PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Zinnat® Tablet 125 mg

Zinnat® Tablet 250 mg

Zinnat® Tablet 500 mg

Sugar free

Zinnat® Suspension 125 mg (Granules for oral suspension)

Cefuroxime axetil

Zinnat® Suspension:

Contains sugar (sucrose 3,062 g/5 ml)

Contains sweetener (aspartame 0,021 g/5 ml)

Read all of this leaflet carefully before you start taking ZINNAT

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- ZINNAT has been prescribed for you personally, and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

The active ingredient is cefuroxime axetil.

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.

ZINNAT is also used to treat:

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

2. What you need to know before you take ZINNAT

You should not take ZINNAT tablets:

- If you are allergic (hypersensitive) to cefuroxime or to any of the other ingredients of ZINNAT (listed in section 6).
- If you are allergic to other cephalosporins or to any other type of beta-lactam antibiotic (penicillin, monobactams and carbapenems).

Warnings and precautions

- If you have ever experienced an allergic reaction to penicillin. If you think this applies to you, consult your doctor first before taking ZINNAT.
- 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): ZINNAT can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain and fever. Tell your doctor as soon as possible if you get any of these symptoms.
- 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. Tell your doctor immediately if you get any of these symptoms.
- 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 a serious skin reaction consisting of severe blisters and bleeding in the lips, eyes, mouth, nose and genitals, large blisters that ends with peeling of layers skin, flu-like symptoms or itchy spots similar to measles rash which starts on limbs, face or other body parts. Tell your doctor immediately if you get any of these symptoms.

Children

ZINNAT is not recommended for children under 3 months as there is no experience in this age group.

Other medicines and ZINNAT:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

- **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.
- The use of ZINNAT and furosemide together should be avoided. If you are taking furosemide, please let your doctor, pharmacist or other health care provider know.
- Medicines used to reduce the amount of acid in your stomach (e.g. antacids used to treat heartburn) can affect how ZINNAT tablets work.

- If you are taking probenecid (medicine used to prevent gout), the blood concentration of cefuroxime may increase and may lead to a worsening of side effects.
- If you are taking medicines to thin your blood, let your doctor, pharmacist or other healthcare provider know.

ZINNAT with food, drink and alcohol

Please refer to section 3 below.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider 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. Do not drive or use machines unless you are feeling well.

ZINNAT suspension contains sucrose and aspartame:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZINNAT suspension. ZINNAT suspension contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.
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 suspension is suitable for you.

3. HOW TO TAKE ZINNAT

Do not share medicines prescribed for you with any other person.

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

Adults and Children

The usual dose is 125 mg to 1 000 mg per day depending on the severity and type of infection.
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 half an hour after food. This will help to make the treatment more effective.

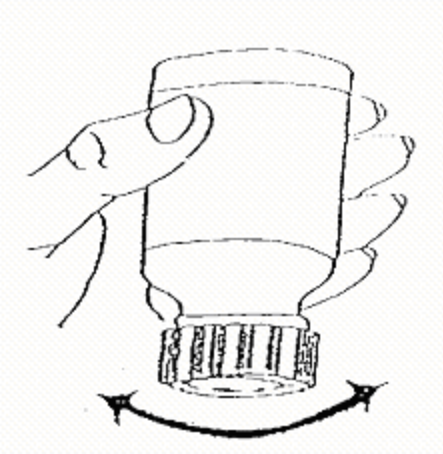
ZINNAT tablets should be swallowed whole with some water. Do not chew, crush or split the tablets; this may make the treatment less effective.

ZINNAT suspension can be diluted in cold fruit juices or milk drinks but should be taken immediately after mixing. Do not mix ZINNAT suspension with hot liquids. For children who cannot take ZINNAT using a spoon, a measuring cup is supplied in the pack so you can measure your child's dose accurately. For step-by-step instructions on how to make up ZINNAT suspension, see below.

It is important that you take the full course of ZINNAT. Do not stop unless your doctor advises you – even if you are feeling better, as your symptoms may disappear before the infection is fully cleared.

Directions for making up the ZINNAT suspension:

1. Shake the bottle to loosen the granules and remove the cap.
2. Add the amount of water stated on the bottle label and replace the 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 immediately in the fridge between 2 °C and 8 °C.

If you take more ZINNAT than you should:

If you take too much ZINNAT you may be more likely to have fits (seizures).

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. If possible, show them the ZINNAT pack.

If you forget to take ZINNAT:

Do not take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

If you stop taking ZINNAT:

It is important that you take the full course of ZINNAT tablets. 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:**

ZINNAT can have side effects.

Not all side effects reported for ZINNAT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ZINNAT, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking ZINNAT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- 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.
- Abdominal or stomach cramps, abdominal tenderness, watery and severe diarrhoea which may also be bloody, and fever. These are signs of Pseudomembranous colitis.
- 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), this is called erythema multiforme.
- A widespread rash with blisters and peeling skin on much of the body surface (toxic epidermal necrolysis), particularly around the mouth, nose, eyes and genitals (Stevens-Johnson Syndrome).
- chest pain, shortness of breath in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to ZINNAT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Fungal infections (such as Candida).
- An increase in a type of white blood cell (eosinophilia).
- Headache.
- Dizziness.
- Diarrhoea.
- Feeling sick (nausea).
- Stomach pain.
- An increase in some substances (enzymes) produced by the liver.

Less-frequent side effects:

- Positive Coomb's test, which is picked up in a blood test.
- A decrease in the number of blood platelets (cells that help blood to clot) called thrombocytopenia.
- A decrease in the number of white blood cells (leukopenia).
- Vomiting.
- Skin rashes.

The frequency of the following side effects is unknown:

- Red blood cells destroyed too quickly (haemolytic anaemia).
- High temperature (fever).
- Inflammation of the liver (hepatitis).
- Allergic skin reactions that can cause swelling, itching and a rash (urticaria).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZINNAT.

Suspected side effects can also be reported directly to the HCR via the link: pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store ZINNAT

- Store all medicines out of the reach of children.
- Do not take after the expiry date shown on the pack.
- ZINNAT Tablets: Store below 30 °C.
- ZINNAT Suspension: Store the granules below 30 °C.
- Once mixed with the correct amount of water, ZINNAT Suspension must be immediately stored in the fridge between 2 °C and 8 °C. Throw away the bottle 10 days after first opening it.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

The active ingredient is cefuroxime axetil.

What ZINNAT Tablets contains:

Each tablet contains either 125 mg, 250 mg or 500 mg cefuroxime axetil.

Preservatives:

ZINNAT TABLET 125 mg: propylene glycol 0,142 % *m/m*, methyl parahydroxybenzoate 0,026 % *m/m*, propyl parahydroxybenzoate, 0,017 % *m/m*.

ZINNAT TABLET 250 mg: propylene glycol 0,096 % *m/m*, methyl parahydroxybenzoate 0,015 % *m/m*, propyl parahydroxybenzoate, 0,013 % *m/m*.
ZINNAT TABLET 500 mg: propylene glycol 0,120 % *m/m*, methyl parahydroxybenzoate 0,019 % *m/m*, propyl parahydroxybenzoate, 0,016 % *m/m*.

The other ingredients are:

Excipient Core: microcrystalline cellulose, croscarmellose sodium, silica colloidal anhydrous, sodium lauryl sulphate, hydrogenated vegetable oil.
Excipient Coating: propylene glycol, methyl para-hydroxybenzoate, propyl para-hydroxybenzoate, Hypromellose, opaspray white M-1-7120J.

What ZINNAT Suspension contains:

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

The other ingredients are:

Aspartame, xanthan gum, acesulfame potassium, povidone K30, stearic acid, sucrose and tutti-frutti flavour.

What ZINNAT looks like and contents of the pack

ZINNAT TABLET 125 mg: White to off-white film-coated, capsule-shaped tablets, engraved ‘GXES5’ on one side and plain on the other.
ZINNAT TABLET 250 mg: White to off-white film-coated, capsule-shaped tablets, engraved ‘GXES7’ on one side and plain on the other.
ZINNAT TABLET 500 mg: White to off-white film-coated, capsule-shaped tablets, engraved ‘GXEG2’ on one side and plain on the other.
ZINNAT SUSPENSION 125 mg: White to off-white free-flowing granules for preparing a suspension, producing a white to pale yellow suspension on reconstitution.

All strengths of ZINNAT tablets are supplied in double foil blister pack of 10 tablets comprising of an aluminium laminate base material and a hard tempered aluminium foil/heat seal lacquer lid.

ZINNAT Suspension: granules for reconstitution are supplied in amber glass bottles of 50 ml and 100 ml with plastic, child-resistant screw closures. A 5 ml dosing spoon and measuring cup are provided in the carton.

Not all packs may be marketed.

Holder of Certificate of Registration

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REGISTRATION NUMBERS:

ZINNAT TABLET 125 mg:	V/20.1.1/362
ZINNAT TABLET 250 mg:	V/20.1.1/363
ZINNAT TABLET 500 mg:	V/20.1.1/364
ZINNAT SUSPENSION 125 mg:	Z/20.1.1/148

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07