Package leaflet: Information for the patient

Azithran 500 mg film coated tablet

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 Azithran is and what it is used for

This medicine contains azithromycin, which is one of a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other micro-organisms, which include:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- ear infections
- skin and soft tissue infections (such as an abscess or boil)
- sexually transmitted diseases caused by organisms called *Chlamydia trachomatis* and *Neisseria gonorrhoea*.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Azithran

Do not take Azithran :

• if you are allergic to azithromycin or any other macrolide antibiotic such as erythromycin or clarithromycin 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 Azithran if you have or have had any of the following conditions:

• kidney problems
• heart conditions
• liver problems: your doctor may need to monitor your liver function or stop the treatment
• myasthenia gravis (a condition that causes certain muscles to become weak)
• or if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with Azithran .

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 Azithran .

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.

Other medicines and Azithran

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

In particular, Azithran may interact with the medicines listed below:

• ergot or ergotamine – see 'Warnings and precautions' section
• warfarin or any similar medicine to prevent blood clots
• ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
• antacids (for indigestion)
• digoxin (used to treat heart failure)
• colchicine (used for gout and familial Mediterranean fever)
• terfenadine (for hay fever or a skin allergy).

Azithran with food and drink
You should take Azithran either 1 hour before a meal or 2 hours after a meal.

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.

Driving and using machines
Azithran is not expected to affect your ability to drive or use machines.

Azithran contain lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

Azithran contain sulfur dioxide, which may rarely cause severe allergic (hypersensitivity) reactions and wheezing (bronchospasm).

3. How to take Azithran

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

The tablets should be swallowed whole.

The recommended dose in adults and children over 45 kg is 500 mg) taken together, once a day, for 3 days. For some diseases such as Chlamydia the recommended dose is 1 g (2tablets) taken all together on one day only. For gonorrhoea the recommended dose is 1 g or 2 g of azithromycin in combination with 250 or 500 mg of ceftriaxone.

Azithran should not be taken by children weighing less than 45 kg.

You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

Doctors sometimes prescribe different doses to the recommended dose. 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.

If you take more Azithran than you should
If you take too much Azithran you may feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately.

If you forget to take Azithran
If you forget to take Azithran take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Azithran
If you stop taking Azithran 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 about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with Azithran as this may be a sign of serious bowel inflammation
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat low blood pressure
- Serious skin reactions:
  - blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome (SJS))
  - blistering of the skin, severe skin reaction (Toxic Epidermal Necrosis (TEN))
  - skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell). A rash appears as small, itchy red bumps (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
  - 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) (Acute Generalized Exanthematous Pustulosis (AGEP)).

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

The most common side effects that occur when taking Azithran 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: may affect more than 1 in 10 people

- stomach cramps, feeling sick, diarrhoea, wind

Common: may affect up to 1 in 10 people

- dizziness, headache
- numbness or pins and needles
- being sick, indigestion
- loss of appetite, taste disturbance
- visual disturbances, deafness
- skin rash and /or itching
- joint pain
- low numbers of lymphocytes (a type of white blood cell), higher number of eosinophils (a type of white blood cell)
- low blood bicarbonate
- tiredness or weakness

Uncommon: may affect up to 1 in 100 people

- yeast infections of the mouth and vagina (thrush)
- low numbers of leukocytes (a type of white blood cell), low number of neutrophils (a type of white blood cell)
- allergic reactions of various severity
- skin more sensitive to sunlight than normal
- feeling nervous
- reduced sense of touch or sensation (hypoesthesia)
- sleepiness or sleeplessness (insomnia)
- poor hearing or ringing in the ears
- heart palpitations, chest pain
- constipation, stomach pain associated with diarrhoea and fever
- inflammation of the liver (hepatitis), changes in liver enzymes
- general loss of strength
- swelling
- general discomfort
- abnormal laboratory test values (e.g. blood or liver tests).

Rare: may affect up to 1 in 1,000 people
- agitation
- vertigo
- changes in liver function

Not known: frequency cannot be estimated from the available data
- fits or fainting
- aggression or anxiety
- feeling hyperactive
- localised muscle weakness
- loss of smell or altered sense of smell, loss of taste
- tongue discolouration
- inflammation of the pancreas (pancreatitis)
- inflammation of the kidney or kidney failure
- yellowing of the skin or eyes (jaundice) or liver failure (rarely life-threatening)
- bruising or prolonged bleeding after injury
- abnormal electrocardiogram (ECG)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness.

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
Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
Fax: + 357 22608649
Website: www.moh.gov.cy/phs

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azithran

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

This medicine does not require any special storage conditions.

Do not take this medicine after the expiry date which is stated on the blister and 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 protect the environment.

6. Contents of the pack and other information

What Azithran contains

The active substance is azithromycin.

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

The other ingredients are pregelatinized starch, crospovidone, anhydrous calcium hydrogen phosphate, sodium lauryl sulfate and magnesium stearate. The coating contains hypromellose, titanium dioxide (E171), lactose monohydrate and triacetin.

What Azithran looks like and contents of the pack

Azithran film coated tablets are oblong, biconvex, film-coated tablets, scored on one side.
The tablet can be divided into two equal doses

They come in blister packs of 3 tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder

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