

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zinatan 250mg Film-coated Tablets

Zinatan 500mg Film-coated Tablets

Cefuroxime

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.

What is in this leaflet:

1. What Zinatan is and what it is used for
2. What you need to know before you take Zinatan
3. How to take Zinatan
4. Possible side effects
5. How to store Zinatan
6. Contents of the pack and other information

1. What Zinatan is and what it is used for

Zinatan 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*.

Zinatan is used to treat infections of:

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

Zinatan can also be used:

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

2. What you need to know before you take Zinatan

Don't take Zinatan:

- **if you are allergic** (*hypersensitive*) to **any cephalosporin antibiotics** or any of the other ingredients of Zinatan.
 - 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 Zinatan** until you have checked with your doctor.

Take special care with Zinatan

Zinatan 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 Zinatan. 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

Zinatan 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 Zinatan.

Other medicines and Zinatan

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 Zinatan works.

Probenecid

Oral anticoagulants

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

Contraceptive pills

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

Pregnancy and breast-feeding and fertility

Tell your doctor before you take Zinatan:

- if you are pregnant, think you might be pregnant or are planning to become pregnant
- if you are breastfeeding.

Your doctor will consider the benefit of treating you with Zinatan against the risk to your baby.

Driving and using machines

Zinatan **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 Zinatan

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

Swallow Zinatan 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 Zinatan is 250 mg to 500 mg twice daily depending on the severity and type of infection.

Children

The usual dose of Zinatan 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
- the weight and age of the child, up to a maximum of 500 mg per day.

Zinatan 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 Zinatan

If you take too much Zinatan 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 Zinatan pack.

If you forget to take Zinatan

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 Zinatan without advice

It is important that you take the full course of Zinatan. 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.

Conditions you need to look out for

A small number of people taking Zinatan 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*).
 - **fungal infections.** Medicines like Zinatan 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 Zinatan for a long time.
 - **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like Zinatan 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 Zinatan 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*).

If you get any side effects

➔ **Tell your doctor or pharmacist.** This includes any possible side effects not listed in this leaflet.

5. How to store Zinatan

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

This medicinal product does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Zinatan contains

The active substance is cefuroxime.

Zinatan 250 mg tablets contain 300.72 mg of cefuroxime axetil per tablet equivalent to 250 mg of cefuroxime.

Zinatan 500 mg tablets contain 601.44 mg of cefuroxime axetil per tablet equivalent to 500 mg of cefuroxime.

The other ingredients are:

Starch pregelatinised, croscarmellose sodium, sodium laurilsulfate, cellulose microcrystalline, silica colloidal anhydrous, hydrogenated vegetable oil. The film coating contains hypromellose (E464), titanium dioxide (E171), propylene glycol (E1520), brilliant blue FCF aluminium lake (E133), indigo carmine aluminium lake (E132).

What Zinatan looks like and contents of the pack

Zinatan 250 mg tablets are light blue, capsule-shaped, film-coated tablets with "250" on one side and "P125" on the other side.

Zinatan 500 mg tablets are light blue, capsule-shaped, film-coated tablets with "500" on one side and "P126" on the other side.

Zinatan tablets are available in blister packs of 2, 5, 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 100 and 250 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:

Clonmel Healthcare Ltd
Waterford Road, Clonmel, Co. Tipperary,
Ireland

Manufacturer:

Clonmel Healthcare Ltd
Waterford Road, Clonmel, Co. Tipperary,
Ireland

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