

PACKAGE LEAFLET: INFORMATION FOR THE USER

Azithromycin 250 mg Capsules

(azithromycin dihydrate)

Read all of this leaflet carefully before you start using 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.

What is in this leaflet:

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

1. What Azithromycin is and what it is used for

Azithromycin is an antibiotic. It belongs to a group of antibiotics called 'macrolides'.

Azithromycin is used to treat bacterial infections caused by 'micro-organisms' such as bacteria. These infections 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 trachomatis and Neisseria 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 use Azithromycin

Do not take Azithromycin if

- you are allergic (hypersensitive) to azithromycin dihydrate or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the other ingredients in 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 if you have or have had any of the following conditions:

- liver problems: your doctor may need to monitor your liver function or stop the treatment
- kidney problems
- heart conditions)
- your blood levels of potassium or magnesium are too low
- myasthenia gravis (a condition that causes certain muscles to become weak)
- 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.

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 any muscle weakness when taking Azithromycin.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- colchicine (used for gout and familial Mediterranean fever)
- antacids (for indigestion)
- ergot or ergotamine – see 'Warnings and precautions' section
- warfarin or any similar medicines 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).

Azithromycin with food and drink

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

Pregnancy and breast-feeding

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

3. How to take Azithromycin

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.

How much to take

Adults and children with a body weight of 45 kg and above:

The recommended dose is 500 mg (2 capsules) taken together, once a day, for 3 days.

For some diseases such as Chlamydia. Your doctor will ask you to take a single dose of 1000 mg (4 capsules) taken all together on one day only. For gonorrhoea the recommended dose is 1 g or 2 g of azithromycin in combination with 250 or 500 mg of ceftriaxone.

Children and adolescents under 45 kg:

The Azithromycin capsules should not be taken by children weighing less than 45 kg. Young people with a body weight of less than 45 kg should use other forms of this medicine such as azithromycin suspension.

Patients with kidney or liver problems

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

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 than you should

If you take more Azithromycin than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Azithromycin

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose, do not take a double dose to make up for a forgotten dose. If you have to skip a dose, still take all of your capsules. This means that you will finish your course a day later.

If you stop taking Azithromycin

If you stop taking Azithromycin 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 straight away if you experience any of the following symptoms after taking this medicine as the symptoms maybe severe- you may need urgent medical treatment:

- difficulty breathing, sudden wheeziness, swelling of the eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe or prolonged diarrhoea, which may have blood or mucus in it during or after treatment with Azithromycin as this may be a sign of serious bowel inflammation.
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat
- low blood pressure
- serious skin reactions;
 - blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome (SJS))
 - blistering of the skin, severe skin reaction (Toxic Epidermal Necrosis (TEN))
 - 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 (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
 - skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalized Exanthematous Pustulosis (AGEP) – rare (may affect 1-10 users in 10,000)

Stop taking azithromycin if you develop these skin symptoms and contact your doctor or seek medical attention immediately.

The most common side effects that occur when taking Azithromycin 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.

Other side effects include:

Very common (affects more than 1 user in 10)

- diarrhoea, stomach cramps, feeling sick, wind

Common (affects 1 to 10 users in 100)

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

Uncommon (affects 1 to 10 users in 1,000)

- yeast infections of the mouth and vagina (thrush)
- low numbers of leukocytes (a type of white blood cell), low number of neutrophils (a type of white blood cell)
- allergic reactions of various severity
- 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 (affects 1 to 10 users in 10,000)

- feeling agitated
- changes in liver function
- vertigo

Not known (frequency cannot be estimated from the available data)

- fits or fainting
- aggression or anxiety
- feeling hyperactive
- localised muscle weakness
- 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
- abnormal electrocardiogram (ECG)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness.

If any of the side effects gets serious, or if you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Your doctor may then decide to reduce your dose or stop treatment.

You can also report side effects directly via the Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azithromycin

- Keep this medicine out of the sight and reach of children.
- Store below 25°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the packaging 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 to protect the environment.

6. Contents of the pack and other information

What Azithromycin contains

The active substance is azithromycin (as dihydrate).

Azithromycin 250 mg capsules contain azithromycin dihydrate equivalent to 250 mg of azithromycin.

The other ingredients are:

Cellulose microcrystalline (E460), Pregelatinised starch (maize), Magnesium stearate (E470b), Sodium laurilsulfate, gelatin, black ink (shellac, propylene glycol, black iron oxide, potassium hydroxide).

What Azithromycin looks like and contents of the pack

Azithromycin 250 mg Capsules consist of a white cap and white body, size “0” hard gelatin opaque capsuls, imprinted in black ink with “250” on cap and body, containing white to off white granular powder.

The capsules are available in blister packages of 2, 4 or 6 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay
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Manufacturer:

Amneal Netherlands B.V.
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