

PATIENT INFORMATION LEAFLET (PIL)

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 is one of a group of antibiotics known as macrolides. It is used to treat bacterial infections caused by microorganisms such as bacteria.

These infections include:

- Chest infections such as bronchitis and pneumonia
- Infections in your sinuses, throat, tonsils or ears
 - Mild to moderate skin and soft tissue infections, e.g. infection of the hair follicles (folliculitis), bacterial infection of the skin and its deeper layers (cellulitis), skin infection with shiny red swelling (erysipelas)
- Infections caused by a bacterium called Chlamydia trachomatis. They can cause inflammation of the tube that carries urine from your bladder (urethra) or where your womb joins your vagina (cervix).

2. What you need to know before you take Azithromycin

Do not take Azithromycin:

- if you are allergic to azithromycin, any other macrolide (such as erythromycin or clarithromycin) or ketolide antibiotic or any of the ingredients of 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 ever had a serious allergic reaction causing swelling of the face and throat, possibly with breathing problems, rash, fever, swollen glands or increase in eosinophils (certain type of white blood cells).

- have severe kidney problems: your doctor may alter the dose
- have liver problems: your doctor may need to monitor your liver function or stop the treatment
- have myasthenia gravis (localised muscle weakness)
- have been diagnosed with a neurological disease, which is a disease of the brain or nervous system
- have mental, emotional or behavioural problems
- are taking medicines known as ergot alkaloids (such as ergotamine), which are used to treat migraine: azithromycin is not recommended (see 'Other medicines and Azithromycin' below)

Since azithromycin may increase the risk of abnormal heart rhythm please tell your doctor if you have any of the following problems before taking this medicine (especially you are female or elderly):

- you are aware of ever being diagnosed to have prolonged QT interval (a heart condition, shown on an electro-cardiogram or ECG machine): azithromycin is not recommended
- are aware that you have a slow or irregular heart beat, or reduced heart function (heart failure): azithromycin is not recommended
- know that you have low levels of potassium or magnesium in your blood: azithromycin is not recommended
- are taking medicines known as antiarrhythmics (e.g. quinidine, procainamide, dofetilide, amiodarone, sotalol: used to treat abnormal heart rhythms), cisapride (used to treat stomach problems) or terfenadine (an antihistamine that is used to treat allergies), or antipsychotic agents (e.g. pimozide), antidepressants (e.g. citalopram), some antibiotics (e.g. moxifloxacin, levofloxacin) that can affect the heart rhythm: azithromycin is not recommended (see 'Other medicines and Azithromycin' below)

If you develop severe and persistent diarrhoea during or after treatment, especially if you notice blood or mucus, tell your doctor immediately.

If your symptoms persist after the end of your treatment with azithromycin, or if you notice any new and persistent symptoms, contact your doctor.

Other medicines and Azithromycin

Tell your doctor before taking Azithromycin, if you are taking any of the medicines listed below:

- Warfarin or any similar medicine to prevent blood clots: concomitant use can increase the risk of bleeding.
- Ergotamine, dihydroergotamine (used to treat migraine): ergotism (ie. itching in the limbs,

muscle cramps and gangrene of hands and feet due to poor blood circulation) may occur. Concomitant use is therefore not recommended.

- Cyclosporin (used to suppress the immune system to prevent and treat rejection of an organ or bone marrow transplant): if concomitant use is required, your doctor will check your blood levels regularly and may adapt the dose.
- Digoxin (for heart failure): digoxin levels may increase. Your doctor will check your blood levels.
- Colchicine (used for gout and familial Mediterranean fever).
- Antacids (for indigestion): Azithromycin should be taken at least 1 hour before or 2 hours after the antacid
- Cisapride (for stomach problems), terfenadine (used to treat hay fever): concomitant use with azithromycin may cause heart disorders.
- Medicines for irregular heart beat (called anti-arrhythmics), or to lower cholesterol (called statins) such as atorvastatin.
- Alfentanil (used for narcosis) or astemizole (used to treat hay fever): concomitant use with azithromycin may increase the effect of these medicinal products.

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

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 : There is insufficient information regarding the safety of azithromycin during pregnancy. Consequently, Azithromycin is not recommended if you are pregnant or planning to become pregnant. However, your doctor may prescribe it under serious circumstances.

Breast-feeding : Azithromycin is excreted in human milk, therefore you should not breast-feed whilst you are taking Azithromycin, because it may cause side effects including diarrhoea and infection in your baby. It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. You may resume nursing two days after stopping your treatment with Azithromycin.

Driving and using machines : Azithromycin may cause dizziness and fits. If affected, do not drive or operate machinery.

Azithromycin contains soya oil : If you are allergic to peanut or soya, do not use this medicinal product (see also section above 'Do not take Azithromycin').

Azithromycin contains sodium : This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodiumfree'.

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.

Azithromycin tablets should be given as a single daily dose. The tablets should be swallowed preferably with a drink of water, and can be taken with or without food. Azithromycin 500mg: The tablet can be divided into equal doses.

The recommended dose is:

Adults (including older patients), children and adolescents with a body weight of over 45 kg: The recommended dose is 1500 mg divided over either 3 or 5 days as follows:

- When taken over 3 days, 500 mg once daily.
- When taken over 5 days, 500 mg as a single dose on the first day and then 250 mg once daily on days 2 through to 5.

Inflammation of the urethra or cervix caused by Chlamydia: 1000 mg taken as a single dose, for one day only.

For infections in your sinuses, treatment is indicated for adults and adolescents 16 years of age and over.

Children and adolescents with a body weight of 45 kg and under: Tablets are not indicated for these patients. Other pharmaceutical forms of azithromycin-containing products (e.g. suspensions) 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.

If you take more Azithromycin than you should

If you (or someone else) swallow a lot of the tablets altogether, or if you think a child has swallowed any of the tablets, contact your doctor or pharmacist immediately. An overdose is likely to cause reversible hearing loss, severe nausea (feeling sick), vomiting and diarrhoea.

Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Azithromycin

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Azithromycin

Do not stop taking your medicine without talking to your doctor first even if you feel better. It is very important that you keep taking Azithromycin for as long as your doctor has told you to; otherwise the infection may come back.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

- A severe skin reaction causing blisters/bleeding of the lips, eyes, nose, mouth and genitals (Stevens-Johnson syndrome).
- yellowing of the skin and whites of the eyes, tiredness and loss of appetite which may be caused by inflammation of the liver (hepatitis).

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

- yellowing of the skin or eyes (jaundice).
- 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).

Very rare (may affect up to 1 in 10,000 people):

- skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell).

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

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).
- severe peeling of the skin or an itchy rash with pink-red rings around a pale centre (toxic epidermal necrolysis, erythema multiforme).
- disturbances in heart rhythm called QT prolongation (delayed conduction of electrical signals which can be seen on an ECG, an electrical recording of the heart). In some people this can develop into a potentially serious heart condition known as Torsades de pointes. This can result in a very fast heartbeat causing a sudden loss of consciousness.
- an irregular heart beat.
- feeling weak and breathless with yellowing of the skin which may be due to a reduced number of red blood cells due to destruction (haemolytic anaemia).
- prolonged diarrhoea with blood and mucus. • stomach pain that moves to the back with feeling and being sick which may be caused by inflammation of the pancreas (pancreatitis).
- pain in the middle of the back and problems passing water, inflammation of the kidney or kidney failure.

- pain in the upper right of the stomach with feeling and being sick, swelling of the stomach, yellowing of the skin and eyes which may be due to liver failure (rarely life-threatening).
- fits.

These are very serious side effects. You may need urgent medical attention or hospitalization. The following side effects have been reported:

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

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

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

- headache
- dizziness, feeling drowsy (somnolence), taste disturbance, numbness or pins and needles (paraesthesia).
- visual disturbances.
- deafness.
- being sick.
- indigestion
- skin rash.
- itching.
- joint pain (arthralgia).
- tiredness.
- changes in white blood cell count in blood tests.
- low blood bicarbonate.

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

- reduced sense of touch or sensation (hypoesthesia).
- changes in liver function.
- skin more sensitive to light than normal.
- yeast infections of the mouth and vagina (thrush), vaginal infections, fungal infections,

bacterial infections, inflammation of the throat, inflammation of the stomach and intestine, breathing difficulties, runny or blocked nose.

- allergic reactions of various severity.
- loss of appetite.
- feeling nervous.
- sleeplessness (insomnia).
- ear disorder, vertigo.
- hearing impairment including hearing loss.
- tinnitus (ringing in your ears).
- heart palpitations.
- hot flushes.
- recurring frequent infections with fever, chills, sore throat, mouth ulcers, which may be caused by a decrease in the number of white cells in the blood.
- serious lung infection with symptoms such as fever, chills, shortness of breath, cough and phlegm (pneumonia).
- general swelling.
- nose bleeds.
- constipation, , inflammation of the lining of the stomach (gastritis), difficulty swallowing, feeling bloated, dry mouth, belching, mouth ulceration, saliva increased.
- , hives, inflammation of the skin (dermatitis), dry skin, increased sweating.
- bone and joint pain, muscle pain, back pain, neck pain.
- pain when passing urine, kidney pain. • abnormal or unexpected bleeding from the vagina.
- problems with your testicles
- general loss of strength, generally feeling unwell, , swelling of the face, chest pain, fever, pain, swelling of the lower limbs.
- abnormal laboratory test values (e.g. blood or liver tests).
- post procedural complication.
- shortness of breath.

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

- agitation
- irritability.

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

- blood taking longer to clot and bruising more easily which may be due to a reduction in number of platelets (thrombocytopenia),
- aggression, anxiety, severe confusion (delirium), seeing, feeling or hearing things that are not there (hallucination)
- fainting, feeling hyperactive, loss of smell or altered sense of smell, loss of taste.
- muscle weakness or worsening of muscle weakness (myasthenia gravis).
- low blood pressure.
- tongue discolouration.
- tooth discolouration.

The following side effects have been reported in prophylactic treatment against Mycobacterium Avium complex (MAC):

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

- diarrhoea. • abdominal pain.
- feeling sick.
- wind.
- abdominal discomfort.
- loose stools.

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

- loss of appetite.
- dizziness.
- headache.
- numbness or pins and needles (paraesthesia).
- taste disturbance.

- visual disturbances.
- deafness.
- skin rash and/or itching.
- joint pain.
- tiredness.

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

- reduced sense of touch or sensation (hypoesthesia).
- poor hearing or ringing in the ears.
- heart palpitations.
- skin more sensitive to sunlight than normal.
- general loss of strength.
- generally feeling unwell.

5. How to store Azithromycin

Keep this medicine out of the sight and reach of children.

Store below 30°C. Do not use this medicine after the expiry date which is stated on the carton and blister 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 protect the environment.

6. Contents of the pack and other information

What Azithromycin 500mg film-coated tablets contain:

The **active substance** in Azithromycin film-coated tablets is Azithromycin as Azithromycin dihydrate. Each film-coated tablet contains 500mg Azithromycin .

The other ingredients are:

Tablet core

Maize Starch , Purified water , Colloidal silicon dioxide , Purified talc , Microcrystalline cellulose pH 112, Sodium lauryl sulphate, Sodium starch glycollate ,Magnesium stearate

Film coat

Opardy Orange , Isopropyl alcohol , Methylene chloride.

What Azithromycin 500mg film-coated tablets look like and contents of the pack

An Orange coloured capsule shaped film coated tablet plain on both sides of the tablet .

Azithromycin is supplied in the pack of:

10 tablets in Alu-PVC blister pack, such 1 blister are packed in a printed carton along with pack insert.

Marketing Authorisation Holder

M/S. TIL HEALTHCARE PVT LTD

Plot No: 100 West, R 5, South, Sri City, SEZ,
Cherivi Village, Irrugulam Post, Satyavedu Mandal,
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