

ZIOMYCIN 250/500

AZITHROMYCIN TABLETS 250MG/500MG

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What Ziomycin is used for

Azithromycin belongs to macrolide antibiotics, known as azalides. It is used to treat bacterial infections. Ziomycin is used in the treatment of the following infections:

- Of the lower respiratory tract: bronchitis (inflammation of bronchi) and pneumonia (inflammation of lung's air sacs).
- Of the upper respiratory tract: sinusitis (inflammation of sinus lining) and pharyngitis/tonsillitis (inflammation of throat/tonsils).
- Acute otitis media (ear infection).
- Of the skin and soft tissues.
- Sexually-transmitted diseases: Uncomplicated genital infections caused by *Chlamydia Trachomatis* or *Neisseria gonorrhoea*, chancroid caused by *Haemophilus ducreyi*.

How Ziomycin works

Ziomycin works by suppressing the protein synthesis in bacteria, by binding to ribosomal subunit 50s which causes inhibition in peptide translocation.

Before you use Ziomycin

When you must not use it

Do not take Ziomycin if you are allergic to azithromycin, other macrolide or ketolide antibiotics, or any of the excipients of Ziomycin.

Pregnancy and lactation

Do not use Ziomycin if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not use Ziomycin if you are breast-feeding. Ask your doctor or pharmacist for advice before taking

any medicine.

Before you start to use it

Tell your doctor if you suffer from any of the following illnesses:

- If you have a serious kidney condition.
- If you have a severe liver condition.
- If you are currently taking ergotamine derivatives and azithromycin.
- If you have heart disease or have electrolyte abnormalities or prolonged QT interval.
- If you have diarrhoea during or after medication.
- If you have allergic reaction.
- As with all antibiotics.

Taking other medicines

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

Azithromycin may interact with other medicines. It is important that you mention if you taking, or have taken any of the following medication:

- Medications for treating migraines such as *Ergot*
- Medicines used to prevent blood clots such as Coumarin-type oral anticoagulants
- Medications used in heart failure such as *Digoxin*
- Medicines used in lowering cholesterol such as *Atorvastatin*
- Medicines used for sedation such as *Midazolam*
- Medicines used in the treatment of fungal/bacterial infections such as *Fluconazole*, *Rifabutin*, *Trimethoprim/sulfamethoxazole*
- Medicines used in the treatment of asthma such as *Theophylline*
- Medicines used in transplant patients such as *Cyclosporin*
- Medicines used to treat allergies such as *Terfenadine*, *Cetirizine* and *Methylprednisolone*
- Medicines used in the treatment of HIV/AIDS such as *Didanosine*, *Indinavir*, *Efavirenz*, *Zidovudine* and *Nelfinavir*
- Medicines used in treating high blood pressure in lungs such as

Sildenafil

- Medicines used as anticonvulsant such as *Carbamazepine*
- Medications used for digestive problems such as *Antacids* and *Cimetidine*
- Medicines used for treating sleep problems such as *Triazolam*

How to use Ziomycin

How much to use

- Always take Ziomycin exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

- The usual dose is one tablet (250mg or 500mg) taken once a day. The maximum recommended total dose for any treatment is 1500mg. Your pharmacist will explain how to use it if you are not sure.

- *Azithromycin* tablets should only be administered to children weighing more than 45kg.

When to use it

Ziomycin should be administered as a single daily dose. The tablets can be taken with or without food.

How long to use it

Your doctor will tell you how long you should take Ziomycin.

If you forget to use it

Do not take a double dose to make up for a forgotten dose. Take Ziomycin as soon as you remember.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking too many tablets may cause severe nausea, vomiting and diarrhoea and reversible hearing loss

While you are using it

Things you must do

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you think you are

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(or might become) pregnant, or if you are breastfeeding.

Things you must not do

Do not stop the treatment early as there may be a risk of relapse of the illness.

Things to be careful of

No studies have been conducted to evaluate the effect of azithromycin on the ability to drive or use machines. However, the possibility of undesirable effects such as dizziness and convulsions should be considered.

Side effects

Like all medicines, ZIOMYCIN can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common effects include diarrhea, abdominal pain, nausea, and flatulence (wind).

Common side effect include indigestion, drowsiness, dizziness, headache, tingling or prickling sensation, change in taste, change in visual, loss of hearing, vomiting, loss of appetite, rash, itchiness, joint pain, tiredness, and decrease or increase in certain blood cell count.

If you experience any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- ZIOMYCIN may cause severe allergy and serious skin reactions. Stop using ZIOMYCIN and seek medical assistance immediately if you experience any of the following symptoms: skin reddening, blisters, rash, fever, sore throat or eye irritation.

- 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).

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.moh.gov.my (Consumer→ Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))

Storage and Disposal of Ziomycin Storage

Store at temperature below 30°C. Keep all medicines out of reach of children.

Disposal

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

Product Description

What it looks like

250mg - Yellow colored, capsule shaped film-coated tablets with engraved "A250" on one side and plain on other side.

500mg - Yellow colored, capsule shaped film-coated tablets with engraved "A500" on one side and plain on other side.

Ingredients

Active ingredients

Azithromycin dihydrate

In-active ingredients

Microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulphate, povidone, isopropyl alcohol, purified talc, magnesium stearate, opadry yellow 04B520005 and purified water

MAL number

250mg: MALxxxxxx
500mg: MALxxxxxx

Manufacturer

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area,
Chopanki, Bhiwadi, Dist. Alwar,
(Rajasthan), India

Product Registration Holder

Synerrv Sdn Bhd,
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