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## 1.4 Product information

### 1.4.3 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.

**What is in this leaflet**

1. What Aziwin-500 (Azithromycin Tablets USP 500 mg) are and what they are used for
2. What you need to know before you take Aziwin-500 (Azithromycin Tablets USP 500 mg)
3. How to take Aziwin-500 (Azithromycin Tablets USP 500 mg)
4. Possible side effects.
5. How to store Aziwin-500 (Azithromycin Tablets USP 500 mg)
6. Further Information.

**1. What Aziwin-500 (Azithromycin Tablets USP 500 mg) are and what they are used for**  
Azithromycin belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to treat infections caused by microorganisms like bacteria.

Azithromycin is used for the treatment of certain infections caused by bacteria that are sensitive to it, such as:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- ear infections
- skin and soft tissue infections, with exception of infected burn wounds.
- infection of the tube that carries urine from the bladder (urethra) or the neck of the womb (cervix) caused by Chlamidia trachomatis bacteria).

**2. What you need to know before you take Aziwin-500 (Azithromycin Tablets USP 500 mg)**

**Do not take Aziwin-500 (Azithromycin Tablets USP 500 mg):**

- if you are allergic to azithromycin dihydrate, erythromycin or any macrolide or ketolide antibiotic, if you are allergic to any of the other ingredients of this medicine (listed in section 6).

**Warnings and Precautions**

**Talk to your doctor 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)

- you develop severe and persistent diarrhoea during or after treatment
- you have severe liver or kidney problems
- you have severe heart problems or problems with your heart beat such as long QT syndrome (shown on an electro-cardiogram or ECG machine)
- your blood levels of potassium or magnesium are too low
- you develop signs of another infection
- you are taking any ergot derivatives such as ergotamine (to treat migraine) as these medicines should not be taken together with Azithromycin (see section “Other medicines and Azithromycin”)
- you have a certain type of muscle weakness called myasthenia gravis
- you have nervous (neurological) or mental (psychiatric) problems.
- your newborn child develops vomiting and irritability during feeding

### **Other medicines and Aziwin-500 (Azithromycin Tablets USP 500 mg)**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- Antacids - used for heartburn and indigestion. Azithromycin should be taken at least 1 hour before or 2 hours after the antacid
- Ergotamine -dihydroergotamine (used for migraine) should not be taken at the same time as serious side effects may develop (ergotism - i.e. itching in the limbs, muscle cramps and gangrene of hands and feet due to poor blood circulation)
- Cholesterol lowering medicines (statins)
- Warfarin or any similar medicines - to prevent blood clots: concomitant use can increase the risk of bleeding
- Hydroxychloroquine (used to treat rheumatic diseases or malaria): heart problems may occur
- Cisapride - (used to treat stomach problems), or terfenadine (used to treat hay fever): should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine)
- Zidovudine or nelfinavir - used to treat HIV infections. Taking nelfinavir with Azithromycin may mean that you get more of the side effects listed in this leaflet
- Rifabutin - used to treat tuberculosis (TB)
- Quinidine - used to treat heart rhythm problems (called antiarrhythmics)
- Cyclosporin - used to suppress the immune system to prevent and treat rejection of an organ or bone marrow transplant. Your doctor will regularly check your blood levels of cyclosporin and may change your dose.

Tell your doctor or pharmacist if you are taking any of the following medicines. Azithromycin can make the effects of these other medicines stronger. Your doctor may change your dose:

- Alfentanil - a painkiller used e.g. during operations
- Theophylline - used for breathing problems such as asthma and chronic obstructive pulmonary disease (COPD)
- Digoxin - used to treat heart failure.
- Colchicine - used for gout and familial Mediterranean fever
- Astemizol - used to treat hay fever



- Pimozide - used to treat mental health problems. Azithromycin with food and drink This medicine can be taken with or without food.

### **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.

There is insufficient information available about the use of Azithromycin during pregnancy. Therefore you should not use Azithromycin during pregnancy, unless explicitly advised by your doctor.

Azithromycin is partially passed through the mother's milk, It is not known whether azithromycin may have adverse effects on the breast-fed infant. Breastfeeding should therefore be discontinued during treatment with Azithromycin. It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. Breast-feeding may be resumed thereafter.

### **Driving and using machines**

There are no data available about the influence of Azithromycin on the ability to drive or operate machines. However Azithromycin may cause dizziness and seizures so make sure you are not affected before driving or operating machinery.

### **3. How to take Aziwin-500 (Azithromycin Tablets USP 500 mg)**

**Always take Aziwin-500 (Azithromycin Tablets USP 500 mg) exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.**

- The recommended dose: For adults and children with a body weight of 45 kg or more Azithromycin is taken as a 3 or 5 day course:
- 3 days course: Take 500 mg (two 250 mg or one 500 mg tablet) once each day
- 5 days course: - Take 500 mg on Day 1 (two 250 mg tablets) - Take 250 mg (one 250 mg tablet) on Days 2, 3, 4 and 5:

#### For infections of the neck of the womb and urethra caused by Chlamydia trachomatis

One dose of 1000 mg, (four 250 mg tablets or two 500 mg tablets) to be taken one time.

#### Children and adolescents under 45kg

The tablets are not recommended. Children with a body weight of less than 45kg should use other forms of this medicine.

#### 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.

#### Dosage for elderly

For elderly the same dosage as for adults applies. 500 mg tablet can be divided into equal doses.

#### Method of administration

The tablets should be taken with ½ glass of water. The tablets can be taken with or without food.

#### If you take more Azithromycin than you should

If you have taken too much Azithromycin, contact your doctor, pharmacist or go to your nearest hospital at once. Symptoms of overdose are loss of hearing, feeling sick or being sick and diarrhoea. In case of overdosage admission into hospital may be necessary.

If you forget to take Azithromycin

If you forget to take Azithromycin, take your dose as soon as possible. If it is almost time for the next dose, just skip that dose and take the next one when it is due. If in doubt, please contact your doctor or pharmacist. If you have to skip a dose, still take all of your tablets. This means that you will finish your course a day later. Do not take a double dose to make up for a forgotten dose.

If you stop taking Azithromycin

Never stop the treatment with Azithromycin on your own, but first discuss this with your doctor. If the prescribed treatment is not completely finished, the infection may come back again. If you have any further questions on 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. If you have any of the following symptoms of a severe allergic reaction stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital. The frequency of these reactions is not known (frequency cannot be estimated from the available data)

- Sudden difficulty in breathing, speaking and swallowing
- Swelling of lips, tongue, face and neck
- Extreme dizziness or collapse
- Severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs.
- 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))

If you experience any of the following side effects contact your doctor as soon as possible

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

- Increased or reduced urine output, or traces of blood in your urine
- 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)

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

- Diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation. This is something that can rarely happen after taking antibiotics
- Yellowing of the skin or whites of the eyes (jaundice) caused by liver problems
- Inflammation of the pancreas (pancreatitis), which causes severe pain in the abdomen and back
- Increased or reduced urine output, or traces of blood in your urine
- Skin rash caused by sensitivity to sunlight
- Unusual bruising or bleeding
- Irregular heart beat. These are all serious side effects.

You may need urgent medical attention. Other side effects include:

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

- diarrhoea • abdominal pain • feeling sick (nausea) • loose wind (flatulence)



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

• lack of appetite (anorexia) • headache • feeling dizzy • sensation of pins and needles or numbness (paraesthesia) • changes in your sense of taste • visual impairment • deafness • being sick (vomiting), stomach pain or cramps, loss of appetite, problems digesting your food • skin rashes and itching • joint pain (arthralgia) • fatigue • change in the quantity of the white blood cells and the concentration of bicarbonate in the blood. Uncommon (may affect up to 1 in 100 people) • thrush (candidiasis) - a fungal infection • bacterial infection • inflammation of the throat (pharyngitis) • breathlessness, chest pain, wheeze and cough (respiratory disorder) • inflammation of the mucous membrane inside the nose (rhinitis) • stomach flu (gastroenteritis) • inflammation inside your vagina (vaginitis) • pneumonia • reduction in the number of white blood cells • angioedema • hypersensitivity • nervousness • reduced sense of touch (hypoesthesia) • feeling drowsy (somnolence) • having difficulty sleeping (insomnia) • ear disorder • dizziness • spinning sensation (vertigo) • palpitations • hot flushes • shortness of breath • nosebleed • inflammation of the lining of the stomach (gastritis) • constipation • difficulty swallowing • swollen abdomen • dry mouth • belching • mouth ulcer • increased salivary flow • liver problems such as hepatitis • allergic skin reactions such as being sensitive to sunlight, red, flaking and swollen skin • skin rash • itching • inflammation of the skin (dermatitis) • dry skin • increased sweating • pain, swelling and reduced motion in your joints (osteoarthritis) • muscle pain • back pain • neck pain • increase in blood urea levels • painful or difficult urination • pain in the upper back (renal pain) • spotting • testicular disorder • urticaria • chest pain • face swelling • fever • pain • swelling of extremities (peripheral edema) • swelling (oedema) • general feeling of being unwell (malaise) • weakness (asthenia) • change in liver enzyme levels and blood levels • post procedural complications • skin more sensitive to sunlight than normal • abnormal laboratory test values (e.g. blood or liver tests).

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

• feeling agitated, feeling of unreality to the self and own feeling • abnormal hepatic function, • allergic skin reactions • 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). • swelling of the hands, feet, lips, genitals or throat (angioneurotic oedema) • kidney problems Not known (frequency cannot be estimated from the available data) • gut (colon) infection (pseudomembranous colitis) • reduced number of red blood cells due to destruction (haemolytic anaemia); reduction in number of platelets (thrombocytopenia) • anaphylactic reaction • feeling angry, aggressive • anxiety • confusion • hallucination • fainting (syncope) • fits (convulsions) • reduced sense of touch (hypoesthesia) • feeling hyperactive • change in your sense of smell (anosmia, parosmia) • change in your sense of taste (ageusia) • exacerbation or aggravation of muscle weakness (myasthenia gravis) • blurred vision • impaired hearing including loss of hearing, ringing in your ears • rapid (ventricular tachycardia) or irregular heart beat, sometimes being life-threatening, changes of the heart rhythm found by an electro-cardiogram (QT prolongation and torsade de pointes) • low blood pressure • inflammation of the pancreas (pancreatitis) • your tongue changes colour • liver failure • severe allergic skin reactions • inflammation within the kidneys.

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 (nausea) • loose wind (flatulence) • abdominal discomfort • loose stools Common (may affect up to 1 in 10 people): • lack of appetite (anorexia) • feeling dizzy • headache • sensation



of pins and needles or numbness (paraesthesia) • changes in your sense of taste • visual impairment • deafness • being sick (vomiting), stomach pain or cramps, loss of appetite, problems digesting your food • skin rashes and itching • joint pain (arthralgia) • fatigue

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

- reduced sense of touch (hypoesthesia) • hearing loss or ringing in your ears • palpitations • liver problems such as hepatitis • severe form of skin flushing • allergic skin reactions such as being sensitive to sunlight, red, flaking and swollen skin • general feeling of being unwell (malaise) • weakness (asthenia)

Reporting of side effects If you get any side effects, talk to your doctor or pharmacist.

**5. How to store Aziwin-500 (Azithromycin Tablets USP 500 mg)**

- Store at controlled room temperature, Preserve in tight containers.
- Store below 30°C.
- Pack size : 1X3's Alu-PVC blister

**6. Further information**

**What Aziwin-500 (Azithromycin Tablets USP 500 mg) contain:**

- Each film coated tablet contains:

Azithromycin Dihydrate USP eq. To

Azithromycin USP .....500 mg

Colour.....Titanium Dioxide BP

The other ingredients are:

Anhydrous calcium Hydrogen Phosphate	BP
Microcrystalline cellulose (PH 101)	BP
Maize starch	BP
Sodium Lauryl Sulphate	BP
Povidone (PVP K30)	BP
Isopropyl Alcohol^	BP
Maize Starch	BP
Croscarmellose sodium	USP/NF
Sodium starch glycollate	USP/NF
Colloidal silicon dioxide	USP/NF
Purified Talc	BP
Sodium Lauryl sulphate	BP
Magnesium stearate	BP
Hypermellose 15 CPS	BP
Isopropyl Alcohol**	BP

## Aziwin-500

### (Azithromycin Tablets USP 500 mg)



Methylene chloride** (Dichloromethan)	BP
Titanium Dioxide	BP
Purified Talc	BP
Polysorbate 80	USP

#### **What Aziwin-500 (Azithromycin Tablets USP 500 mg) look like and the contents of the pack:**

- Aziwin-500 (Azithromycin Tablets USP 500 mg) are White oval shaped film coated tablets with a break-line on one surface.

#### **The marketing authorisation holder and manufacturer**

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