
PATIENT INFORMATION LEAFLET

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 questions, please ask your doctor or pharmacist.

ZINNAT has been prescribed for you personally, and should not be shared with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Zinnat® Tablet 125 mg

Zinnat® Tablet 250 mg

Zinnat® Tablet 500 mg

Zinnat® Suspension 125 mg (Granules for oral suspension)

Cefuroxime axetil

WHAT ZINNAT CONTAINS:

The active ingredient is cefuroxime axetil.

ZINNAT tablets come in different strengths:

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

Sugar-free.

Preservatives:

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

% *m/m*, propyl parahydroxybenzoate, 0,017 % *m/m*.

V1.0 (29.04.2022)

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 microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, sodium lauryl sulphate, hydrogenated vegetable oil, propylene glycol, methyl hydroxypropylcellulose, methyl parahydroxybenzoate, propyl parahydroxybenzoate, hypromellose, titanium dioxide, sodium benzoate.

ZINNAT suspension:

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

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

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

The other ingredients are aspartame, xanthan gum, acesulfame potassium, povidone K30, stearic acid, sucrose and tutti frutti flavour.

WHAT ZINNAT 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.

ZINNAT is also used to treat:

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

BEFORE YOU TAKE ZINNAT:

V1.0 (29.04.2022)

Do not take ZINNAT:

- If you are allergic (hypersensitive) to antibiotics or to any of the other ingredients of ZINNAT listed at the beginning of this leaflet.

If you are not sure whether you should be taking ZINNAT, please discuss with your doctor before taking ZINNAT.

Take special care with ZINNAT:

- If you have ever experienced an allergic reaction to penicillin. If you think this applies to you, consult your doctor first before taking ZINNAT.
- **Fungal infections:**

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.

V1.0 (29.04.2022)

- **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.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

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.

Important information about some of the ingredients of ZINNAT suspension:

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.

Taking other medicines with ZINNAT:

Always tell your healthcare professional if you are taking any other medicine. (This includes 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.

HOW TO TAKE ZINNAT:

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 250 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.

ZINNAT is not recommended for children under 3 months.

Take ZINNAT 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.

V1.0 (29.04.2022)

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 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 take too much ZINNAT:

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

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

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.

V1.0 (29.04.2022)

Severe allergic reactions:

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.

Frequent side effects:

- fungal infections (such as candida)
- headache
- dizziness
- diarrhoea
- nausea (feeling sick)
- stomach pain.

Frequent 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.

V1.0 (29.04.2022)

Less frequent side effects

- vomiting
- skin rashes.

Less frequent 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 (leucopenia)
- red blood cells destroyed too quickly (haemolytic anaemia)
- severe diarrhoea (pseudomembranous colitis)
- allergic reactions
- severe skin reactions
- high temperature (fever)
- yellowing of the whites of the eyes or skin (jaundice)
- inflammation of the liver (hepatitis).

If any of these side effects get serious, please tell your doctor or pharmacist.

STORAGE AND DISPOSING OF 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.

PRESENTATION OF ZINNAT:

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.

IDENTIFICATION OF ZINNAT:

ZINNAT TABLETS 125 mg: White to off-white film-coated, capsule-shaped tablets, engraved 'GXES5' on one side and plain on the other.

ZINNAT TABLETS 250 mg: White to off-white film-coated, capsule-shaped tablets, engraved 'GXES7' on one side and plain on the other.

ZINNAT TABLETS 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.

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

V1.0 (29.04.2022)

NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd

Magwa Crescent West

Jukskei View

Waterfall City

Midrand

2090

DATE OF PUBLICATION:

Registration date:

ZINNAT TABLET 125 mg: 25 September 1989

ZINNAT TABLET 250 mg: 25 September 1989

ZINNAT TABLET 500 mg: 25 September 1989

ZINNAT SUSPENSION 125 mg: 10 August 1993

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¹Company Reg. No.: 1990/001979/07

