

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Azithromycin 250 mg Capsules

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Azithromycin 250 mg capsules are and what they are used for

Azithromycin is one of the group of 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)
- Ear infections
- Sexually transmitted diseases caused by an organism called *Chlamydia*.

2 Before you take Azithromycin 250 mg capsules

Do not take Azithromycin Capsules

- If you are allergic (hypersensitive) to azithromycin or to any other macrolide or ketolide antibiotics (e.g. clarithromycin, erythromycin, telithromycin), or to any of the other ingredients of Azithromycin Capsules
- If you are taking any of the medicines listed under 'Taking other medicines; Do not take'.

Take special care with Azithromycin Capsules

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

- have heart problems
- are taking cisapride or terfenadine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor or pharmacist if you are taking:

- Antacids. Your Azithromycin Capsules should be taken at least one hour before or two hours after you take your antacids.
- Cyclosporin (a medicine used for skin conditions, rheumatoid arthritis, or following organ transplants)
- Digoxin (for heart problems)
- Ergot derivatives e.g. ergotamine or dihydroergotamine (medicines used for migraines or reducing blood flow)
- Rifabutin (for HIV or tuberculosis)
- Theophylline (for breathing problems)
- Warfarin or other medicines to thin your blood
- 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.

Taking Azithromycin Capsules with food and drink

Your medicine should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, may be pregnant or are breast-feeding. Azithromycin Capsules should not be used during pregnancy or breast-feeding unless this has been discussed with your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Azithromycin Capsules

This medicine contains sulphur dioxide (E220) which may rarely cause severe allergic reactions and cause difficulty in breathing.

3 How to take Azithromycin 250 mg capsules

Always take Azithromycin Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

Respiratory tract and skin or soft tissue infections: 500 mg (two capsules) once daily for three days.

Sexually transmitted diseases: 1000 mg (four capsules) as a single dose.

Elderly

The usual adult doses may be used.

Children

Azithromycin Capsules are not recommended for use in children weighing less than 45kg. For children weighing more than 45kg the usual adult dose may be used.

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.

It is very important that you follow your doctor's instructions as to the dosage of Azithromycin Capsules and for how long you should continue to take your capsules. Keep taking then for as long as your doctor tells you.

If you take more capsules than you should

It is important to stick to the dose on the label of your medicine. If you or someone else swallows several of these capsules all together, or you think a child has swallowed any of these capsules, contact your doctor, pharmacist or hospital emergency department immediately. Always take any capsules left over with you and also the box, as this will allow easier identification of the capsules. Symptoms of overdose may include severe nausea, vomiting and diarrhoea and reversible loss of hearing.

If you forget to take your capsules

Do not take a double dose to make up for a forgotten dose. If a dose is forgotten, it

should be taken as soon as it is remembered. However, if it is nearly time for the next doses, miss the forgotten dose altogether and continue with the rest of the medicine as normal.

If you stop taking your capsules

Even when you start to feel better it is important for you to keep on taking your capsules for as long as your doctor tells you.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side-effects

Like all medicines, Azithromycin Capsules 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 capsules 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 capsules:

- 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 diarrhoea especially if it has blood or mucus in it (this may be Pseudomembranous colitis).

Very common side-effects (affecting more than 1 in 10 people):

- Diarrhoea, abdominal pain, feeling sick, flatulence.

Common side-effects (affecting less than 1 in 10 people):

- Loss of appetite
- Dizziness, headache, pins and needles, taste disturbance
- Visual impairment
- Deafness
- Vomiting, indigestion
- Rash, itching
- Joint pain
- Tiredness
- Reduction in the number of white blood cells in the blood, identified by blood tests, which can make you more susceptible to infections, such as mouth ulcers and sore throat
- Change to the acidity of the blood, identified by blood tests.

Uncommon side-effects (affecting less than 1 to 100 people):

- Thrush, a fungal infection, infection of the mouth, vaginal infection
- Nervousness
- Reduced sense of touch, sleepiness,

inability to sleep

- Hearing impaired, ringing in the ears
- Awareness of your heartbeat, which may be faster than usual
- Inflammation of the stomach, constipation
- Inflammation of the liver
- Hives
- Chest pain, swelling, general feeling of being unwell, muscle weakness
- Change in liver enzymes (shown by blood tests)
- Change in levels of certain chemicals in the blood (shown by blood tests).

Rare side-effects (affecting less than 1 to 1000 people):

- Agitation
- Dizziness
- Abnormal liver function.

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

- Reduction in the number of red blood cells in the blood, which may cause you to bruise more easily
- Aggression, anxiety
- Fainting, fits, hyperactivity, lack of smell, loss of taste, disturbance of ability to smell
- Muscle weakness and tiredness (symptoms of a condition called myasthenia gravis)
- Heart problems, such as a fast heart beat, or a life-threatening irregular heart beat

- Inflammation of the pancreas, tongue discolouration
- Liver failure and other liver problems, yellowing of the skin and eyes
- Acute kidney failure, and other kidney problems

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Azithromycin 250 mg capsules

Do not store above 25°C.

Store your capsules in the original package. **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**

Do not use this medicine after the 'Expiry' date on the carton. The expiry date refers to the last day of that month. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. If you have any capsules that are out of date, return them to your pharmacist for disposal.

6 Further information

What Azithromycin Capsules contain

The active substance is azithromycin. Other ingredients are cellulose microcrystalline, sodium lauryl sulphate and magnesium stearate. The capsule is made of gelatin, sulphur dioxide (E220) and the colouring agents titanium dioxide (E171), FD & C Blue 2 (E132) and indigo carmine (E132).

What Azithromycin Capsules look like and contents of pack

These are light and dark blue capsules. Each capsule contains 250 mg of the active substance azithromycin (as azithromycin dihydrate).

Azithromycin 250 mg Capsules are available in packs of 2, 4, 6 or 100 capsules, although not all pack sizes may be marketed.

Marketing Authorisation Holder

TEVA UK Limited, Eastbourne, BN22 9AG.
Manufacturer
Pliva Hrvatska d.o.o. (Pliva Croatia Ltd.),
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