

Product Name: P-AZITH-500	
Generic Name: Azithromycin Tablets USP 500 mg	
PATIENT INFORMATION LEAFLET	

PATIENT INFORMATION LEAFLET (PIL)

P-AZITH-500

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 P-AZITH-500 is and what it is used for
2. What you need to know before you take P-AZITH-500
3. How to take P-AZITH-500
4. Possible side effects
5. How to store P-AZITH-500
6. Contents of the pack and other information

1. What P-AZITH-500 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 P-AZITH-500

Do not take P-AZITH-500:

- if you are allergic to P-AZITH-500 or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the ingredients listed in section 6. An allergic reaction may cause skin rash or wheezing
- if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as

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these medicines should not be taken together with P-AZITH-500.

Warnings and precautions

Talk to your doctor or pharmacist before taking P-AZITH-500 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
- and if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with P-AZITH-500.

Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heart beat, or get dizzy or faint or suffer from any muscle weakness when taking P-AZITH-500.

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 P-AZITH-500

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

In particular, P-AZITH-500 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)
- terfenadine (for hay fever or a skin allergy)

P-AZITH-500 with food and drink

You should take P-AZITH-500 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

P-AZITH-500 is not expected to affect your ability to drive or use machines.

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3. How to take P-AZITH-500

Always take P-AZITH-500 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The capsules should be swallowed whole.

The usual dose in adults and children over 7 stones (45 kg) is 500 mg (2 capsules) taken together, once a day, for 3 days. For some diseases such as Chlamydia the dose is 1 g (4 capsules) taken altogether on one day only. For gonorrhoea the recommended dose is 1 g or 2 g of azithromycin in combination with 500 or 500 mg of ceftriaxone.

P-AZITH-500 Tablets 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 these. 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 P-AZITH-500 than you should

If you take too much P-AZITH-500 you may feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately.

If you forget to take P-AZITH-500

If you forget to take P-AZITH-500 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 P-AZITH-500

If you stop taking P-AZITH-500 too soon, the infection may return. Take tablets for the full time of treatment, even when you begin to feel better.

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

4. Possible side effects

Like all medicines P-AZITH-500 can cause side effects although not everybody gets

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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 P-AZITH-500 as this may be a sign of serious bowel inflammation
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat
- low blood pressure

The most common side effects that occur when taking P-AZITH-500 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 side effects (may affect more than 1 in 10 people):

- stomach cramps, feeling sick, diarrhoea, wind

Common side effects (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 (type of white blood cells), higher number of eosinophils (type of white blood cells)
- low blood bicarbonate
- tiredness or weakness

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

- yeast infections of the mouth and vagina (thrush)
- low numbers of leukocytes (type of white blood cells), low number of neutrophils (type of white blood cells)
- allergic reactions of various severity
- blistering of the skin, mouth, eyes and genitals
- skin more sensitive to sunlight than normal
- feeling nervous
- reduced sense of touch or sensation (hypoesthesia)
- sleepiness or sleeplessness (insomnia)

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- 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 side effects (may affect up to 1 in 1,000 people):

- agitation
- vertigo
- changes in liver function

Other side effects that have been reported, but 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
- blistering of the skin, severe skin reaction
- abnormal electrocardiogram (ECG)

Reporting of side effects

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

5. How to store P-AZITH-500

- 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 stamped on the pack 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.

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6. Further Information

What P-AZITH-500 contains

The active substance is Azithromycin (500 mg).

The other ingredients are Maize Starch, Di basic Calcium Phosphate, Microcrystalline cellulose, Kyron T-314, Gelatin, Sodium Benzoate, Sodium Methyl Paraben, Sodium Propyl Paraben, Talcum, Magnesium Stearate, Sodium Starch Glycolate

What P-AZITH-500 looks like and contents of the pack

White coloured, Oblong Shaped, Biconvex, Film coated tablets with break line on one side. They come in blister packs of 3.

7) Supplier and Manufacturer

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