

Reason for update: Article 61(3) MAH name correction, layout & dimensions changes, GSK Logo (NOT MARKETED)

Market: UK

Agency Approval Date:

Text Date: 15/12/2016

Text Issue and Draft No.: issue5draft2

[GlaxoSmithKline Logo]

Package Leaflet: Information for the Patient

Zinnat® Tablets 500 mg cefuroxime axetil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

Zinnat 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*.

Zinnat is used to treat infections of:

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

Zinnat can also be used:

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

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

2. What you need to know before you take Zinnat

Do not Zinnat:

Reason for update: Article 61(3) MAH name correction, layout & dimensions changes, GSK Logo (NOT MARKETED)

Market: UK

Agency Approval Date:

Text Date: 15/12/2016

Text Issue and Draft No.: issue5draft2

- **if you are allergic** to cefuroxime axetil or **any cephalosporin antibiotics** or any of the other ingredients of Zinnat (listed in section 6).
- if you have ever had a severe allergic (hypersensitive) reaction to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).
- ➔ If you think this applies to you, **don't take Zinnat** until you have checked with your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zinnat.

Children

Zinnat 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 diarrhoea (*pseudomembranous colitis*) while you are taking Zinnat. 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 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.

Other medicines and Zinnat

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Probenecid

Oral anticoagulants

- ➔ **Tell your doctor or pharmacist** if you are taking any medicine like this.

Contraceptive pills

Zinnat may reduce the effectiveness of the contraceptive pill. 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.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Reason for update: Article 61(3) MAH name correction, layout & dimensions changes, GSK Logo (NOT MARKETED)

Market: UK

Agency Approval Date:

Text Date: 15/12/2016

Text Issue and Draft No.: issue5draft2

Driving and using machines

Zinnat **can make you dizzy** and have other side effects that make you less alert.

➔ **Don't drive or use machines** if you do not feel well.

3. How to take Zinnat

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

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

Swallow Zinnat tablets whole with some water.

Don't chew, crush or split the tablets — this may make the treatment less effective.

The recommended dose

Adults

The recommended dose of Zinnat is 250 mg to 500 mg twice daily depending on the severity and type of infection.

Children

The recommended dose of Zinnat is 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

Zinnat is not recommended for children aged under 3 months, as the safety and effectiveness are not known in this age group.

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.

Patients with kidney problems

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

➔ **Talk to your doctor** if this applies to you.

If you take more Zinnat than you should

If you take too much Zinnat you may have neurological disorders, in particular 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.

If you forget to take Zinnat

Reason for update: Article 61(3) MAH name correction, layout & dimensions changes, GSK Logo (NOT MARKETED)
Market: UK
Agency Approval Date:
Text Date: 15/12/2016
Text Issue and Draft No.: issue5draft2

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop taking Zinnat

Don't stop Zinnat without advice

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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions you need to look out for

A small number of people taking Zinnat get an allergic reaction or 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 need to look out for while taking Zinnat include:

- **fungal infections.** Medicines like 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.
 - **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like Zinnat can cause inflammation of the colon (large intestine), causing severe diarrhoea, 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 for Lyme disease. This is known as the *Jarisch-Herxheimer reaction*. Symptoms usually last a few hours or up to one day.
- ➔ **Contact a doctor or nurse immediately if you get any of these symptoms.**

Common side effects

Reason for update: Article 61(3) MAH name correction, layout & dimensions changes, GSK Logo (NOT MARKETED)

Market: UK

Agency Approval Date:

Text Date: 15/12/2016

Text Issue and Draft No.: issue5draft2

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

- fungal infections (such as *Candida*)
- headache
- dizziness
- diarrhoea
- feeling sick
- 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:

- being sick
- 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 white blood cells
- positive Coomb's test.

Other side effects

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

- severe diarrhoea (*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*).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

Reason for update: Article 61(3) MAH name correction, layout & dimensions changes, GSK Logo (NOT MARKETED)

Market: UK

Agency Approval Date:

Text Date: 15/12/2016

Text Issue and Draft No.: issue5draft2

5. How to store Zinnat

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

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

Do not use Zinnat if the tablets are chipped or there are other visible signs of deterioration.

Don't throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zinnat contains

- The active substance in each tablet is 500 mg cefuroxime (present as cefuroxime axetil).
- The other ingredients are microcrystalline cellulose, croscarmellose sodium type A, sodium lauryl sulphate, hydrogenated vegetable oil, silica colloidal anhydrous, methylhydroxypropyl cellulose, propylene glycol, methyl parahydroxybenzoate, propyl parahydroxybenzoate and Opaspray white M-1-7120J [containing titanium dioxide (E171) and sodium benzoate (E211)].

What Zinnat looks like and contents of the pack

Zinnat Tablets 500 mg are white, film-coated, capsule-shaped tablets plain on one side and engraved with 'GXEG2' on the other. They are packaged in aluminium foil blister packs, enclosed in a carton. Each pack contains 2, 4, 14 and 50 tablets.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder: Glaxo Wellcome UK Limited, Stockley Park West, Uxbridge, Middlesex. UB11 1BT

Manufacturer: Glaxo Wellcome Operations, Harmire Road, Barnard Castle, Co. Durham DL12 8DT

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Zinnat Tablets 500 mg**

Reference number 10949/0119

Reason for update: Article 61(3) MAH name correction, layout & dimensions changes, GSK Logo (NOT MARKETED)

Market: UK

Agency Approval Date:

Text Date: 15/12/2016

Text Issue and Draft No.: issue5draft2

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in September 2016.

Zinnat is a registered trade mark of the GSK group of companies

© 2016 GSK group of companies. All rights reserved

[GlaxoSmithKline Logo]