

ZINNAT SUSPENSION

Cefuroxime axetil (125 mg/5 ml, 250 mg/5 ml)

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

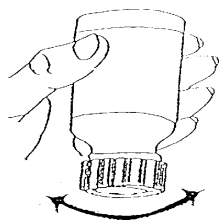
- Ear, nose and throat
 - Lungs or chest
 - Urinary tract
 - Skin and soft tissues
- Zinnat is also used to treat:
- Sexually transmitted infections (gonorrhoea, urethritis and cervicitis)

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

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

Before you use Zinnat

- When you must not use it



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, do not take Zinnat until you have checked with your doctor.
- Before you start to use it

Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactams.

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.

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

- Taking other medicines

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.

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.

How to use Zinnat

- How much to use

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.

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

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 or more than one course of treatment may be needed.

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.

1. Shake the bottle to loosen the granules and remove the bottle cap.
2. Add the amount of water stated on the bottle label and replace the bottle cap.
3. Turn the bottle upside down and rock vigorously (for at least 15 seconds) as shown below.
4. Turn the bottle the right way up and shake vigorously.
5. Zinnat suspension must be stored in the fridge between 2°C and 8°C.

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Directions for using the dosing syringe (if supplied):

1. If you are using a dosing syringe, allow the suspension to stand for at least one hour before taking the first dose.
2. Remove the bottle cap and push the bung firmly into the top of the bottle.
3. Push the dosing syringe firmly into the top of the bung.
4. Turn the bottle upside down.
5. Pull the plunger of the syringe back so that the medicine is drawn from the bottle into the syringe. Pull the plunger back to the point on the scale that corresponds to the dose prescribed for your child.
 - Contact your doctor or pharmacist if you are at all confused about how much medicine to draw into the syringe.
6. Turn the bottle back the right way up and carefully remove the syringe from the bung, holding it by the barrel rather than the plunger.
7. Gently put the tip of the syringe into the child's mouth, to the inside of the child's cheek.
8. Slowly and gently push the plunger down to gently squirt the medicine into the inside of your child's cheek. Allow them to swallow it.
9. Remove the syringe from your child's mouth.
10. Remove the bung and replace the lid on the bottle.
11. Rinse the bung and syringe in warm water and leave to dry.
12. Repeat the above for each dose as instructed by your doctor or pharmacist.

- When to use it

For multidose bottle only:

- 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 with hot liquids.
- For children who can't take Zinnat 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.

- How long to use it

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 forget to use it

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

- If you use too much (overdose)

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.

While you are using it

- Things you must do

Take your medicine as your doctor has told you. If you are not sure ask your doctor or pharmacist.

- Things you must not do

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.

- Things to be careful of

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.

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.

Side Effects

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

Zinnat may cause severe allergy and serious skin reactions. Stop using ZINNAT and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation

Look out for important symptoms:

Severe allergic reactions

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

- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- 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 any of these symptoms.

Fungal infections

On rare occasions, medicines like

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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.

- 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.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Zinnat

- Storage

Keep out of the reach and sight of children.

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

For multidose bottle only: Store granules below 30°C. Once mixed with the correct amount of water, Zinnat suspension must be stored in the fridge between 2°C and 8°C.

Disposal

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.

Product Description

- What it looks like

Dry, white to off-white, tutti-frutti

flavoured granules for oral suspension.

- Ingredients

- Active ingredient(s)

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

- Inactive ingredient(s)

Aspartame, Xanthan gum, Acesulfame potassium, Povidone K30, Stearic acid, Sucrose, Tutti frutti flavour, Purified water.

- MAL number

Zinnat Suspension 125mg/5ml
MAL19921571ARZ

Zinnat Suspension 250mg/5ml
MAL20000728ARZ

Manufacturer

Sandoz GmbH
Biochemiestraße 10, 6250 Kundl,
Austria

Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
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Date of Revision

July 2026

Serial Number

NPRA (R1/5) 07062024/109