

Package leaflet: Information for the user
Azithromycin 500 mg Film-coated tablets

Azithromycin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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- 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 symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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 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

Your medicine belongs to a class of medicines called macrolide antibiotics. It is used to treat a number of infections including:

- upper and lower respiratory tract infections (eg tonsillitis, pharyngitis, sinusitis, bronchitis and pneumonia)
- skin and soft tissue infections (eg abscesses and other infections)
- acute ear infections
- uncomplicated genital infections caused by an organism called *Chlamydia*

2. What you need to know before you take Azithromycin

Do not take Azithromycin

- if you are allergic to azithromycin (the active ingredient in your medicine), erythromycin or to any other macrolide or ketolide antibiotic, or to any of the other ingredients of Azithromycin (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking azithromycin.

Talk to your doctor before you start to take this medicine if you

- have severe kidney problems
- have liver problems: your doctor may need to monitor your liver function or stop the treatment
- Fungal infections may occur
- In rare cases severe allergic reactions may occur

- Medicines known as ergot derivatives e.g. ergotamine or dihydroergotamine (medicines used for migraines or reducing blood flow) should not be taken together with azithromycin
- Care must be taken if you suffer from severe heart problems
- Care must be also taken if you suffer from neurological or psychiatric diseases
- There is the possibility of getting diarrhoea which in some cases can be severe
- In some cases there is the possibility of developing a serious intestinal inflammation known as pseudomembranous colitis
- This medicine shall not be used to treat infected burn wounds
- There are some references to worsening of severe fatigued (a symptom of a disease known as miastenia gravis)

Other medicines and Azithromycin

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

- Your Azithromycin should be taken at least one hour before or two hours after you take your antiacids
- digoxin (for heart problems)
- zidovudine (for HIV). Azithromycin may reduce the blood levels of Zidovudine and should therefore be taken at least 1-2 hours before or after zidovudine
- rifabutin (for HIV or tuberculosis)
- medicines known as ergot derivatives e.g. ergotamine or dihydroergotamine (medicines used for migraines or reducing blood flow) should not be taken together with azithromycin
- warfarin or other medicines to thin your blood
- ciclosporin (a medicine used for skin conditions, rheumatoid arthritis, or following organ transplants)
- terfenadine (an antihistamine)
- theophylline (for breathing problems)
- cisapride (a medicine used to treat gastroesophageal reflux disease)

Azithromycin with food, drink and alcohol

You may take your medicine with or without food as it does not affect the absorption of your tablets.

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

Azithromycin should not be used during pregnancy or breast-feeding unless this has been discussed with your doctor.

Driving and using machines

Azithromycin may make you feel dizzy. If affected, do not drive or operate machinery.

Azithromycin 500 mg film-coated tablets 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.

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.

This medicine should be taken in a single daily dose. The tablets should be swallowed whole and may be taken with or without food. The length of treatment for various infectious diseases is set out below.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

The recommended dose is:

Adults: Respiratory tract and skin or soft tissue infections: 500 mg once daily for three days.
Uncomplicated genital infections: 1000 mg (2 tablets) as a single dose.

Elderly: The usual adult doses may be used

Use in children: For children weighing more than 45kg the usual adult dose may be used

Children and adolescents with a body weight below 45 kg:

Tablets are not indicated for these patients. Other pharmaceutical forms of azithromycin may be used, such as suspensions.

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. .

If you take more Azithromycin than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

It is important to stick to the dose on the label of your medicine. Always take any tablets left over with you and also the box, as this will allow easier identification of the tablets. Symptoms of overdose may include severe nausea, vomiting and diarrhoea and reversible loss of hearing.

If you forget to take Azithromycin

If you forgot to take a dose of your medicine then do not take the missed dose between meals. Wait until your next scheduled dose and meal and continue taking your tablets as per normal Do not take a double dose to make up for a forgotten dose.

If you stop taking Azithromycin

If you stop taking Azithromycin too soon, the infection may return. Take the medicine 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, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them. These are usually mild to moderate, and stop when treatment is stopped.

If you suffer from any of the following side-effects, stop taking your tablets and either tell your doctor IMMEDIATELY or go to your nearest hospital emergency department. You may be experiencing a rare severe allergic reaction to the tablets:

- swelling of the hands, feet, ankles, face, lips, mouth or throat
- problems with swallowing or breathing
- serious skin reactions including Stevens-Johnson Syndrome (a severe skin rash) and other severe skin

rashes which may involve blistering or peeling (these may be severe allergic reactions)

- severe, persistent diarrhea especially if it has blood or mucus in it (this may be Pseudomembranous colitis)

The following side effects have also been reported:

• Very common (affects more than 1 user in 10)
• Common (affects 1 to 10 users in 100)
• Uncommon (affects 1 to 10 users in 1,000):
• Rare (affects 1 to 10 users in 10,000):
• Very rare (affects less than 1 user in 10,000)
• not known - frequency cannot be estimated from available data

Very Common:

- Diarrhoea
- abdominal pain
- Nausea
- intestinal gas (wind)

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Common

- Loss of appetite
- Dizziness
- Headache
- Numbness in the fingers
- Change in the sense of taste
- Problems in sight
- Hearing problems
- Indigestion
- rashes or itching
- Joint pain
- feeling tired or weak
- Changes in blood test levels

Uncommon:

- vaginal infections
- changes to the number of certain types of blood cells
- vaginal infections
- Allergic reactions which may range from skin rash, swollen itchy skin and skin eruptions to difficulty in breathing and dizziness
- Nervousness
- Somnolence
- inability to sleep
- hearing problems, hearing loss or tinnitus (ringing in the ears)
- heart palpitations (a strong or forceful heartbeat)
- Stomach pain
- Constipation
- hepatitis (an inflammation of the liver)
- Severe hypersensitivity reaction with high fever, red spotted skin, joint pain and /or inflammation of the eyes
- increased sensitivity to sunlight and sun beds, or other serious skin reactions

- Chest pain
- Swelling (oedema)
- General sensation of malaise
- feeling tired or weak
- Changes in laboratory tests
- headache, dizziness or fits
- allergic reactions with rashes or itching
- taste disturbances, indigestion, inflammation of the gut, loss of appetite or wind
- joint pain

Rare:

- Restlessness
- vertigo
- liver problems
- allergic reactions

Not known - frequency cannot be estimated from available data

- Severe prolonged diarrhea which may indicate a very rare inflammation of the large intestine
- Reduction in blood cells with bruises and tendency to bleed (thrombocytopenia)
- Anaemia (decrease in red blood cells)
- Severe allergic reactions which may reach shock (drop in blood pressure, weak rapid pulse, clammy skin, reduced consciousness)
- aggressive reaction, anxiety,
- Fainting or fits
- Hyperactivity
- Changes or loss in the sense of taste and smell
- Worsening of the symptoms of myasthenia gravis (muscular weakness and fatigue)
- Heart symptoms with change in the speed of your heart beat
- Decrease of blood pressure
- Inflammation of the pancreas (pancreatitis)
- tongue discoloration
- hepatitis (an inflammation of the liver), jaundice (yellowing of the skin or the whites of the eyes), liver failure and liver damage
- Kidney damage

If you get any side effects, talk to your doctor, pharmacist or nurse . This includes any possible side effects not listed in this leaflet.

5. How to store Azithromycin

Keep this medicine out of the sight and reach of children

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Azithromycin contains

The active substance is azithromycin.

Each film-coated tablet of Azithromycin contains 500 mg of the active substance azithromycin.

The other ingredients are pregelatinised starch, croscopovidone, calcium hydrogen phosphate, anhydrous, sodium laurilsulfate and magnesium stearate. The coating contains hypromellose, titanium dioxide (E171), lactose monohydrate and triacetin.

What Azithromycin look like and contents of pack

White, oblong, biconvex, film coated tablets, scored on one side.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Azithromycin 500 mg film-coated tablets is available in packs of 3 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturer:

Bluepharma Indústria Farmacêutica S.A.

S. Martinho do Bispo

3045-016 COIMBRA

Tel: 351 239 800300

Fax: 351 239 800333

Email: bluepharma@bluepharma.pt

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

This medicinal product is authorised in the Member States of the EEA under the following names:

<[To be completed nationally]>

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