

ZITHROLIDE TABLET

Azithromycin (250mg, 500mg)

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What Zithrolide Tablet is used for

Zithrolide Tablet is used to treat the following infections:

- 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.
- 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 Zithrolide Tablet works

Azithromycin is a macrolide antibiotic belonging to the azalide group.

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 Zithrolide Tablet

When you must not use it

Do not take Zithrolide Tablet if:

- You are allergic to azithromycin, erythromycin, any macrolide or ketolide antibiotic, or any of the other ingredients of this medicine.
- Your children weigh less than 45kg.

- Before you start to use it

Your doctor needs to know before you take Zithrolide Tablet if you have or have had any of the following conditions:

- Heart disease
- kidney problems
- liver problems: your doctor may need to monitor your liver function or stop the treatment
- Have myasthenia gravis (weakness and rapid tiredness of any of the muscles)
- Have or had any medical problems or any allergies/ skin reactions.
- Taking medicine derived from ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with Zithrolide Tablet.
- Have signs of other infections
- Currently having diarrhoea

Pregnancy and lactation:

Do not take Zithrolide Tablet if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Zithrolide Tablet if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

You should tell your doctor, if you are taking any medicines as it may interact with Zithrolide Tablet:

- Antacids

- Carbamazepine
- Cimetidine
- Cyclosporin
- Digoxin and colchicine
- Ergot derivatives
- Methylprednisolone
- Terfenadine
- Theophylline
- Coumarin-Type Oral Anticoagulants
- Zidovudine
- Didanosine (dideoxyinosine)
- Rifabutin
- Cetirizine
- Atorvastatin
- Efavirenz
- Fluconazole
- Indinavir
- Nelfinavir
- Sildenafil
- Triazolam
- Trimethoprim/ sulfamethoxazole
- Midazolam

You should always tell your doctor if you are taking or have recently taken any other medicines including those obtained without a prescription.

How to use Zithrolide Tablet

- How much to use

Always take Zithrolide Tablet exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The tablets should be swallowed whole.

Zithrolide Tablet should be administered as a single daily dose and can be taken with or without food.

Adults:

Disease	Dose
Sexually transmitted disease (Chlamydia)	1000 mg once daily

<i>Trachomatis, Haemophilus Ducreyi and Neisseria gonorrhoeae</i>)	
All other indication	500 mg daily for 3 days; or 500 mg on day 1 and 250 mg daily on day 2 to 5.

Children:

Maximum total dose for any treatment is 1500 mg. Zithrolide 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

You should take Zithrolide Tablet as directed by your doctor or pharmacist.

- How long to use it

Continue taking Zithrolide Tablet for as long as your doctor recommends.

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 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)

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.

While you are using it**- Things you must do**

Take your medicine exactly as your doctor has told you.

Discuss with your doctor on the dos'and don'ts' while taking this medicine. Tell all the doctors, dentists and pharmacist treating you that you are taking Zithrolide Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking this medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Zithrolide Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Serious hypersensitivity reactions with swelling of face, mouth and throat (sometimes fatal) have been rarely reported. If such symptoms occur, stop taking Zithrolide Tablet and contact your doctor immediately.

Antibiotics can cause diarrhoea, which may be a sign of a serious bowel inflammation. If you have diarrhoea that is watery or bloody, call your doctor. Do not use any medicine to stop the

diarrhoea unless your doctor has told you to.

Side effects

Like all medicines Zithrolide Tablet can cause side effects although not everybody gets them.

Tell your doctor if any of these side effects continue to bother you.

- Transient episodes of mild neutropenia (a condition in which there is a lower-than-normal number of neutrophils (a type of white blood cell) in the blood)
- Hearing impairment (including hearing loss, deafness, ringing in the ears, severe dizziness or feeling a spinning sensation in the body)
- Nausea, vomiting, diarrhoea, loose stools, abdominal discomfort, and flatulence
- Indigestion
- Difficulty to pass
- Pseudomembranous colitis (inflammation of the colon associated with an overgrowth of bacteria)
- Inflammation of pancreas
- Tongue discoloration
- Abnormal liver function
- Infantile hypertrophic pyloric stenosis (thickening or narrowing of the pylorus (a muscle in the stomach))
- Allergic reactions including rash, angioedema (swelling of the deeper layers of the skin), itchiness, photosensitivity, swelling and hives
- Serious skin adverse reactions (SCARs) including:
 - Erythema multiforme
 - AGEP, skin eruption that is characterized by the rapid appearance of areas of red skin studded with small pustules
 - SJS, blistering of the skin, mouth, eyes and genital
 - TEN, blistering of the skin, severe skin reaction

- DRESS, a skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils
- Local pain and inflammation at the site of infusion
- Moniliasis (a yeast infection) and vaginitis (inflammation of the vagina)
- Thrombocytopenia (a condition where there aren't enough platelets in the blood)
- Anaphylaxis (severe, potentially life-threatening allergic reaction)
- Anorexia
- Aggressive reaction, nervousness, agitation, and anxiety
- Dizziness, convulsion, headache, hyperactivity, somnolence and syncope
- Hypoesthesia (total or partial loss of sensation in a part of the body)
- Paresthesia (burning or prickling sensation)
- Taste/ smell perversion and/or loss
- A rapid pulsation (palpitation) and problem with the rate or rhythm of your heartbeat (arrhythmias)
- QT prolongation (extended interval between the heart contracting and relaxing)
- *Torsades de pointes* (a type of very fast heart rhythm)
- Low blood pressure
- Liver inflammation
- Yellowing of the skin or eyes
- Liver necrosis
- Liver failure
- Joint stiffness
- Kidney becomes swollen
- Acute renal failure
- Lack of energy and strength
- Fatigue
- Malaise

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

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 visiting the website npra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Zithrolide Tablet

- Storage

Keep all medicines out of the sight and reach of children.

Store below 30°. Protect from light.

Do not take this medicine after the expiry date stamped on the pack.

- Disposal

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

Product Description

- What it looks like

Zithrolide Tablet 250 mg:

White to off white, oblong, biconvex film coated tablet with Pharmaniaga icon on one side and scored on the other.

Zithrolide Tablet 500 mg:

White to off white, oblong, biconvex film coated tablet with Pharmaniaga icon on one side and plain on the other

Ingredients

Zithrolide Tablet 250 mg

-Active ingredient:

Azithromycin 250 mg.

-Inactive ingredient:

Polyvinyl alcohol, microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, magnesium stearate, titanium dioxide, macrogol and talc.

Zithrolide Tablet 500mg

-Active ingredient:

Azithromycin 500 mg.

-Inactive ingredient:

Polyvinyl alcohol, microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, magnesium stearate, titanium dioxide, macrogol and talc.

- MAL numbers:

Zithrolide Tablet 250mg

MAL12055035AZ

Zithrolide Tablet 500mg

MAL12055032AZ

Manufacturer

Pharmaniaga Manufacturing Berhad (198001006232),
No.11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad (198001006232),
No.11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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