

ZITHROMAX[®] TABLET

Azithromycin dihydrate (250 mg, 500 mg)

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What Zithromax is used for

Zithromax is used to treat infections caused by bacteria which include:

- respiratory tract infections;
- ear infections;
- skin and soft tissue infections;
- sexually transmitted diseases (genital infections).

How Zithromax works

Zithromax contains azithromycin dihydrate which is a type of antibiotic called macrolides. It works by stopping the growth of the bacteria causing the infection.

Before you use Zithromax

- When you must not use it

Do not take Zithromax if you are allergic to:

- azithromycin, erythromycin, other similar antibiotic or any of the other ingredients of this medicine (listed in Product Description).

- Before you start to use it

Tell your doctor before you take Zithromax, if you have or have had any of the following:

- history of diarrhea when using antibiotics
- signs of fungal infection
- history of serious allergic reaction causing swelling of the face and throat, possibly with breathing problems, rash, fever, swollen glands
- liver, heart or kidney problems;
- muscle weakness;
- if you have diabetes.

Please tell your doctor if you have any

of the following problems:

- are taking medicines that can affect heart rhythm such as medicines used for irregular heartbeat, psychosis, depression and fluoroquinolone antibiotic;
- have low levels of potassium or magnesium in your blood.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Zithromax must only be used during pregnancy if the benefits is more than the risks to the fetus.

Zithromax is secreted into breast milk. Your doctor will discuss the risks and benefits of breastfeeding while you're taking Zithromax.

- Taking other medicines

Tell your doctor before taking or giving Zithromax, if you/your child are/is taking any of the following medicines:

- antacids (for hyperacidity);
- digoxin (used to treat heart failure);
- colchicine (used to treat gout);
- zidovudine (used to treat HIV infections);
- warfarin (anticoagulants);
- cyclosporin (used to prevent rejection of a transplanted organ or bone marrow);
- ergot derivatives, such as ergotamine (used to treat migraine);
- atorvastatin (to lower cholesterol)

How to use Zithromax

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

In adults and children weighing more than 45 kg:

For sexually transmitted diseases, the dose is 1 g daily taken as a single oral dose.

For all other infections, the usual dose in adults is 500 mg, taken as a single dose, daily for 3 days or for 5 days with 500 mg given on Day 1, then 250 mg daily on Days 2 to 5.

- When to use it

Take once a day or as directed by your doctor or pharmacist. Zithromax can be taken with or without food.

The tablet should be swallowed whole.

- How long to use it

Use Zithromax for the duration as your doctor recommends.

- 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 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 Zithromax only with a doctor's prescription.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you, that you are taking Zithromax.

Tell your doctor immediately if you

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become pregnant while taking this medication.

Stop using Zithromax and seek medical assistance immediately if you or your child experience any of the following symptoms after taking this medicine:

- Skin reddening, blisters, rash, fever, sore throat or eye irritation;
- yellowing of the skin or eyes (jaundice);
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with Zithromax;

- Things you must not do

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

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

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

Side Effects

Like all medicines, Zithromax 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.

Zithromax may cause severe allergy and serious skin reactions.

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

- skin reddening, blisters, rash, fever, sore throat or eye irritation.

The following side effects have been reported:

- low levels of white blood cells or platelet count;
- hearing impairment, ringing in the ears, spinning sensation;
- nausea, vomiting, diarrhea, indigestion, constipation, abdominal pain/cramps, flatulence, inflammation of large intestine and tongue discoloration;
- rash, swelling of the skin and mucous membranes, itching, light sensitivity, hives;
- weakness, fatigue, discomfort;
- yeast infection of the mouth and throat, inflammation of the vagina;
- eating disorder (anorexia);
- aggressive reaction, nervousness, agitation, and anxiety;
- dizziness, seizure, headache, hyperactivity, reduced or abnormal sense of touch, drowsiness, and loss of consciousness;
- palpitation and abnormal heartbeat;
- low blood pressure;
- liver inflammation and yellowish discoloration of the skin and eyes (jaundice);
- joint pain;
- kidney inflammation or failure.

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

Storage and Disposal of Zithromax

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- 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

Zithromax Tablet 250 mg:

Azithromycin film coated tablets are white to off-white, scored, modified oval film coated tablets engraved “ZTM 250” on one side and “PFIZER” on the other side.

Zithromax tablets are packed in Opaque PVC/aluminium blister packs of 6’s (250 mg).

Zithromax Tablet 500 mg:

Azithromycin film coated tablets are white to off-white, scored, oval film coated tablets engraved “ZTM 500” on one side and “PFIZER” on the other side.

Zithromax tablets are packed in Opaque PVC/aluminium blister packs of 3’s (500 mg).

- Ingredients

- Active ingredients
Azithromycin dihydrate

- Inactive ingredients
Pregelatinized starch, calcium phosphate dibasic anhydrous, croscarmellose sodium, white opadry II, magnesium stearate and sodium lauryl sulphate.

- MAL numbers

Zithromax Tablet 250 mg
MAL19985908ACZ

Zithromax Tablet 500 mg
MAL19985909ACZ

Manufacturer

Haupt Pharma Latina S.r.l.
Strada Statale 156 Km 47,600,
04100 Borgo San Michele
Latina, Italy

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
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No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

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