Zinnat® 500mg film-coated tablets
(cefuroxime)

Patient Information Leaflet

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 any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 further 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

Don't take Zinnat:
* if you are allergic to any cephalosporin antibiotics, to cefuroxime or to 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.

Take special care with Zinnat

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 any other medicines, if you've started taking any recently or you start taking new ones. This includes medicines you can obtain without a prescription.

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

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 usual dose

Adults

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

Children

The usual 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 too much Zinnat

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

Don't take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

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.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Zinnat®  500mg film-coated tablets  
(cefuroxime)

Patient Information Leaflet (continued)

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
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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

How to store Zinnat
Do not store above 25°C. Do not use Zinnat if the tablets are chipped or there are other visible signs of deterioration. 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. 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.

How to store Zinnat

Contents of the pack and other further 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, sodium lauryl sulphate, hydrogenated vegetable oil, colloidal silicon dioxide hypromellose, propylene glycol, methyl-4-hydroxybenzoate E218, propyl-4-hydroxybenzoate E216, Opaspray white M-1-7120 (hypromellose, titanium dioxide E171, sodium benzoate E211, industrial methylated spirits 74 OP

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

What this medicine looks like and contents of the pack
Zinnat 500 mg Film Coated tablets 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 14 tablets.

Parallel Product Authorisation Holder is:
LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Repackaged by: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Manufacturer: GlaxoWellcome Operations, Barnard Castle, Great Britain
Zinnat is a registered trademark of GlaxoSmithKline group of companies.

POM  
PPA1562/163/001

Revision date: 11/06/2015

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone LTT Pharma Limited, Tel: +44 (0)1527 505414 for help.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, United Kingdom – Zinnat
Germany – Elobact
Greece – Zinadol
Italy – Zoref
Italy – Oraxim
Portugal – Zoref
Spain – Cefuroxima Allen
Spain – Cefuroxima Solasma