

Package leaflet: information for the user

Zithromax 250, tablets 250 mg
Zithromax 500, tablets 500 mg
azithromycin dihydrate

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

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1. What is Zithromax and what is it used for?

Zithromax belongs to a group of medicines called antibiotics. Antibiotics are used to help fight infections in the body caused by bacteria.

Zithromax is used in the treatment of infections of:

- the respiratory organs (trachea and lungs)
- the sinuses
- the throat and tonsils
- the middle ear
- the skin and subcutaneous tissues (excluding burn infections)
- for the treatment of infections of the urethra or cervix caused by the bacterium *Chlamydia trachomatis*.

Zithromax can also be used to prevent a so-called MAC infection in patients infected with HIV.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You are allergic to erythromycin or other so-called macrolide or ketolide antibiotics.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- Sometimes allergic reactions (itching, rash) can occur as a result of using Zithromax. However, if a severe allergic reaction occurs, you will notice it in the form of rapid swelling of the face and throat (angioedema) causing a feeling of tightness or by suddenly becoming very ill (shock). High fever, rash, blisters on the skin, peeling of the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome, toxic epidermal necrolysis, DRESS syndrome, or acute generalized exanthematous pustulosis) can also be signs of severe allergic reactions. In such cases, you must contact your doctor immediately.
- If you have liver disease, you must tell your doctor before starting to use Zithromax. Cases of very severe liver inflammation have been observed with the use of Zithromax, which can lead to life-threatening liver dysfunction. You should contact your doctor if you experience symptoms such as rapid onset of physical weakness (asthenia) accompanied by jaundice, dark urine, tendency to bleed, decreased consciousness (hepatic encephalopathy). Your doctor will examine your liver functions and will likely advise you to stop using Zithromax.
- If you get diarrhea. Almost all antibiotics (medicines against bacterial infections) can cause diarrhea due to a shift in the balance of intestinal bacteria. This can lead to excessive growth of bacteria that are insensitive to the used medicine and that produce certain (toxic) waste products (toxins). The severity of the diarrhea can vary. If you develop severe, bloody diarrhea after starting Zithromax, you should consult your doctor.
- Antibiotics like Zithromax are known to affect (the functioning of) the heart. If any of the following situations apply to you, especially if you are a woman or of older age, you should tell your doctor before using Zithromax:
 - you have a condition called prolonged QT interval (the heart cells take longer than normal to prepare for the next heartbeat)
 - you are using another medicine that prolongs the QT interval (for example, a medicine for irregular heartbeat)
 - you have too little potassium or magnesium in your blood
 - you have a severely slowed heart rate, a heart rhythm disorder, or your heart function is severely reduced
- If you have myasthenia gravis (a certain form of muscle weakness).

Children and adolescents up to 18 years

If tablets cannot be taken properly, for example by small children, the use of Zithromax suspension could be considered. The tablet form of Zithromax is not suitable for children weighing less than 45 kg.

If you give this medicine to a newborn baby (less than 6 weeks old) and they vomit or become irritable during feeding, tell your doctor immediately.

Are you using any other medicines?

Are you using any other medicines besides Zithromax, or have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Antacids:

If you are being treated for excess stomach acid with antacids, make sure you do not take these medicines at the same time as Zithromax. There should be at least two hours between taking Zithromax and the antacid.

Ergotamine medications:

Ergotamine medications are prescribed for migraines. The use of Zithromax in combination with ergotamine medications is not recommended.

If you are using any of the following medicines, you may need to be monitored more frequently during treatment:

- digoxin (used for insufficient heart pumping function); the amount of digoxin in the blood should be monitored extra and the digoxin dose may need to be adjusted
- ciclosporin (used in organ transplants); the amount of ciclosporin in the blood should be monitored extra and the ciclosporin dose may need to be adjusted
- colchicine (medicine for gout and familial Mediterranean fever); the amount of colchicine in the blood should be monitored extra and the colchicine dose may need to be adjusted
- coumarin anticoagulants (blood thinners that counteract blood clotting); although the blood-thinning effect of coumarin medicines does not seem to be affected by Zithromax, it may be necessary for your blood clotting to be checked more often by the thrombosis service and for the medicine dose to be adjusted

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

If you are pregnant, you should only use Zithromax after consulting your doctor.

Breastfeeding

It has been reported that Zithromax is excreted in breast milk. No serious side effects of azithromycin were observed in infants. Consult your doctor before taking Zithromax if you are breastfeeding.

Driving and using machines

If you are going to drive or operate machinery, be aware that Zithromax can sometimes cause dizziness and drowsiness.

Zithromax contains lactose and sodium

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before using this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

You should take the daily dose of Zithromax all at once.

You can take the tablets with or without food and with water if necessary.

It is very important that you complete the course prescribed by the doctor, even if the symptoms have disappeared.

The recommended dosage is:

Adults and children from 45 kg

The dosage is usually 500 mg once a day. A treatment of three days is usually prescribed. However, your doctor may prescribe a different dose for a different period.

For cervical infections and infections of the urethra, the dosage is a single dose of 1000 mg. You should take the tablets all at once.

To prevent a so-called MAC infection (Mycobacterium Avium-intracellulare Complex infection) in patients infected with HIV, the weekly dosage is: 1200 mg to be taken all at once.

Elderly

For elderly patients, a doctor will prescribe the same dose as for adults.

Patients with liver and kidney disorders

Inform your doctor if you have a liver or kidney disorder. Your doctor may need to adjust the dosage.

Use in children and adolescents up to 18 years

Children and adolescents weighing 45 kg or more can follow the adult dosage.

For children from 1 year, dosing is based on body weight and the tablets are not suitable. A suspension is available that can be dosed accurately per ml.

Zithromax 500, tablets 500 mg: the score line is not intended for breaking the tablet.

Have you used too much of this medicine?

If you have used too much Zithromax, you may experience severe nausea, vomiting, or diarrhea. You may also lose your hearing, but it will return after you stop using Zithromax.

Have you forgotten to use this medicine?

Do not take a double dose to make up for a forgotten dose.

If you have forgotten a dose, take it as soon as possible. Take the next dose 24 hours later. Also inform your doctor.

If you stop using this medicine

If you do not complete the prescribed treatment, there is a chance that the infection will return.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Very common side effects (occur in more than 1 in 10 users): Diarrhea, abdominal pain, nausea, flatulence, discomfort in the abdomen, loose stools.

Common side effects (occur in less than 1 in 10 users):

Loss of appetite (anorexia), dizziness, headache, drowsiness, taste disorder (dysgeusia), sensation of tingling, itching, or tingling without cause (paresthesia), visual impairment, deafness, vomiting, belching, and heartburn (dyspepsia), rash, itching (pruritus), joint pain (arthralgia), fatigue, decreased number of lymphocytes (a type of white blood cell), increased number of eosinophils (a type of red blood cell), decreased blood bicarbonate levels, increased number of basophils, monocytes, and neutrophils (a type of white blood cell).

Uncommon side effects (occur in less than 1 in 100 users): Candidiasis (a type of fungal infection), oral candidiasis (fungal infection of the mouth), vaginal fungal infection, pneumonia, fungal infection, bacterial infection, sore throat (pharyngitis), inflammation of the stomach and intestines (gastroenteritis), respiratory disorder, inflammation of the nasal mucosa characterized by a blocked nose, sneezing, and runny nose (rhinitis), deficiency of certain white blood cells that results in increased susceptibility to infections (leukopenia, neutropenia, and eosinophilia), sudden fluid accumulation in the skin and mucous membranes (e.g., throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioedema), hypersensitivity, nervousness, insomnia, reduced ability to feel (hypoesthesia), hearing problems, dizziness (vertigo), ringing in the ears (tinnitus), palpitations, hot flashes, shortness of breath (dyspnea), nosebleed (epistaxis), constipation, stomach inflammation (gastritis), swallowing disorder (dysphagia), abdominal swelling, dry mouth, belching (eructation), mouth ulcers, excessive salivation, abnormal liver function, liver inflammation (hepatitis), rash with severe itching and bump formation (urticaria), skin inflammation (dermatitis), dry skin, excessive sweating (hyperhidrosis), severe allergic reaction with high fever, blisters on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome), sensitivity to light or sunlight causing skin abnormalities (photosensitivity reaction), joint damage usually occurring in the elderly without inflammation (osteoarthritis), muscle pain (myalgia), back pain, neck pain, difficulty or painful urination (dysuria), kidney pain, irregular uterine bleeding (metrorrhagia), testicular disorder, (fluid retention (edema), general physical weakness (asthenia), feeling of discomfort (malaise), facial swelling (facial edema), chest pain, fever, pain, fluid retention in arms or legs (peripheral edema), increased or decreased blood values, complications after surgery.

Rare side effects (occur in less than 1 in 1000 users): Irritability, jaundice, a red, scaly rash with thickening under the skin and blisters (acute generalized exanthematous pustulosis) and systemic disease (DRESS syndrome) as an allergic reaction to the drug.

Very rare side effects (occur in less than 1 in 10,000 users): Drug reaction that can cause rash, fever, inflammation of internal organs, and blood abnormalities.

Side effects with unknown frequency (cannot be determined from available data):

Inflammation of the colon (pseudomembranous colitis), blood disorder with symptoms of bruising and bleeding tendency (thrombocytopenia), anemia, allergic reaction, aggression, anxiety, delirium, hallucinations, loss of consciousness (syncope), seizure/convulsion, excessive movements, inability to smell (anosmia), reduction of taste (ageusia), perception of odors that are not present (parosmia), myasthenia gravis (a certain form of muscle weakness), abnormal heart function, low blood pressure (hypotension), inflammation of the pancreas with symptoms of severe pain in the upper abdomen radiating to the back and nausea and

vomiting (pancreatitis), discoloration of the tongue, discoloration of the teeth, liver failure, abnormal liver function, severe sudden allergic reaction with symptoms of fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis), rash with irregular red spots (erythema multiforme), acute kidney failure, inflammation of the kidneys with symptoms of blood in the urine, fever, and flank pain (interstitial nephritis).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help provide more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date. This can be found on the box. It includes a month and a year. The last day of that month is the expiry date. On the blister pack, this date is after “exp”.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is azithromycin dihydrate. In Zithromax 250, this corresponds to 250 mg of anhydrous azithromycin per tablet. In Zithromax 500, this corresponds to 500 mg of anhydrous azithromycin per tablet.
- The other substances in this medicine are pregelatinized starch, anhydrous dibasic calcium phosphate, croscarmellose sodium (see section 2 'Zithromax contains sodium'), magnesium stearate, and sodium lauryl sulfate. The tablets are coated with a layer (a coating) containing hydroxypropyl methylcellulose, lactose (see section 2 'Zithromax contains lactose'), triacetin, and titanium dioxide (E171).

What does Zithromax look like and what is in a package?

Zithromax 250, tablets are white to off-white, oval film-coated tablets with a score line, marked with “ZTM 250” on one side and “PFIZER” on the other side. The score line on the tablets is not intended to break the tablet.

Zithromax 250, film-coated tablets are supplied in blister packs of 4 or 6 tablets and in bottles of 10 tablets.

Zithromax 500, tablets are white to off-white, oval film-coated tablets with a score line, marked with "ZTM 500" on one side and "PFIZER" on the other side. The score line on the tablets is not intended to break the tablet.

Zithromax 500, film-coated tablets are supplied in blister packs of 2 or 3 tablets and in polyethylene bottles of 10 tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Pfizer bv
Rivium Westlaan 142
2909 LD Capelle a/d IJssel

Manufacturer
Haupt Pharma Latina S.r.l.
Italy

For questions about this medicine, call 0800-MEDINFO (63 34 636).

Zithromax 250, tablets 250 mg are registered under RVG 19432er registered under RVG 19432

Zithromax 500, tablets 500 mg are registered under RVG 19433

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