

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Zinnat Tablets 125 mg

Each tablet contains Cefuroxime (as axetil) 125 mg

Zinnat Tablets 250 mg

Each tablet contains Cefuroxime (as axetil) 250 mg

Zinnat Tablets 500 mg

Each tablet contains Cefuroxime (as axetil) 500 mg

A list of the additional ingredients is detailed in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Zinnat Tablets 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* (second-generation).

Zinnat Tablets is used to treat infections of:

- the throat
- the sinus
- the middle ear
- the lungs or chest
- the urinary tract
- the skin and soft tissues.

Zinnat Tablets can also be used:

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

Your physician may test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to Zinnat Tablets during your treatment.

Therapeutic group:

Second-generation cephalosporin antibiotic.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to cefuroxime axetil or to any cephalosporin antibiotics or to any of the additional ingredients contained in the medicine (as listed in section 6).
- If you have ever had a severe allergic (hypersensitive) reaction to any other type of beta-lactam antibiotic (penicillins, monobactams and carbapenems).

→ If you think this applies to you, **don't take Zinnat Tablets** before checking it with your physician.

Special warnings regarding use of the medicine

Children

Zinnat Tablets 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 diarrhea (*pseudomembranous colitis*) while you are taking Zinnat Tablets. 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 Tablets 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 Tablets.

Other medicines and Zinnat Tablets

If you are taking, have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist.

Especially if you are taking:

- Medicines used to reduce the amount of acid in your stomach (e.g., *antacids* used to treat heartburn) can affect how Zinnat Tablets works.
- Probenecid
- Oral anticoagulants

Use of the medicine and food

Take Zinnat Tablets after food. This will help to make the treatment more effective.

Contraceptive pills

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to become pregnant, consult your physician or pharmacist before taking this medicine.

Driving and using machines

Zinnat Tablets can make you dizzy and has other side effects that make you less alert.

→ **Don't drive or use dangerous machines while using the medicine** if you do not feel well. Children should be warned against riding bicycles or playing near the road, and the like.

Important information regarding some of the ingredients of the medicine:

- Zinnat Tablets contains:
 - Methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed)
 - Sodium benzoate:
 - 0.00152 mg in each 125 mg tablet.
 - 0.00203 mg in each 250 mg tablet.
 - 0.00506 mg in each 500 mg tablet.
- This medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions.

Check with the physician or the pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the physician only. The usual dosage is generally:

Adults

The usual dosage of Zinnat Tablets is generally 250 mg to 500 mg twice daily, depending on the severity and type of infection.

Children

The usual dosage of Zinnat Tablets is generally 10 mg/kg (up to a maximum of 125 mg) to 15 mg/kg (up to a maximum of 250 mg) twice daily, depending on the severity and type of infection.

Usual duration of treatment is 7 days (may range from 5-10 days).

Do not exceed the recommended dose.

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.

Zinnat Tablets should be swallowed whole with a little water, **after food**. **Don't chew, crush or split the tablets** - it may make the treatment less effective.

For little children who cannot swallow tablets, the suspension should be used.

Patients with kidney problems

If you have a kidney problem, your physician may change your dose.

→ **Talk to your physician** if this applies to you.

If you accidentally take a higher dosage

If you take too much Zinnat Tablets, you may suffer from neurological disorders, and in particular, you may be **more likely to have fits (seizures)**.

→ If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

Don't take a double dose to make up for a forgotten dose. Take your next dose at the usual time and consult a physician.

Adhere to the treatment regimen recommended by the physician.

Don't stop taking Zinnat Tablets without getting advice.

It is important that you complete the full course of treatment with Zinnat Tablets. Don't stop taking the medicine unless your physician advises you to stop. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician, because if you don't complete the full course of treatment, the infection may come back.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Zinnat Tablets may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Conditions you need to look out for

A small number of people taking Zinnat Tablets may develop an allergic reaction or a 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 should look out for while taking Zinnat Tablets include:

- **fungal infections.** Medicines like Zinnat Tablets 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 Tablets for a long time.
- **severe diarrhea (*pseudomembranous colitis*).** Medicines like Zinnat Tablets can cause inflammation of the colon (large intestine), causing severe diarrhea, usually with blood and mucus, stomach pain, fever.
- **Jarisch-Herxheimer reaction.** Some patients may develop a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with Zinnat Tablets for Lyme disease. This is known as the *Jarisch-Herxheimer reaction*. Symptoms usually last a few hours or up to one day.

→ **Contact a physician immediately if any of these symptoms appear.**

Additional side effects

Common side effects

These may affect **up to 1 in 10** people:

- fungal infections (such as *Candida*)
- headache
- dizziness
- diarrhea
- nausea
- stomach pain.

Common side effects that may show up in blood tests:

- 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:

- vomiting
- skin rashes.

Uncommon side effects that may show up in blood tests:

- a decrease in the number of platelets (cells that help blood to clot)
- a decrease in the number of the white blood cells
- positive Coombs test.

Other side effects

Other side effects have occurred in a very small number of people, but their exact frequency is unknown:

- severe diarrhea (*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 (*hemolytic anemia*).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect that has not been mentioned in the leaflet, consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store below 30°C in the original pack in a dry place.

Do not use the medicine if the tablets are chipped or if you notice other visible signs of deterioration of the medicine.

Do not discard medicines in wastewater or household waste. Consult the pharmacist regarding how to dispose of medicines that are not in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains -

Tablet Core: Microcrystalline cellulose, Croscarmellose sodium Type A, Hydrogenated vegetable oil, Sodium lauryl sulphate, Silica colloidal anhydrous.

Film Coat: Hypromellose, Propylene glycol, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Opaspray White M-1-7120J (Titanium dioxide, Hypromellose, Industrial methylated spirits, Sodium benzoate, Purified water).

What the medicine looks like and the contents of the package -

Zinnat Tablets 125 mg are white to off-white, film-coated, capsule-shaped, biconvex tablets, plain on one side and engraved with "GX ES5" on the other. They are packaged in aluminium foil blister packs, enclosed in a carton. Each pack contains 10 or 50 tablets.

Zinnat Tablets 250 mg are white to off-white, film-coated, capsule-shaped, biconvex tablets, plain on one side and engraved with "GX ES7" on the other. They are packaged in aluminium foil blister packs, enclosed in a carton. Each pack contains 10 or 50 tablets.

Zinnat Tablets 500 mg are white to off-white, film-coated, capsule-shaped, biconvex tablets, plain on one side and engraved with "GX EG2" on the other. They are packaged in aluminium foil blister packs, enclosed in a carton. Each pack contains 2, 10 or 50 tablets.

Not all pack sizes may be marketed.

License Holder and Address: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

Manufacturer and Address: Glaxo Operations UK Limited (Trading as Glaxo Wellcome Operations), Barnard Castle, UK.

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Zinnat Tablets 250 mg: 41-42-25802

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