

Azithromycin 250mg and 500mg Film-coated Tablets

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 is and what it is used for**
- 2 What you need to know before you take 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 belongs to a group of medicines called macrolide antibiotics. It is used to treat infections caused by certain bacteria and other micro-organisms such as:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- ear infections
- skin and soft tissue infections, with exception of infected burn wounds e.g. infection of the tube that carries urine from the bladder (urethra) or the neck of the womb (cervix) caused by *Chlamydia trachomatis* (bacteria).

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

Do not take Azithromycin if you:

- are **allergic** to azithromycin dihydrate or any other macrolide antibiotic such as erythromycin or clarithromycin or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Azithromycin if:

- you have severe liver problems: your doctor may need to monitor your liver function or stop the treatment
- you have severe kidney problems
- you have heart problems
- your blood levels of potassium or magnesium are too low
- you develop signs of another infection
- you are taking any ergot derivatives such as ergotamine (to treat migraine) as these medicines should not be taken together with azithromycin (see section "Other medicines and Azithromycin")
- you have a certain type of muscle weakness called myasthenia gravis.

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:

- antacids - used for heartburn and indigestion
- ergotamine - used for migraine, should not be taken at the same time as serious side effects may develop (with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain)
- warfarin or similar medicines - used to thin the blood. Azithromycin can thin the blood even more
- terfenadine - used to treat hay fever or skin allergy, should not be taken at the same time as this may cause severe heart problems (shown on an ECG)
- zidovudine or nelfinavir - used to treat HIV infections. Taking nelfinavir with Azithromycin may mean that you get more of the side effects listed in this leaflet
- rifabutin - used to treat tuberculosis (TB)
- quinidine - used to treat heart rhythm problems
- ciclosporin - used to stop your body rejecting an organ transplant. Your doctor will regularly check your blood levels of ciclosporin and may change your dose.

Tell your doctor or pharmacist if you are taking any of the following medicines. Azithromycin can make the effects of these other medicines stronger. Your doctor may change your dose:

- digoxin - used to treat cardiac impairment
- colchicine - used for gout and familial Mediterranean fever.

Azithromycin with food and drink

This medicine can be taken with or without food.

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. There is insufficient information available about the use of azithromycin during pregnancy. Therefore you should not use Azithromycin during pregnancy, unless explicitly advised by your doctor.

Azithromycin is partially passed through the mother's milk.

It is not known whether azithromycin may have adverse effects on the breast-fed infant. Breast-feeding should therefore be discontinued during treatment with Azithromycin. It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. Breast-feeding may be resumed thereafter.

Driving and using machines

There are no data available about the influence of azithromycin on the ability to drive or operate machines. However Azithromycin Tablets may cause dizziness and seizures so make sure you are not affected before driving or operating machinery.

Azithromycin contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicinal product contains less than 1mmol sodium (23mg) per film-coated tablet, i.e. essentially 'sodium-free'.

3 How to take Azithromycin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose

For adults, children and adolescents with a body weight of 45kg or over

500mg (two 250mg or one 500mg tablets) once daily for three days with a total dose of 1500mg. Alternatively, your doctor may decide to prescribe the total dose of 1500mg over a period of 5 days, with 500mg the first day and 250mg on days 2 to 5.

For infections of the neck of the womb and urethra caused by *Chlamydia trachomatis*

One dose of 1000mg (four 250mg or two 500mg tablets).

Children and adolescents under 45kg

Azithromycin tablets should not be taken by children or adolescents weighing less than 45kg. Other dosage forms are available for this group of patients.

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.

Method of administration

The tablets can be taken with or without food.

The tablets should be taken with half a glass of water.

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 have taken too much Azithromycin, contact your doctor, pharmacist or go to your nearest hospital immediately. Symptoms of overdose are loss of hearing, feeling sick or being sick and diarrhoea. In case of overdose admission into hospital may be necessary.

If you forget to take Azithromycin

If you forget to take Azithromycin, take your dose as soon as possible. If it is almost time for the next dose, just skip that dose and take the next one when it is due. If in doubt, please contact your doctor or pharmacist. If you have to skip a dose, still take all of your tablets. This means that you will finish your course a day later.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Azithromycin

Never stop the treatment with Azithromycin on your own, but first discuss this with your doctor. If you stop taking Azithromycin too soon, the infection may return. Take the tablets 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.

If you have any of the below symptoms of a severe allergic reaction stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital.

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

- swelling of the face, lips, tongue, throat, hands, feet or genitals
- blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).

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

- skin rash accompanied by other symptoms such as fever, swollen glands and an increase in a type of white blood cell (eosinophilia). A rash appears as small, itchy red bumps (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

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

- sudden difficulty in breathing, speaking and swallowing
- extreme dizziness or collapse
- severe rash involving reddening, peeling and swelling of the skin (Toxic Epidermal Necrolysis).

If you experience any of the following serious side effects, contact your doctor as soon as possible as you may need urgent medical attention.

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

- inflammation of the liver (hepatitis)
- signs of infection such as a sore throat and high temperature caused by a reduction in the number of white blood cells (leukopenia or neutropenia).

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

- skin eruption that is characterised by the rapid appearance of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP)).

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

- severe or prolonged diarrhoea, which may have blood or mucous in it. This can be a sign of a serious bowel inflammation. This is something that can occasionally happen after taking antibiotics
- reduced number of red blood cells due to destruction (haemolytic anaemia); unusual bruising or bleeding caused by a reduction in the number of platelets (thrombocytopenia)
- yellowing of the skin or whites of the eyes (jaundice) or liver failure (rarely life-threatening)
- inflammation of the pancreas, which causes severe pain in the abdomen and back
- inflammation of the kidney or kidney failure, increased or reduced urine output, or traces of blood in your urine
- a skin rash that has raised patches or blisters and may be itchy (erythema multiforme)
- rapid (ventricular tachycardia) or irregular heart beat, sometimes being life-threatening, changes of the heart rhythm found by an electro-cardiogram (QT prolongation and torsade de pointes).

Other side effects include:

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

- diarrhoea
- abdominal pain
- feeling sick (nausea)
- wind (flatulence).

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

- lack of appetite (anorexia)
- feeling dizzy
- headache
- sensation of pins and needles or numbness (paraesthesia)
- changes in your sense of taste
- visual impairment
- deafness
- being sick (vomiting), stomach pain or cramps, loss of appetite, problems digesting your food
- skin rashes and itching
- joint pain (arthralgia)
- fatigue
- change in the quantity of the white blood cells and the concentration of bicarbonate in the blood.

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

- yeast infection of the mouth and vagina (thrush)
- nervousness
- reduced sense of touch (hypoesthesia)
- feeling drowsy (somnolence)
- having difficulty sleeping (insomnia)
- hearing loss or ringing in your ears
- palpitations
- inflammation of the lining of the stomach (gastritis)
- constipation
- skin more sensitive to sunlight than normal
- urticaria
- chest pain
- swelling (oedema)
- general feeling of being unwell (malaise)
- weakness (asthenia)
- change in liver enzyme levels and blood levels.

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

- feeling agitated
- spinning sensation (vertigo)
- abnormal liver function.

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

- aggression or anxiety
- fainting (syncope)
- fits (convulsions)
- feeling hyperactive
- change in your sense of smell (anosmia, parosmia)
- change in your sense of taste (ageusia)
- exacerbation or aggravation of muscle weakness (myasthenia gravis)
- low blood pressure
- your tongue changes colour.

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 the Yellow Card Scheme at: 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.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 contains

- The active substance is: azithromycin dihydrate.
- Azithromycin 250mg Film-coated Tablets contain 250mg azithromycin (as dihydrate).
- Azithromycin 500mg Film-coated Tablets contain 500mg azithromycin (as dihydrate).
- The other ingredients are: Core: croscarmellose sodium (E468), magnesium stearate (E572), microcrystalline cellulose (E460), silicon dioxide, (E551), poloxamer, povidone (E1201), talc, and lactose. Coating: hypromellose (E464), hydroxypropylcellulose, macrogol and titanium dioxide (E171).

What Azithromycin looks like and contents of the pack

Film-coated tablet.

Azithromycin 250mg Film-coated Tablets are white to off-white oval, 6.7 x 13.5 mm, biconvex film-coated tablets marked "250" on one side and plain on the other side. Azithromycin 500mg Film-coated Tablets are white to off-white oval, 9.7 x 17.9 mm, biconvex film-coated tablets marked "500" on one side and plain on the other side.

250mg tablets are available in a OPA-PVC-Alu/Alu blister of 4 film-coated tablets. 500mg tablets are available in a OPA-PVC-Alu/Alu blister of 3 film-coated tablets.

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Manufacturer

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If you would like a leaflet with larger text, please contact 01271 385257.