Package leaflet: Information for the patient

Azithromycin Pfizer Capsules 250mg
azithromycin dihydrate

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 Azithromycin Pfizer is and what it is used for
2. What you need to you know before you take Azithromycin Pfizer
3. How to take Azithromycin Pfizer
4. Possible side effects
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1. What Azithromycin Pfizer is and what it is used for

Azithromycin Pfizer 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.

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 Azithromycin Pfizer

Do not take Azithromycin Pfizer:

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Azithromycin Pfizer 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)
- or if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with Azithromycin Pfizer.

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 Azithromycin Pfizer.

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.

Other medicines and Azithromycin Pfizer
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, Azithromycin Pfizer 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).

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

Azithromycin Pfizer with food and drink
You should take Azithromycin Pfizer capsules 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
Azithromycin Pfizer is not expected to affect your ability to drive or use machines.

Azithromycin Pfizer capsules contain lactose
Azithromycin Pfizer capsules contain lactose, a type of sugar. If you have been told by your doctor you have an intolerance to some sugars contact your doctor before taking Azithromycin Pfizer.

3. How to take Azithromycin Pfizer

Always take this medicine 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 recommended 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 recommended 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.

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

Doctors sometimes prescribe different doses to the recommended dose. 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 Azithromycin Pfizer than you should

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

If you forget to take Azithromycin Pfizer

If you forget to take Azithromycin Pfizer 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 Azithromycin Pfizer

If you stop taking Azithromycin Pfizer 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 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.

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 Azithromycin Pfizer 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: may affect more than 1 in 10 people

- stomach cramps, feeling sick, diarrhoea, wind.

Common: may affect up to 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 (a type of white blood cell), higher number of eosinophils (a type of white blood cell)

- low blood bicarbonate
- tiredness or weakness.

Uncommon: may affect up to 1 in 100 people
- yeast infections of the mouth and vagina (thrush)
- low number of leukocytes (a type of white blood cell), low number of neutrophils (a type of white blood cell)
- 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: may affect up to 1 in 1,000 people
- agitation
- vertigo
- changes in liver function.

Very rare: may affect up to 1 in 10,000 people
- Skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell). A rash appears as small, itchy red bumps.

Not known: frequency cannot be estimated from the available data
- 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 Azithromycin Pfizer 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).

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 Azithromycin Pfizer

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Do not 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 protect the environment.

6. Contents of the pack and other information

What Azithromycin Pfizer contains

The active substance is azithromycin. Each capsule contains 250mg of active substance.

The other ingredients are lactose anhydrous (see section 2, Azithromycin Pfizer contains lactose), magnesium stearate, maize starch, sodium lauryl sulfate, gelatin, black iron oxide (E172), shellac and titanium dioxide (E171).

What Azithromycin Pfizer looks like and contents of the pack

Azithromycin Pfizer capsules are white and have Pfizer and ZTM 250 printed on them. They come in blister packs of 4 or 6.
Not all pack sizes may be marketed.

Product Authorisation Holder

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom.

Manufacturer

Haupt Pharma Latina S.r.I.
Strada Statale No. 156 Km 50
04010 Borgo San Michele
Latina
Italy.

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.
Telephone: 1800 633 363.

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