

Package Leaflet: Information for the User

Zithromax® 250mg Capsules (azithromycin (as dihydrate))

Your medicine is available using the name Zithromax 250mg Capsules but will be referred to as Zithromax throughout this 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Zithromax is and what it is used for

This medicine contains azithromycin, which is one of a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other micro-organisms, which include:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- ear infections
- skin and soft tissue infections (such as an abscess or boil)
- sexually transmitted diseases caused by organisms called chlamydia or gonorrhoea.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Zithromax

Do not take Zithromax:

- if you are allergic to Zithromax or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the ingredients listed in section 6. An allergic reaction may cause skin rash or wheezing.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zithromax if you have or have had any of the following conditions:

- kidney problems
- heart conditions
- liver problems: your doctor may need to monitor your liver function or stop the treatment
- myasthenia gravis (localised muscle weakness)
- if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with Zithromax.

Tell your doctor immediately:

- if you feel your heart beating in your chest or have an abnormal heartbeat, get dizzy or faint, or suffer from muscle weakness when taking Zithromax.
- if you develop diarrhoea or loose stools during or after treatment, tell your doctor at once. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues, please inform your doctor.
- if you feel you are having an allergic reaction (e.g. difficulty in breathing, dizziness, swelling of the face or throat, rash, wheals, blistering). Stop taking this medicine and seek urgent medical advice.
- if you develop signs of liver problems (e.g. dark urine, profound loss of appetite or yellowing of the skin or whites of the eyes). Stop taking this medicine and seek urgent medical advice.
- if you are giving this medicine to an infant (less than 6 weeks of age) and they vomit or become irritable when fed.

Other medicines and Zithromax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, Zithromax may interact with the medicines listed below:

- ergot or ergotamine – see ‘Warnings and precautions’ section
- warfarin or any similar medicine to prevent blood clots
- ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- digoxin (used to treat heart failure)
- terfenadine (for hay fever or a skin allergy)
- atorvastatin (for reducing blood cholesterol levels).

If you are taking antacids (for indigestion), Zithromax should be taken one hour before, or two hours after taking antacids.

Zithromax with food and drink

You should take Zithromax either 1 hour before a meal or 2 hours after a meal.

Pregnancy, 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.

Driving and using machines

Zithromax is not expected to affect your ability to drive or use machines.

Zithromax contains lactose

Zithromax contains lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking Zithromax.

3. How to take Zithromax

Always take Zithromax exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The capsules should be swallowed whole.

The usual dose in adults and children over 7 stones (45kg) is 500mg (2 capsules) taken together, once a day, for 3 days. For some diseases such as Chlamydia the dose is 1g (4 capsules) taken all together on one day only. For gonorrhoea the recommended dose is azithromycin 2g as a single oral dose together with ceftriaxone 500mg intramuscularly as a single dose.

You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

Zithromax capsules should not be taken by children weighing less than 45kg.

Doctors sometimes prescribe different doses to these. The label on the pack will tell you which dose you should take. If you are still not sure, ask your doctor or pharmacist.

Always continue with the course even if you feel better. If your infection gets worse or you do not start to feel better within a few days or a new infection develops, go back and see your doctor.

If you take more Zithromax than you should

If you take too much Zithromax you may feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately.

If you forget to take Zithromax

If you forget to take Zithromax take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zithromax

If you stop taking Zithromax too soon, the infection may return. Take the capsules for the full time of treatment, even when you begin to feel better.

If you have any further questions about the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Zithromax can cause side effects although not everybody gets them. **Tell your doctor immediately** if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat
- low blood pressure
- vomiting and diarrhoea can rarely cause dehydration. It is important to drink plenty of fluid if you experience sickness and/or diarrhoea
- diarrhoea may occur during, or after completing, treatment with antibiotics and could be a sign of serious bowel inflammation.

The most common side effects that occur when taking Zithromax are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

Very common side effects (may affect more than 1 in 10 people):

- diarrhoea.

Common side effects (may affect up to 1 in 10 people):

- headache
- feeling sick, being sick
- low number of lymphocytes (type of white blood cells), higher number of eosinophils (type of white blood cells), and other blood changes
- low blood bicarbonate.

Uncommon side effects (may affect up to 1 in 100 people):

- yeast infections of the mouth and vagina (thrush)
- fungal or bacterial infections such as severe sore throat, gastroenteritis
- breathing problems, runny nose, nose bleeds
- low number of leukocytes (type of white blood cells)
- allergic reactions of various severity
- feeling nervous
- sleepiness or sleeplessness (insomnia)
- visual disturbances
- feeling dizzy, ear problems, vertigo
- heart palpitations, chest pain
- loss of appetite, taste disturbance
- constipation, wind, burping, indigestion
- stomach pain associated with diarrhoea and fever
- mouth ulcers, dry mouth, difficulty swallowing, excess saliva
- kidney pain, pain when urinating
- general loss of strength, tiredness or weakness, numbness or pins and needles

- swelling, swollen or painful muscles, back pain, neck pain
- general discomfort
- abnormal blood test values
- rash, red, dry or itchy skin, or excess sweating
- bleeding between periods in women
- testicular pain in men
- hot flushes.

Rare side effects (may affect up to 1 in 1,000 people):

- agitation
- skin more sensitive to sunlight than normal
- changes in liver function, yellowing of the skin and eyes.

Other side effects that have been reported, but frequency cannot be estimated from the available data:

- fits, fainting, twitching muscles
- aggression, anxiety, delirium, hallucinations, sleep disturbances (e.g. nightmares, night terrors)
- feeling hyperactive
- localised muscle weakness
- painful joints
- deafness, hearing loss, ringing in the ears
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with Zithromax as this may be a sign of serious bowel inflammation
- loss of smell or altered sense of smell, loss of taste
- tongue discolouration
- inflammation of the pancreas (pancreatitis)
- inflammation of the kidney or kidney failure
- bruising or prolonged bleeding after injury
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- low blood pressure
- blistering of the skin, severe skin reaction
- abnormal electrocardiogram (ECG).

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.

5. How to store Zithromax

Keep this medicine out of the sight and reach of children. Do not store above 30°C.

Do not refrigerate. Store in the original carton.

Do not take this medicine after the expiry date stamped on the pack after EXP. The expiry date refers to the last day of that month.

If your doctor decides to stop the treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.

If your medicine appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.

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

6. Contents of the pack and other information

What Zithromax contains

The active substance is azithromycin (as dihydrate). Each capsule contains 250mg of azithromycin (as dihydrate).

The capsule contents are: anhydrous lactose, magnesium stearate, sodium lauryl sulphate, corn starch (without gluten).

The capsule shell contains: gelatine, titanium dioxide (E171). Printing ink contains: black ink composed of (shellac) 45%, black iron oxide (E172), propylene glycol and ammonium hydroxide 28% or lacquer (Shellac), black iron oxide (E172), propylene glycol, strong solution of ammonium and potassium hydroxide.

What Zithromax looks like and contents of the pack

Zithromax are white capsules marked with Pfizer and ZTM 250 on the cap and the body.

Zithromax is available in blister pack of 6 capsules.

Manufacturer

Manufactured by: Farmasierra Manufacturing S.L. Ctra. N-1, Km 26,200, 28700 San Sebastián de los Reyes, Madrid, Spain.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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