

AZITHRO[®] CAPSULE

Azithromycin (250mg)

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What Azithro Capsule is used for

Azithro is indicated for infections caused by bacteria in lower respiratory tract infections, lung infections, in teeth infections, in ear infections and in upper respiratory tract infections including swollen and severe sore throat. This medicine is also used for sexually transmitted diseases in men and women. Azithro Capsule can be used in combination with ethambutol for the treatment of disseminated Mycobacterium Avium Complex (DMAC) infection in individuals with advanced HIV infection.

How Azithro Capsule works

Azithromycin is a macrolide antibiotic. This medicine works by killing or stopping the growth of bacteria causing the infection.

Before you use Azithro Capsule

- When you must not use it

Do not take Azithro Capsule

- If you are allergic (hypersensitive) to azithromycin or any of the macrolide antibiotics.

If any of these applies to you, you should not be given Azithro Capsule. Tell your doctor immediately.

- Before you start to use it

Tell your doctor:

- If you have a liver problem.
- If you have a kidney problem.
- If you have or had any medical problems or any allergies/skin reactions.
- If you are pregnant or breast-feeding

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Your doctor may limit your use of azithromycin or other medicines, or you may need to take a different medicine.

It is especially important to mention:

- If you are taking digoxin, the macrolide antibiotic may raise the digoxin levels in the body.
- If you are taking ergot derivatives such as ergotamine and dihydroergotamine .
- If you are taking anticoagulants such as warfarin to prevent blood clots.
- If you are taking cyclosporin for immunosuppressant.
- If you are taking terfenadine for the treatment of allergic conditions.
- If you are taking rifabutin for the treatment of tuberculosis.
- If you are taking zidovudine and efavirenz for the treatment of HIV.
- If you are taking antacids, cetirizine, didanosine, cimetidine, carbamazepine, atorvastatin, fluconazole, indinavir, methylprednisolone, midazolam, nelfinavir, sildenafil, theophylline, triazolam or trimethoprim/sulfamethoxazole.

How to use Azithro Capsule

- How much to use

Always use Azithro Capsule exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will adjust your treatment to the optimal dose that best control your symptoms. Under no circumstances should you change the dose without first speaking to your doctor. Azithro Capsule should be administered as single daily dose. The period of dosing with regard to infection is given below:

Adults and the elderly:

- Treatment of sexually transmitted disease caused by Chlamydia

trachomatis, Haemophilus ducreyi or Neisseria gonorrhoea: 1000mg as single dose.

- Prophylaxis against infection by Mycobacterium infections (termed as Mycobacterium Avium Complex (MAC)): 1200mg once per week
- Treatment of infection by Mycobacterium (termed as Disseminated Mycobacterium Avium Complex (DMAC)) infections: 600mg once a day

For all other indications in which the oral formulation is administered, the total dosage of 1500mg should be given as 500mg daily for 3 days.

Children:

Azithro Capsule should only be administered to children weighing more than 45kg, with the recommended dose as per adults.

Individuals with kidney impairment: No dose adjustment is necessary in individuals with mild to severe renal impairment

Individuals with liver impairment: The same dosage in individuals with normal liver function may be used in individuals with mild to moderate liver disease.

- When to use it

Use as directed by your doctor or pharmacist. Your doctor or pharmacist will decide when it is appropriate for you to take Azithro Capsule according to the type of infection you are having.

- How long to use it

Follow the recommendations and advices from your doctor or pharmacist.

- If you forget to use it

Take it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, just take the next dose at the correct time. Do not double the dose.

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- If you use too much (overdose)

Symptoms: The symptoms were similar to those seen at normal doses.

In case of accidental intake of an excessive dose of Azithro Capsule inform immediately your doctor or go to the nearest hospital.

While you are using it

- Things you must do

Always use Azithro Capsule exactly as your doctor has told you. You must check with your doctor or pharmacist if you are not sure.

If you feel that the medicine is not very effective, always talk to your doctor.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not give Azithro Capsule to anyone else without consulting the doctor, even if they have the same symptoms or condition as you.

- Things to be careful of

- if you have an allergy to erythromycin and other macrolides, contact your doctor before taking Azithro Capsule.

Side effects

Like all medicines, Azithro Capsule can cause side effects, although not everybody gets them. It is advisable to consult doctor/pharmacist for further information.

Azithromycin is well tolerated with a low incidence of side effects. If you developed any of the following side effects, stop taking your capsules and tell your doctor immediately or go to the nearest hospital.

Most common effects:

- Nausea, headache, vomiting, diarrhea, abdominal discomfort, flatulence, abnormal liver function, allergy reactions, indigestion, itch, lack of energy, tired, general feeling of discomfort and pain in joint.

Less common effects:

- Hearing impairment and abnormal vision, irregular heartbeat, convulsions, drowsiness, hyperactivity, burning/prickling sensation and temporary loss of consciousness

Rare effects:

- Tongue discoloration, dehydration due to diarrhea and taste disturbance.
- Short term blood disorder
- Hypersensitivity: a rare serious allergic reaction which includes serious skin reaction, eg Stevens-Johnsons Syndrome and Toxic Epidermal Necrolysis.
- Alteration of the heart rhythm (called prolongation of QT intervals) which may lead to cardiac disease.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems/Side Effects/AEFI/Vaccine Safety).

Storage and Disposal Azithro Capsule

Storage

Keep Azithro Capsule out of reach and sight of children.

Store below 30°C. Keep container well closed and protect from light. Do not use the product beyond the expiry date indicated on the outer pack and the inner label.

- Disposal

Medicines should not be disposed in water or domestic waste. Ask your pharmacist about how to dispose not used medicines. This will help protect the environment.

Product Description

- What it looks like

Azithro Capsule for oral administration is a white powder in capsule, imprinted with M&H in

black on white cap and body, in the box of 6 capsules.

- Ingredients

Active Ingredient (s):

Azithromycin 250mg

Inactive Ingredient(s) :

Anhydrous lactose, magnesium stearate, silicon dioxide, corn starch and sodium starch glycolate.

- MAL number

MAL10100178AZ

Manufacturer

M&H Manufacturing Co. LTD
41, Sukhmuvit Road, Samutprakarn, Thailand

Product Registration Holder

Germax Sdn. Bhd.
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