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Package leaflet: Information for the user

Azithromycin 250 mg Capsules

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 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

This medicine contains azithromycin, which is one of a group of antibiotics called macrolides, which block the growth of susceptible bacteria. Azithromycin is taken for the treatment of following infections:

Adults and adolescents weighing 45kg and over

- Infections of the tonsils (tonsillitis), or throat (pharyngitis) caused by streptococcal bacteria
- Bacterial sinus infection (sinusitis)
- Bacterial infections of the middle ear (otitis media)
- Pneumonia (community-acquired pneumonia, not contracted in a hospital)
- Bacterial infections of the skin and underlying tissues
- Early localised Lyme disease (erythema migrans, mainly caused by tick bites)
- Bacterial infections of the gums (periodontitis) or abscess in gums (periodontal abscess)
- Infections of urethra and cervix caused by Chlamydia trachomatis bacteria
- Infections of urethra and cervix caused by Neisseria gonorrhoeae bacteria. Azithromycin should be used in combination with another antibiotic that is selected by your doctor or pharmacist.
- Chronic inflammation of the prostate caused by Chlamydia trachomatis bacteria
- Bacterial infections of genitals with painful sores (chancroid)
- Infections caused by Mycobacterium avium complex (MAC) bacteria in people with advanced HIV infection. Azithromycin should be used in combination with another antibiotic called ethambutol.

Azithromycin is also taken for prevention of infections caused by Mycobacterium avium complex (MAC) bacteria in people living with HIV infection.

Adults:

- Bacterial infections in patients with long-term inflammation of the lungs (chronic bronchitis)
- Bacterial infection of the womb, fallopian tubes and ovaries (pelvic inflammatory disease) always in combination with another antibiotic(s) that is selected by your doctor or pharmacist.

2. What you need to know before you take Azithromycin

Do not take Azithromycin:

- if you are allergic to Azithromycin, Erythromycin any macrolide or ketolide antibiotic or 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 or have had any of the following conditions:

- Kidney problems
- Heart problems(e.g. problems with your heart rhythm or cardiac insufficiency) or low levels of potassium or magnesium in your blood: these conditions may contribute to serious cardiac side effects of azithromycin
- Liver problems: your doctor may need to monitor your liver function or stop the treatment
- severe diarrhoea after administration of any other antibiotics
- 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.
- Localised muscle weakness (myasthenia gravis), as the symptoms of this disease may worsen during treatment
- if you are giving this medicine to an infant (less than 6 weeks of age) and they vomit or become irritable when fed.

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.

Stop taking this medicine and contact your doctor immediately (see also “Serious side effects” in section 4):

- if you feel you are having an allergic reaction (e.g. difficulty in breathing, swelling of the face or throat, rash, blistering).
- if you notice any of the symptoms as described in section 4 related to serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP), which have been reported in association with azithromycin treatment.
- if you feel you have an abnormal heartbeat or palpitations, get dizzy or faint when taking Azithromycin.
- if you develop signs of liver problems (e.g. dark urine, loss of appetite or yellowing of the skin or whites of the eyes).
- if you develop severe diarrhoea during or after treatment. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues or reappears within the first weeks after treatment, please also inform your doctor.

Superinfection

Your doctor may observe you for signs of additional bacterial or fungal infections that cannot be treated with Azithromycin (superinfection).

Sexually transmitted infections

Your doctor may test for and exclude a potential infection with syphilis, a sexually transmitted disease that may otherwise progress undetected and be diagnosed delayed. Furthermore, in any case of sexually transmitted bacterial infections your doctor will initiate laboratory follow-up tests to monitor the success of therapy.

Children and adolescents

This medicinal product is not recommended if:

- You are less than 18 years old and have been diagnosed with pelvic inflammatory disease
- You are less than 12 years old and you are infected or at risk of being infected with organisms that belong to the Mycobacterium avium complex which usually affect people living with HIV who have low defences as its efficacy and safety have not been studied in these cases.

If you weigh less than 45 kg, other medicinal products containing azithromycin exist that may be more convenient for you to take.

Other medicines and Azithromycin

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

Taking Azithromycin at the same time as some other medicines may result in side effects. Therefore, it is particularly important that you tell your doctor if you are using any of the following medicines:

- Atorvastatin and other medicines from the statins group (to lower blood cholesterol and prevent heart disease, including heart attacks and strokes)
- Ciclosporin (to prevent rejection of organ transplants by the body)
- Colchicine (to treat gout and familial Mediterranean fever)
- Dabigatran (to prevent and treat blood clot formation (anticoagulant))
- Digoxin (to treat heart diseases)
- Warfarin or similar medicines used to thin the blood (anticoagulants)
- Medicines that may cause the heart muscle to take longer to contract and relax than usual (QT prolongation), such as the following:
 - Quinidine, procainamide, dofetilide, amiodarone and sotalol (to treat an irregular heartbeat, including a too fast or too slow heartbeat - cardiac arrhythmia)
 - Pimozide (to treat mental illness)
 - Citalopram (to treat depression)
 - Moxifloxacin and levofloxacin (antibiotics)
 - Cisapride (to treat disorders in the gastrointestinal tract)
 - Hydroxychloroquine or chloroquine (to treat autoimmune diseases including rheumatoid arthritis, or to treat or prevent malaria)

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.

Pregnancy

Your doctor will decide if you should take this medicine during pregnancy, only after making sure that the benefits outweigh the potential risks.

Breast-feeding

Azithromycin passes into breast milk. Your doctor will decide therefore whether you should stop breast-feeding or should avoid treatment with azithromycin taking into account both the benefit of breast-feeding for your child and the benefit of therapy for you.

Driving and using machines

Azithromycin has a moderate influence on the ability to drive and use machines. Azithromycin has been reported to cause dizziness, drowsiness and seizures, as well as problems with seeing and hearing in some people. These possible side effects may have an influence on your ability to drive and use machines. .

Important information about some of the ingredients of this medicine

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 Azithromycin 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 amount of Azithromycin that you need to take each day depends on the bacterial infection that you are being treated for and the specific treatment course that your doctor or pharmacist has instructed you to follow.

Adults and adolescents weighing at least 45 kg

| Infection | Treatment course with azithromycin |
|--|--|
| Infections of the tonsils (tonsillitis) or throat (pharyngitis) caused by streptococcal bacteria | There is a 3-day or a 5-day treatment course for these infections, and the amount of Azithromycin to take each day is described for these treatment courses below; |
| Bacterial sinus infections (sinusitis) | <i>3-day treatment course</i> 500 mg taken once daily for 3 days. |
| Bacterial infections of the middle ear (otitis media) | <i>5-day treatment course</i> 500 mg taken on the first day of treatment and then 250mg taken once daily for the following 4 days. |
| Bacterial infections in patients with long-term inflammation of the lungs (chronic bronchitis)* | |
| Pneumonia (community acquired pneumonia, not contracted in a hospital)# | |
| Bacterial infections of the skin and underlying tissues | |
| Bacterial infections of the gums (periodontitis) or abscess in gums (periodontal abscess) | |
| Early localised Lyme disease (erythema migrans, mainly caused by tick bites) | 1000 mg taken on the first day of treatment and then 500 mg taken once daily for the following 9 days. |
| Infections of urethra and cervix caused by <i>Chlamydia trachomatis</i> bacteria | 1000 mg taken as a single dose |
| Infections of urethra and cervix caused by <i>Neisseria gonorrhoeae</i> bacteria. Azithromycin should be used in combination with another antibiotic that is selected by your doctor or pharmacist. | 1000 mg or 2000 mg* taken as a single dose |
| Bacterial infection of thewomb, fallopian tubes and ovaries (pelvic inflammatory disease). Azithromycin should be used in combination with another antibiotic that is selected by your doctor or pharmacist* | Only if treatment has been started with intravenous azithromycin: 250 mg once daily to complete a 7day course of treatment |
| Chronic inflammation of the prostate caused by <i>Chlamydia trachomatis</i> bacteria | 500 mg/day taken on 3 consecutive days per week for a total of 3 weeks |
| Bacterial infections of genitals with painful sores (chancroid) | 1000 mg taken as a single dose |
| Infections caused by Mycobacterium avium complex (MAC) bacteria in people with advanced HIV infection. Azithromycin should be used in combination with another antibiotic called ethambutol. | <500 mg> or <600 mg> once per day |
| Prevention of infections caused by Mycobacterium avium complex (MAC) bacteria in people living with HIV infection | <1200 mg> or <1250 mg> once per week |
| *only for adult patients #for adult patients oral treatment may follow an initial intravenous treatment | |

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Use in children and adolescents

If your weight is less than 45 kg < or you are not able to swallow this medicinal product, ask your doctor or pharmacist as other medicinal products containing azithromycin are also available that may be more appropriate for you.

Use in people with kidney or liver problems

Please talk to your doctor first if you have liver or kidney problems. Your doctor will then decide if the dose needs to be adjusted.

Use in the elderly

No dose adjustment is needed. You should receive the dose of azithromycin as shown in the table above. However, you should talk to your doctor or pharmacist if you have heart problems (see section 2. What you need to know before you take Azithromycin).

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.

Method of Administration

Hard capsules

For oral use.

Azithromycin should be taken by mouth as a single daily dose. Capsules should be swallowed whole with some water. The capsules should be taken at least one hour before or two hours after a meal.

If you take more Azithromycin than you should

If you take more Azithromycin than you should then you may feel unwell. Typical signs of an overdose are vomiting, diarrhoea, abdominal pain and nausea. Tell your doctor or contact your nearest hospital emergency department immediately.

If you forget to take Azithromycin

If you forget to take Azithromycin take it as soon as you can, as long as this is at least 12 hours before the next dose is due. If it is less than 12 hours left to your next dose, skip the missed dose and take your next dose at the usual time. 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 Azithromycin 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, this medicine can cause side effects, although not everybody gets them.

Serious side effects: Stop using Azithromycin and seek medical attention immediately if you notice any of the following symptoms:

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching especially affecting the whole body(anaphylactic reaction, frequency not known)
- 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 (cardiac arrhythmia or torsades de pointes tachycardia, frequency not known)
- low blood pressure
- dark urine, loss of appetite or yellowing of the skin or whites of the eyes, which are signs of liver disorders (hepatic failure or hepatic necrosis (frequency not known), hepatitis* (uncommon: may affect up to 1 in 100 people)).
- severe diarrhoea with abdominal cramps, bloody stools and/or fever may mean that you have an infection of the large intestine (antibiotic-associated colitis, frequency not known). Do not take medicines against diarrhoea that inhibit the bowel movements (antiperistaltics).
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome(SJS)* or toxic epidermal necrolysis(TEN), frequency not known).
- small widespread rash, itchy red bumps, high body temperature, an increase of eosinophils (a type of white blood cell)and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms-*DRESS syndrome* or *drug hypersensitivity syndrome*, rare (may affect up to 1 in 1,000 people)).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (*acute generalised exanthematous pustulosis*, rare (may effect up to 1 in 1,000 people)).

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.

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

- stomach cramps
- diarrhoea, wind
- abdominal discomfort*

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

- dizziness, headache
- numbness or pins and needles
- being sick(vomiting), indigestion, stomach pain*
- feeling sick(nausea)*
- loss of appetite, taste disturbance
- visual disturbances, deafness
- skin rash and /or itching
- joint pain
- Changes in blood test results (lymphocytes count decreased(type of white blood cells), eosinophil count decreased (type of white blood cells), basophil count increased, monocyte count increased, neutrophil count increased, blood bicarbonate decreased
- blood bicarbonate decreased
- tiredness or weakness
- changes in the number of white blood cells

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

- thrush (candidiasis) - a fungal infection of the mouth and vagina, other fungal infections, changes in white blood cells (leukopenia, neutropenia, eosinophilia, platelet count increased, haematocrit decreased)
- pneumonia, bacterial infection of the throat, inflammation of the gastrointestinal tract, respiratory disorder, inflammation of the mucous membrane inside the nose, vaginal infection
- allergic reactions, swelling of the hands, feet and face (angiooedema)
- blistering of the skin, mouth, eyes and genitals
- skin more sensitive to sunlight than normal
- spinning sensation (vertigo),
- nervousness, difficulty sleeping (insomnia)
- lack of appetite*
- reduced sense of touch or sensation (hypoesthesia)
- feeling dizzy*, feeling drowsy (somnia), change in your sense of taste (dysgeusia)*, sensation of pins and needles or numbness (paraesthesia)*
- impaired vision*
- sleepiness or sleeplessness (insomnia)
- ear disorder
- feeling your heartbeat (palpitations), chest pain
- hot flush
- sudden wheeziness, bleeding from the nose
- constipation, wind* , stomach pain associated with diarrhoea and fever, impaired digestion (dyspepsia), inflammation of the lining of the stomach (gastritis), difficulty in swallowing (dysphagia), swollen belly, dry mouth, belching (eructation), mouth ulceration, increased salivation
- rash* , itching* , hives (urticaria), dermatitis, dry skin, abnormally increased sweating (hyperhidrosis)

- swelling and pain in the joints (osteoarthritis), muscle pain, back pain, neck pain
- painful urination (dysuria), kidney pain
- inflammation of the liver (hepatitis), changes in liver enzymes
- menstrual bleeding at irregular intervals (metrorrhagia), testicular disorder
- general feeling of being unwell, weakness, tiredness*
- swelling due to fluid retention, especially of the face, ankles and feet (oedema, face oedema, peripheral oedema)
- general discomfort
- chest pain, pain
- post procedural complication
- abnormal laboratory test results (e.g. blood or liver tests).

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

- feeling irritated
- increased sensitivity to sunlight*
- Liver problems, yellowing of the skin or eyes

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

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

- fits (seizures)
- fainting (syncope)
- hallucination
- aggressive, feeling angry, feeling of fear and concern (anxiety), acute confusional state (delirium)
- feeling hyperactive
- localised muscle weakness (myasthenia gravis)
- loss of smell or change in your sense of smell (anosmia, parosmia),
- loss of taste (ageusia)
- Your tongue changes colour (tongue discolouration)
- inflammation of the pancreas causing severe pain in the belly and back (pancreatitis)
- inflammation of the kidney (*interstitial nephritis*) and kidney failure
- yellowing of the skin or eyes (jaundice) or liver failure (rarely life-threatening)
- reduction in number of platelets which can lead to bruising or prolonged bleeding after injury (thrombocytopenia)
- blistering of the skin, severe skin reaction
- abnormal electrocardiogram (ECG) heart tracing (QT prolongation)
- reduced number of red blood cells due to increased cell breakdown which can cause tiredness, breathlessness and pale skin (haemolytic anaemia)
- deafness* , reduced hearing* or ringing in your ears (tinnitus)*
- low blood pressure
- joint pain (arthralgia)*
- reduced sensation to touch, pain and temperature (hypoesthesia)*

* These side effects were only seen during azithromycin administration for the prophylaxis and/or therapy of Mycobacterium avium complex infections in people living with HIV with insufficient recovery of the immune system.

These side effects were more common during azithromycin administration for the prophylaxis and/or therapy of Mycobacterium avium complex infections in people living with HIV with insufficient recovery of the immune system.

Reporting of side effects

If you get any side effects, talk to your doctor or 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. Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azithromycin

Keep all medicines out of the sight and reach of children. Do not store above 30°C.

Do not take 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.

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 (250 mg).

The other ingredients (excipients) are: lactose, magnesium stearate, maize starch, sodium lauryl sulphate.

The capsule shells contain: gelatin, titanium dioxide, shellac (E904).

Printing ink on capsule contains: propylene glycol (E1520), black iron oxide, potassium hydroxide.

What Azithromycin looks like and contents of the pack

Azithromycin capsules are white marked SOMEX and 250. They come in blister packs of 2, 4 or 6 capsules

Not all pack sizes may be marketed

Marketing Authorisation Holder

Strandhaven Limited t/a Somex Pharma, Ilford, Essex, IG3 8BS, UK.

Manufacturer

Strandhaven Limited t/a Somex Pharma, Ilford, Essex, IG3 8RA, UK.

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

Azithromycin 250 mg Capsules.

Other sources of information:

To request a copy of this leaflet in braille or large print please call, 020 8590 9399 (UK Only).

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