

# AXCEL AZITHROMYCIN TABLET

Azithromycin Dihydrate (250mg & 500mg)

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## What Axcel Azithromycin Tablet is used for

Axcel Azithromycin Tablet is used for:

- Lower respiratory tract infections including bronchitis (inflammation of lining of bronchial tubes that carry air to and from your lungs) and pneumonia (lung infection).
- Skin and soft tissue infections.
- In acute otitis media (an ear infection where the middle ear becomes inflamed and infected).
- Upper respiratory tract infections including sinusitis and pharyngitis / tonsillitis (inflammation of sinuses, pharynx and tonsils).
- Uncomplicated genital (reproductive organ) infection and chancroid (bacterial sexually transmitted disease).

## How Axcel Azithromycin Tablet works

Azithromycin is an antibacterial drug against a wide range of bacteria that cause the infections such as respiratory infections, skin infections, ear infections and sexually transmitted diseases. The bactericidal action of azithromycin results from the inhibition of protein synthesis in bacteria by binding to essential target proteins and preventing translocation of peptides.

## Before you use Axcel Azithromycin Tablet

### – When you must not use it

Do not take Axcel Azithromycin Tablet if:

- You are allergic to azithromycin, erythromycin, any macrolide or ketolide antibiotic.
- You are taking any ergot derivatives (used to treat migraine headache, and enhance uterine contraction and control bleeding after childbirth).

### – Before you start to use it

You need to tell your doctor if:

- You are allergic to any medicines.
- You are taking any other medicines (including those not prescribed by your doctor).
- You have kidney or liver disease
- You are pregnant or nursing babies.

### – Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Azithromycin Tablet.

- Antacids
- Cetirizine
- Didanosine (Dideoxyinosine)
- Digoxin and colchicine
- Zidovudine
- Ergotamine derivatives
- Atorvastatin
- Carbamazepine
- Cimetidine
- Coumarin-Type Oral Anticoagulants
- Cyclosporin
- Efavirenz
- Fluconazole
- Indinavir
- Methylprednisolone
- Midazolam
- Nelfinavir
- Rifabutin
- Sildenafil
- Terfenadine
- Theophylline
- Triazolam
- Trimethoprim/sulfamethoxazole
- Astemizole, alfentanil
- Cisapride

## How to use Axcel Azithromycin Tablet

### – How much to use

For oral administration only. It should be administered as a single daily dose, and can be taken with or without food.

### Adults:

| Disease                                                                                                         | Dose                                                                                                               |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Sexually transmitted disease                                                                                    | 1000mg once daily                                                                                                  |
| <ul style="list-style-type: none"> <li>• <i>Chlamydia trachomatis</i> and <i>Haemophilus ducreyi</i></li> </ul> | 1000mg once daily                                                                                                  |
| <ul style="list-style-type: none"> <li>• <i>Neisseria gonorrhoeae</i></li> </ul>                                | 1000mg or 2000mg in combination with 250 mg or 500 mg ceftriaxone according to local clinical treatment guidelines |
| All other indications                                                                                           | 500mg daily for 3 days; or 500mg on day 1 and 250mg daily on day 2 to 5.                                           |

### Children:

Maximum total dose for any treatment is 1500mg. Axcel Azithromycin Tablet should only be used for children weighing more than 45kg, with same dosage used as in adult patients.

### Elderly:

Same dosage as in adult patients.

### Patients with kidney or liver impairment:

Follow the dose as recommended by your doctor.

### – When to use it

Your doctor will decide when it is appropriate for you to use Axcel Azithromycin Tablet according to the type of condition you have.

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## – How long to use it

Follow recommendations and advices from your doctor. You should not take this product more than once a day.

## – If you forget to use it

- Consult your doctor or pharmacist on what you should do if you forget to use it.
- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

## – If you use too much (overdose)

You must inform your doctor immediately or go to the Emergency Department of your nearest hospital if you have taken too much Axcel Azithromycin Tablet.

## **While you are using it**

### – Things you must do

- Take your medicine exactly as your doctor has told you.
- Discuss with your doctor the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines
- Tell your doctor immediately if you become pregnant while taking this medication.
- Tell your doctor if you experience any side effects that are not listed in this leaflet.

### – Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Azithromycin Tablet to anyone else, even if they have the same symptoms or condition as you.

### – Things to be careful of

- Follow the dosage as recommended.
- Not indicated for use in children weighing less than 45kg.

## **Side effects**

Like all medicines, Axcel Azithromycin Tablet can cause side effects although not everybody gets them. You are advised to consult doctor / pharmacist for further information. The following side effects have been reported:

- Neutropenia (abnormally low concentration of neutrophils – a type of white blood cell)
- Hearing loss, deafness and/or tinnitus (ringing in the ears)
- Gastrointestinal disorders – diarrhea, nausea, abdominal pain, vomiting, and flatulence (farting). If you notice the child vomits and/or experiences irritability with feeding, contact doctor immediately as it may be due to the Infantile Hypertrophic Pyloric Stenosis (IHPS).
- Abnormal liver function
- Allergic reactions including rash and angioedema (swelling of the area beneath the skin)
- Abnormal vision
- Headache
- Joint pain
- Nervousness

Axcel Azithromycin Tablet may cause severe allergy and serious skin reactions. Stop using Axcel Azithromycin 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 visiting the website [nptra.moh.gov.my](http://nptra.moh.gov.my) (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

## **Storage and disposal of Axcel Azithromycin Tablet**

### – Storage

Keep Axcel Azithromycin Tablet out of reach of children.  
Store below 30°C. Protect from light.

## – Disposal

Do not use Axcel Azithromycin Tablet after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer required. These measures will help to protect the environment.

## **Product description**

### – What it looks like

Axcel Azithromycin-250mg Tablet is white to off white colour, biconvex, oval shape tablet, embossed Kotra logo on one side and plain on other side.

Axcel Azithromycin-500mg Tablet is white to off white colour, biconvex, capsule shape tablet, embossed Kotra logo on one side and breakline on the other side.

### – Ingredients

Active Ingredient:  
Azithromycin Dihydrate

Inactive Ingredients:  
Pregelatinized Starch, Croscarmellose Sodium, Dibasic Calcium Phosphate Anhydrous, Sodium Lauryl Sulfate, Magnesium Stearate, Opadry II White, Purified Water.

### – MAL Number

MAL

## **Manufacturer and product registration holder**

Kotra Pharma (M) Sdn Bhd  
No. 1, 2 & 3, Jalan TTC 12,  
Cheng Industrial Estate,  
75250 Melaka, Malaysia.

### **Date of revision**

27/02/2020

### **Serial number**

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