**PACKAGE LEAFLET**

**Package Leaflet: Information for the patient**

**Azromax 250mg Film-coated Tablets**
azithromycin

**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 Azromax is and what it is used for

Azromax 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 Azromax

**Do not take Azromax:**
- 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 Azromax 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 Azromax' 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): Azromax is not recommended
- are aware that you have a slow or irregular heartbeat, or reduced heart function (heart failure): Azromax is not recommended
- know that you have low levels of potassium or magnesium in your blood: Azromax 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: Azromax is not recommended (see 'Other medicines and Azromax 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 Azromax, or if you notice any new and persistent symptoms, contact your doctor.

**Other medicines and Azromax**

Tell your doctor **before** taking Azromax, 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.
- Ciclosporin (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**): Azromax 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-arrythmics**), 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.

You should not use this medicine during pregnancy unless your doctor has specifically recommended it.

This medicine passes into human milk. You should talk to your doctor before taking this medicine if you are breast-feeding.

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

**Azromax contains lactose**
). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**Azromax contains sodium.**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take Azromax

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

Azromax 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.

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 Azromax 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 Azromax**
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 Azromax**
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 Azromax 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 hospitalisation.

**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 (hypoaesthesia)
- 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 (hypoaesthesia)
- poor hearing or ringing in the ears
- heart palpitations
- skin more sensitive to sunlight than normal
- general loss of strength
- generally feeling unwell

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 HPRA Pharmacovigilance website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Azromax

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

This medicinal product does not require any special storage conditions. Do not transfer the tablets to another container. 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. Content of the pack and other information

**What Azromax film-coated tablet contains**

- The active substance is azithromycin.
  Each tablet contains 250 mg of the active ingredient azithromycin (as azithromycin dihydrate).
- The other ingredients (excipients) are: microcrystalline cellulose (E460), pregelatinised maize starch, sodium starch glycolate (Type A), anhydrous colloidal silica (E551), sodium lauryl sulphate, magnesium stearate (E470b). Tablet Film-coating ingredients are: hypromellose, lactose monohydrate, titanium dioxide (E171) and macrogol..

**What Azromax Film-coated tablets looks like and contents of the pack**
Azromax 250 mg tablets are white to off-white, oblong film-coated tablets and plain on both sides.
The 250 mg tablets are available in pack sizes of 4, 6, 12, 24, 50 or 100 tablets in blister strips.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

**Manufacturer**
McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
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**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

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|---|---|
| Czech Republic ‘ | Azitromycin Mylan 500 mg potahovane tablety |
| Denmark | Azithromycin Mylan |
| Ireland | Azromax 250 mg Film-coated Tablets |
| Italy | Azitromicina Mylan |
| The Netherlands | Azitromycine Mylan 250 mg & 500mg filmomhulde tabletten |
| Portugal | Azitromicina Mylan |
| Slovakia | Azitromycin Mylan 500 mg |
| Sweden | Azithromycin Mylan 250 mg & 500 mg filmdragerad tablett |
| United Kingdom (Northern Ireland) | Azithromycin 250 mg & 500 mg Film-Coated Tablets |

**This leaflet was last revised in March 2022.**