurately.

If you take more Zinnat than you should

If you take too much Zinnat 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

Don't take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zinnat can cause side effects, although not everybody gets them.

Look out for important symptoms

Severe allergic reactions

These are very rare in people taking Zinnat. Signs include:

- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse.

→ Contact a doctor immediately if you get any of these symptoms.

Serious skin reactions

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) erythema multiforme
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis), particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

→ Contact a doctor immediately if you get these symptoms.

Fungal infections

On rare occasions, 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 for a long time.

→ Tell your doctor as soon as possible if you think you have a fungal infection. Your doctor may need to stop your treatment.

Severe diarrhoea (Pseudomembranous colitis)

On rare occasions, medicines like Zinnat can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain, fever.

→ Tell your doctor as soon as possible 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
- nausea (feeling sick)
- stomach pain.

Common side effects that may show up in blood tests:

- increase in a type of white blood cell (eosinophilia)
- increase in some substances (enzymes) produced by the liver.

Uncommon side effects

These may affect up to 1 in 100 people:

- vomiting
- skin rashes.

Uncommon side effects that may show up in blood tests:

- decrease in number of blood platelets (cells that help blood to clot) called thrombocytopenia
- decrease in the number of white blood cells (leukopenia).

Rare side effects

These may affect up to 1 in 1,000 people:

- severe diarrhoea (pseudomembranous colitis).

Very rare side effects

These may affect up to 1 in 10,000 people:

- allergic reactions
- severe skin reactions

- high temperature (fever)
- yellowing of the whites of the eyes or skin (jaundice)
- inflammation of the liver (hepatitis).

Very rare side effects that may show up in blood tests:

- red blood cells destroyed too quickly (haemolytic anaemia).

If you get side effects

→ Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE ZINNAT

Keep out of the reach and sight of children.

Zinnat tablets should be stored at temperatures not exceeding 30°C.

Do not take Zinnat after the expiry date shown on the pack.

Tablets only:

Store in the original packaging.

If you have any unwanted Zinnat tablets, don't dispose of them in your waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Oral suspension only:

Once mixed with the correct amount of water, Zinnat suspension, must be stored in the fridge between 2°C and 8 C.

Throw away the bottle 10 days after first opening it, but don't dispose of the medicine in your waste water or your household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. FURTHER INFORMATION

What Zinnat contains:

Tablets only:

The active substance is cefuroxime axetil.

Zinnat tablets come in different strengths.

Each tablet contains either:

125 mg, 250 mg or 500 mg cefuroxime axetil.

The other ingredients are:

Microcrystalline cellulose.

Croscarmellose sodium.

Hypromellose Sodium lauryl sulphate.

Hydrogenated vegetable oil.
Silicon dioxide.
Propylene glycol.
Methylhydroxybenzoate (E218).
Propylhydroxybenzoate (E216).
Titanium dioxide (E171).
Sodium benzoate (E211).

Oral suspension only:

The active substance is cefuroxime axetil.

Each 5 ml of solution contains 125 mg / 250 mg cefuroxime axetil when mixed with the correct amount of water.

The other ingredients are:

Aspartame

Xantham gum A

cesulfame potassium

Povidone K30

Stearic acid

Sucrose

Tutti-frutti flavour.

What Zinnat looks like and contents of the pack:

Tablets only:

The 500 mg, 250mg and 125mg tablets are white to cream in color. They are film coated tablets in a 10-tablet blister double foil pack.

Oral suspension only:

Cefuroxime axetil suspension is provided as a dry, white to off-white, tutti-frutti flavoured granule. When reconstituted as directed, it provides the equivalent of 125 mg / 250 mg of cefuroxime (as cefuroxime axetil) per 5 ml of suspension.

Manufacturer

Glaxo Operations UK Limited, Harmire Road, Barnard Castle, County Durham, UK Ltd, DL12 8DT, United Kingdom.

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