

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACIST'S REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a physician's prescription only

Zinnat Suspension 125 mg/5 ml

Granules for preparation of suspension

Each 5 ml contains 125 mg of cefuroxime (as axetil)

Each 1 ml contains 25 mg of cefuroxime (as axetil)

Zinnat Suspension 250 mg/5 ml

Granules for preparation of suspension

Each 5 ml contains 250 mg of cefuroxime (as axetil)

Each 1 ml contains 50 mg of cefuroxime (as axetil)

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

Important information about some of the ingredients of the medicine is detailed in section 2.

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/your child. 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 Suspension 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 Suspension 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 Suspension can also be used:

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

The physician may test the type of bacteria causing your/your child's infection and monitor whether the bacteria are sensitive to Zinnat Suspension during your treatment.

Therapeutic group:

Cephalosporin antibiotics, second-generation.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- **If you/your child are/is sensitive (allergic)** to cefuroxime (as axetil) or to **any cephalosporin antibiotics** or to any of the additional ingredients contained in the medicine (as listed in section 6).
 - If you/your child have/has 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/your child, **do not take/give Zinnat Suspension** before checking it with your/his physician.

Special warnings regarding use of the medicine

Children

Zinnat Suspension 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/your child are/is taking Zinnat Suspension. This will reduce the risk of any problems. See 'Conditions you/your child need/s to look out for' in Section 4.

If you/your child need/s a blood test

Zinnat Suspension can affect the results of a test for blood sugar levels, or a blood screen called the *Coombs test*. If you/your child need/s a blood test:

→ **Tell the person taking the sample** that you/your child are/is taking Zinnat Suspension.

Other medicines and Zinnat Suspension

If you/your child are/is taking, have/has recently taken, or may start taking any other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist, especially if you/your child are/is taking:

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

Use of the medicine and food

Take/give Zinnat Suspension after food. This will help to make the treatment more effective.

Contraceptive pills

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

Pregnancy, breast-feeding and fertility

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

Driving and operating machinery

Zinnat Suspension **can make you/your child dizzy** and has other side effects that make you/your child less alert.

→ **Do not drive or operate machinery while using the medicine** if you/your child do not / does 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 Suspension contains **sugar (sucrose)**. If you/your child are/is diabetic, you/he must take this into account for your/his diet. If you have been told by a physician that you/your child have/has an intolerance to certain sugars, refer to the physician before taking/giving this medicine. The sugar may harm the teeth.

Zinnat Suspension contains **aspartame**, which is a source of phenylalanine. This can be harmful if you/your child suffer/s from **phenylketonuria (PKU)**, a rare genetic disorder in which phenylalanine accumulates because the body can not eliminate it properly.

Zinnat Suspension contains benzyl alcohol (E1519) which can cause allergic reactions.

Each 5 ml dose of Zinnat Suspension 125 mg/5 ml contains:

0.021 grams aspartame

3 grams sucrose

6 mg propylene glycol (E1520)

4.5 mg benzyl alcohol (E1519).

Each 5 ml dose of Zinnat Suspension 250 mg/5 ml contains:

0.045 grams aspartame

2.3 grams sucrose

4.6 mg benzyl alcohol (E1519).

→ **Check with your/your child's physician** that Zinnat Suspension is suitable for you/him.

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 Suspension is generally 250 mg to 500 mg twice daily, depending on the severity and type of infection.

Children

The usual dosage of Zinnat Suspension is generally 10 mg/kg (to a maximum of 125 mg) to 15 mg/kg (to a maximum of 250 mg), twice daily, depending on:

- the severity and type of infection
- the weight and age of the child, up to a maximum of 500 mg per day.

Zinnat Suspension is not recommended for children aged under 3 months.

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 respond/s to treatment, the initial dose may be changed or more than one course of treatment may be needed.

Take/give Zinnat Suspension after food.

Shake the bottle before use.

Opening instructions: to remove the cap, press down and twist to the left (turning counter-clockwise) at the same time.

Closing instructions: close the bottle tightly with the cap, twisting to the right (turning clockwise) until it locks.

While taking the medicine, prepared Zinnat Suspension (reconstituted) can be diluted in cold fruit juices, or milk drinks, but should be taken immediately.

Do not mix Zinnat Suspension with hot liquids.

For step-by-step instructions on how to prepare Zinnat Suspension see '**Instructions for reconstitution**' at the end of this leaflet.

Take care to measure the dose using the measuring appliance included in the package.

Patients with kidney problems

If you/your child have/has a kidney problem, your/his physician may change your/his dosage.

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

If you accidentally take/give a higher dosage

If you take/give too much Zinnat Suspension, you/your child may suffer from neurological disorders, and in particular, you/ your child **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 to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take/give the medicine

Do not take/give a double dose to make up for a forgotten dose.

Take/give the next dose at the usual time and consult a physician.

Adhere to the treatment regimen recommended by the physician.

If you stop taking/giving the medicine

Do not stop taking/giving Zinnat Suspension without getting advice.

It is important that you/your child complete/s the full course of treatment with Zinnat Suspension. Do not stop taking/giving the medicine unless your/your child's physician advises you to stop. Even if there is an improvement in your/your child's health, do not stop treatment with the medicine without consulting the physician, because if you/your child do not / does not complete the full course of treatment, the infection may come back.

Do not take/give medicines in the dark! Check the label and the dose each time you take/give 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 Suspension may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You/your child may not suffer from any of them.

Conditions you/your child need/s to look out for

A small number of people taking Zinnat Suspension 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/your child should look out for while taking Zinnat Suspension include:

- **fungal infections.** Medicines like Zinnat Suspension 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/your child take/s Zinnat Suspension for a long time.
- **severe diarrhea (*pseudomembranous colitis*).** Medicines like Zinnat Suspension 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 get a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with Zinnat Suspension 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 blood platelets (cells that help blood to clot)
- a decrease in the number of the white blood cells
- a 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 (*haemolytic anaemia*).

If a side effect occurs, if one of the side effects worsens or if you/your child suffer/s from a side effect not mentioned in this leaflet, consult with 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://sideeffects.health.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) appearing on the package. The expiry date refers to the last day of that month.

Before preparation, the medicine should be kept below 30°C.

The prepared suspension has to be stored in a fridge (between 2°C to 8°C) at all times. Do not freeze. It can be kept in the fridge for up to 10 days.

Do not use the medicine if you notice signs of damage to the drug.

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

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains - Sucrose, stearic acid, tutti frutti flavour (contains propylene glycol (E1520) and benzyl alcohol (E1519)), acesulfame potassium, aspartame (E951), povidone K30, xanthan gum.

See section 2 for further important information about some of the ingredients in Zinnat Suspension.

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

Child resistant pack.

Zinnat Suspension is supplied in an amber, glass, multidose bottle.

The bottle contains:

Zinnat Suspension 125 mg/5 ml - the bottle contains 50 ml of suspension.

Zinnat Suspension 250 mg/5 ml - the bottle contains either 50 ml or 100 ml of suspension.

This medicine should be prepared with water using the original granules that were supplied in the bottle. The bottle is supplied in a carton package.

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.,
Barnard Castle, UK.

Revised in April 2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Zinnat Suspension 125 mg/5 ml: 055-83-26733

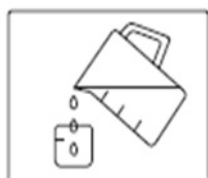
Zinnat Suspension 250 mg/5 ml: 111-33-29425

Instructions for reconstitution

Directions for making up the suspension



Shake the bottle to loosen the contents. The granules should move freely in the bottle. Remove the cap and the seal. If the seal is damaged or not present, return the preparation to the pharmacist.



Add the total amount of cold water stated on the package or up to the volume line marked on the cup provided (if supplied). If the water was previously boiled, it must be allowed to cool to room temperature before adding. Do not mix Zinnat Suspension granules with hot or warm liquids. Cold water must be used to prevent the suspension from becoming too thick.



Pour the total amount of cold water into the bottle. Replace the cap. Allow the bottle to stand to allow the water to fully soak through the granules - for about 1 minute.



Invert the bottle and shake well (for at least 15 seconds) until all the granules have mixed with the water.



Turn the bottle into an upright position and shake well for at least one minute until all the granules have mixed with the water. Store the Zinnat Suspension immediately between 2°C to 8°C (do not freeze) and let it rest for at least one hour before taking the first dose.

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Zinn Sus PT v5A