

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Azithromycin 250mg Film-Coated Tablets**  
**Azithromycin 500mg Film-Coated Tablets**

**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.

**The name of your medicine is Azithromycin 250mg Film-Coated Tablets or Azithromycin 500mg Film-Coated Tablets. In the rest of this leaflet it is called Azithromycin Tablets.**

**What is in this leaflet:**

1. What Azithromycin Tablets are and what they are used for
2. What you need to know before you take Azithromycin Tablets
3. How to take Azithromycin Tablets
4. Possible side effects
5. How to store Azithromycin Tablets
6. Contents of the pack and further information

**1. WHAT AZITHROMYCIN TABLETS ARE AND WHAT THEY ARE USED FOR**

Azithromycin 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 acute worsening of chronic 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 an organism called Chlamydia.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AZITHROMYCIN TABLETS**

**Do not take Azithromycin Tablets:**

- 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 Azithromycin Tablets 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 azithromycin.

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 Azithromycin Tablets.

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 Azithromycin Tablets**

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

In particular, Azithromycin Tablets 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).

#### **Azithromycin Tablets with food and drink**

Azithromycin Tablets can be taken with or without food.

#### **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**

Azithromycin Tablets are not expected to affect your ability to drive or use machines.

### **3. HOW TO TAKE AZITHROMYCIN TABLETS**

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

The recommended dose in adults and adolescents over 45 kg is 500mg, once a day, for three days. Alternatively, the dosage may be staggered over five days (500 mg as a single dose on the first day, and then 250 mg once daily).

For some diseases such as Chlamydia the dose is 1g taken all together on one day only.

Azithromycin Tablets should not be taken by children and adolescents weighing less than 45kg.

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 Azithromycin Tablets than you should**

If you take too many Azithromycin Tablets you may feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately.

#### **If you forget to take Azithromycin Tablets**

If you forget to take Azithromycin Tablets 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 Azithromycin Tablets**

If you stop taking Azithromycin Tablets too soon, the infection may return. Take the 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 for advice.

**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 Azithromycin Tablets 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 Generalised 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 Azithromycin Tablets 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 (type of white blood cells), higher number of eosinophils (type of white blood cells) (as seen in blood test results)
- low blood bicarbonate (as seen in blood test results)
- tiredness or weakness.

**Uncommon:** 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) (as seen in blood test results)
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517;

Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

## 5. HOW TO STORE AZITHROMYCIN TABLETS

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

Do not use this medicine after the expiry date which is stated on the blister label and outer carton after {EXP}. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Azithromycin Tablets contain

The active substance is azithromycin.

Azithromycin 250mg Film-Coated Tablets contain 250mg azithromycin (anhydrous), equivalent to 250mg azithromycin base. Azithromycin 500mg Film-Coated Tablets contain 500mg azithromycin (anhydrous), equivalent to 500mg azithromycin base.

The other ingredients are microcrystalline cellulose, maize starch, croscarmellose sodium, magnesium trisilicate (E553a), magnesium stearate, colloidal silicon dioxide (E551), hydroxypropyl cellulose (E463), sodium lauryl sulfate and the coating material, Opadry Y-1-7000 white (contains hypromellose (E464), titanium dioxide (E171) and polyethylene glycol 400).

### What Azithromycin Tablets look like and contents of the pack

Azithromycin 250mg Film-Coated Tablets are a white to off-white film-coated oval shaped biconvex tablet debossed with W 961 on one side and plain on the other. They are available in packs of 2, 3, 4, 6, 9, 12 and 24 film-coated tablets. Not all pack sizes may be marketed.

Azithromycin 500mg Film-Coated Tablets are a white to off-white film-coated oval shaped biconvex tablet debossed with W 964 on one side and plain on the other. They are available in packs of 2 and 3 film-coated tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder:** Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK  
**Manufacturer:** CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference number
Azithromycin 250mg Film-Coated Tablets	PL 29831/0537
Azithromycin 500mg Film-Coated Tablets	PL 29831/0512

This is a service provided by the Royal National Institute of Blind People.  
For the republic of Ireland please call +44 1978 661261.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

UK and Ireland: Azithromycin 250mg Film-Coated Tablets and Azithromycin 500mg Film-Coated Tablets.

Cyprus: Azithromycin Wockhardt 250mg Film-Coated Tablets and Azithromycin Wockhardt 500mg Film-Coated Tablets.

This leaflet was last revised in 05/2018.