

# AZYTRO TABLET 250MG

Azithromycin (250mg)

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## What is Azytro Tablet used for

It is used to treat infections caused by certain bacteria and other micro-organisms, which include:

- lower and upper respiratory tract infections
- skin and soft tissue infections
- ear infections
- sexually transmitted diseases caused by organisms called Chlamydia trachomatis and Neisseria gonorrhoea

It is used in combination with another antibacterial, known as rifabutin for prevention against Mycobacterium avium-intracellulare complex (MAC) infection in human immunodeficiency virus (HIV) patients.

## How Azytro Tablet works

Azithromycin is the antibiotic which inhibits bacteria from producing proteins that are essential for their growth in human body.

## Before you use Azytro Tablet

### -When you must not use it

Do not use Azytro Tablet if you are allergic to Azithromycin or any other ingredients in this medicine.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, stop taking the medicine and contact your doctor immediately or go to the nearest hospital.

### -Before you start to use it

Tell your doctor or pharmacist before using Azytro Tablet if you:

- have history of severe allergic reaction (oedema and anaphylaxis) with Erythromycin or other macrolides.
- have arrhythmia (irregular or slow heart beat).
- have kidney or liver problem.
- Tell your doctor if you are pregnant or plan to become pregnant.

Azithromycin is not recommended if you are pregnant but your doctor will assess the benefit if required.

- Tell your doctor if you are breastfeeding. Azithromycin is excreted into the breast milk. Your doctor will tell you whether you should take it and temporarily stop breastfeeding while you are taking the tablets.

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Azytro Tablet.

### -Taking other medicines

Tell your doctor or pharmacist if you are taking or having recently taken any other medicines e.g. Antacids, Cyclosporin, digoxin, ergot derivatives, Terfenadine, Theophylline and Coumarine-type oral anticoagulants, Zidovudine. This includes any medicines which you have bought without a prescription.

## How to use Azytro Tablet

### -How much to use

Adults:

- 3-day course: 500mg daily
- 5-day course: 500mg on 1<sup>st</sup> day, 250mg daily from 2<sup>nd</sup> to 5<sup>th</sup> day
- For genital infection: single dose of 1000mg
- For infection in HIV patient: 1200mg once per week
- If you have kidney or liver impairment, your doctor might prescribe you a lower dose.
- Azytro Tablet should only be administered to children weighing more than 45 kg.

### -When to use it

Recommend to be taken with food.

Follow the prescription from your doctor or pharmacist.

### -How long to use it

Follow the prescription from your doctor or pharmacist. Ask your doctor or pharmacist before prolonged use of this medicine.

Do not stop taking medication, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

### -If you forget to use it

Use it as soon as you remember, unless it is nearly time for your next dose, skip the missed dose. Then go on as before. Never

double up on the next dose to make up for the one missed.

### -If you use too much (overdose)

You may experience some side effects as listed in the 'Side Effects' section.

Seek immediate medical attention if you have used too much or are worried with your condition.

## While you are using Azytro Tablet

### -Things you must do

- Always wash your hand before handle the medicine. Swallow the tablets with water and take it at the same time each day.
- If you are taking Azytro Tablet for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.
- Tell your doctor if you become pregnant while taking Azytro Tablet.
- If you get diarrhoea tell your doctor or pharmacist immediately.

### -Things you must not do

Do not chew the medicine. Swallow it with water.

Do not use this medicine by yourself without prescription from your doctor or pharmacist.

### -Things to be careful of

Be careful driving or operating machinery until you know how Azytro Tablet affects you.

## Side Effects

- Diarrhoea, nausea, indigestion, abdominal pain, heartburn, bloating, constipation
- Tongue discoloration
- Loss of appetite
- Hearing loss
- Blood disorder
- Headache, dizziness, insomnia
- Itchiness, oedema, skin reaction e.g. erythema multiforme, Steven Johnson syndrome, toxic epidermal necrolysis.
- Joint pain
- Jaundice, hepatitis
- Behavioral change
- Irregular heartbeat
- Fatigue and feeling weak

If you notice that the child vomits and/or irritability with feeding occurs, contact doctor immediately as it may be due to the Infantile Hypertrophic Pyloric Stenosis (IHPS).

Azytro Tablet may cause severe allergy and serious skin reactions.

Stop using Azytro Tablet and seek medical assistance immediately if you experience any of the following symptoms:

Skin reddening, blisters, rash, fever, sore throat or eye irritation.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### **Storage and Disposal of Azytro Tablet**

#### -Storage

Store below 30°C.

Keep out of the reach of the children.

Do not use this medicine after expiry date.

#### -Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

### **Product Description**

#### -How Azytro Tablet looks like

White, oval shape, film-coated tablet engraved with “ΛV” on one side and plain on the other side.

Available in blister pack of 6’s in packing of 30 tablets per box.

#### -Ingredients

Active ingredient

Azithromycin Dihydrate

Inactive Ingredients

Lactose, Isopropyl Alcohol, Sodium Lauryl Sulphate, Povidone, Purified Water, Microcrystalline Cellulose, Opadry II 31K58901, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Maize Starch, Magnesium Stearate.

#### -MAL Number

MAL17065021ACZ

### **Manufacturer**

Xepa-Soul Pattinson (Malaysia) Sdn Bhd  
1-5 Cheng Industrial Estate,  
75250 Melaka, Malaysia.

### **Product Registration Holder**

Apex Pharmacy Marketing Sdn Bhd  
2, Jalan SS13/5,  
47500 Subang Jaya, Malaysia.

### **Date of Revision**

07/01/2020

### **Serial Number**

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