

Package Leaflet: Information for the User

Zithromax™ 250mg Capsules azithromycin (as dihydrate)

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Zithromax is and what it is used for

Zithromax 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 an organism called chlamydia.

2. 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.
- You are allergic to soya or peanut due to the risk of hypersensitivity reactions from the ingredient soya lecithin.

Take special care with Zithromax

Your doctor needs to know **before** you take 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)

- and 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, or 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.

Taking other medicines

Tell your doctor **before** taking Zithromax, if you are taking any of the medicines listed below:

- ergot or ergotamine – see 'Take special care' 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).

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

You should always tell your doctor if you are taking, or have recently taken, any other medicines including those obtained without a prescription.

Taking Zithromax with food and drink

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

Pregnancy and breast-feeding

If you are pregnant, trying to get pregnant or are breast-feeding you should not take Zithromax without discussing it with your doctor first.

Driving and using machines

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

Important information about some of the ingredients of Zithromax

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

Zithromax contains soya lecithin, please see Section 2 'Do not take'

3. How to take Zithromax

Always take Zithromax exactly as your doctor has told you. You should 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 (45 kg) 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.

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 for advice.

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 (occurring in at least 1 in 10 people):

- stomach cramps, feeling sick, diarrhoea, wind.

Common side effects (likely to occur in less than 1 in 10 people):

- dizziness, headache
- numbness or pins and needles
- being sick, indigestion
- loss of appetite, taste disturbance
- visual disturbances, deafness
- skin rash and/or itching
- joint pain
- low number of lymphocytes (type of white blood cells), higher number of eosinophils (type of white blood cells)
- low blood bicarbonate
- tiredness or weakness.

Uncommon side effects that occur in less than 1 in 100 people taking Zithromax are:

- yeast infections of the mouth and vagina (thrush)
- low number of leukocytes (type of white blood cells), low number of neutrophils (type of white blood cells)
- allergic reactions of various severity
- blistering of the skin, mouth, eyes and genitals
- skin more sensitive to sunlight than normal
- feeling nervous
- reduced sense of touch or sensation (hypoesthesia)
- sleepiness or sleeplessness (insomnia)
- poor hearing or ringing in the ears
- heart palpitations, chest pain
- constipation, stomach pain associated with diarrhoea and fever
- inflammation of the liver (hepatitis), changes in liver enzymes
- general loss of strength
- swelling
- general discomfort
- abnormal laboratory test values (e.g. blood or liver tests).

Rare side effects that occur in less than 1 in 1,000 people taking Zithromax are:

- agitation
- vertigo
- changes in liver function.

Other side effects that have been reported, but it is not known how frequently they occur:

- fits or fainting
- aggression or anxiety
- feeling hyperactive
- localised muscle weakness

- 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
- yellowing of the skin or eyes (jaundice) or liver failure (rarely life-threatening)
- 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).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Zithromax

Keep all medicines out of the sight and reach of children.

Store below 30°C. Do not refrigerate. Store in the original container.

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and further information

What Zithromax contains

The active substance is azithromycin (as dihydrate)

Each capsule contains 250mg of azithromycin

The other ingredients are lactose, magnesium stearate, maize starch, sodium laurilsulfate, and(gelatin and titanium dioxide(E171) in the capsule shell) and,(black iron oxide (E172), shellac ,antifoam 1510, alcohol n-butyl, soya lecithin in the printing ink)

What Zithromax looks like and contents of the pack

Zithromax capsules are white hard capsules marked 'Pfizer' and 'ZTM 250'. They come in blister packs of 6.

On the blister pack, the wording 'Dia 1' means Day 1, 'Dia 2' means Day 2, 'Dia 3' means Day 3

Manufacturer

Farmasierra Manufacturing S.L. Ctra N-1, Km 26,200.28700 San Sebastian de Los Reyes, Madrid

Procured from within the EU by the parallel product authorisation holder:

Primecrown 2010 Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt Middlesex UB5 5QS

Repackaged by Primecrown Ltd 4/5 Northolt Trading Estate, Northolt, Middlesex, UB5 5QS.UK or Propak Health Ltd 3-4 Ballyboggan Industrial Estate, Ballyboggan Road, Finglas, Dublin 11.

Company contact address:

For further information on your medicine contact Medical Information at the following address:

Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.
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