

PACKAGE LEAFLET: INFORMATION FOR THE USER

Azithromycin Aurobindo 250 mg, film-coated tablets

Azithromycin Aurobindo 500 mg, film-coated tablets

Azithromycin

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 questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it is prescribed only for you. It may be harmful to others, 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? Then contact your doctor or pharmacist.

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2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
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1. WHAT IS AZITHROMYCIN AUROBINDO AND WHAT IS THIS MEDICINE USED FOR? USED FOR?

Azithromycin Aurobindo belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to treat infections caused by microorganisms such as bacteria.

Azithromycin Aurobindo is used to treat certain infections caused by bacteria sensitive to this medicine, such as:

- chest, throat, or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis), and sinusitis)
- ear infections
- infections of the skin and subcutaneous tissues (such as an abscess or boil)
- infections of the urethra or cervix caused by *Chlamydia trachomatis* (bacteria).

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 azithromycin dihydrate, erythromycin, or any of the antibiotics from the so-called macrolide or ketolide group
- you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine if:

- you have ever had a severe allergic reaction causing swelling of the face and throat occurred, possibly with breathing problems, skin rash, fever, swollen glands or an increase of eosinophils (certain types of white blood cells);
- you develop severe and persistent diarrhea during or after treatment
- you have severe liver or kidney problems
- you have severe heart problems or problems with your heart rhythm, such as long QT syndrome (shown by an electrocardiogram or ECG)
- you have low potassium or magnesium in your blood
- you develop symptoms of another infection
- you are also using an ergotamine derivative such as ergotamine (used for the treatment of migraine); these medicines should not be used simultaneously with azithromycin (see section "are you using any other medicines?")
- you suffer from a certain muscle weakness called myasthenia gravis
- you have neurological problems (problems with your nervous system) or mental (psychiatric) problems
- your newborn baby vomits and becomes irritable during feeding.

Are you using any other medicines?

Tell your doctor or pharmacist if you are using, have used, or might use any other medicines in the near future.

Tell your doctor or pharmacist if you are using one or more of the following medications:

- antacids - used for heartburn and indigestion. You should take Azithromycin Aurobindo at least 1 hour before or 2 hours after the antacid
- ergotamine - (used for the treatment of migraines) should not be taken simultaneously as it can cause serious side effects (such as numbness or tingling in the limbs, muscle cramps, headache, seizures, abdominal pain, or chest pain)
- cholesterol-lowering medications (statins)
- warfarin or similar agents - used to thin the blood. Azithromycin Aurobindo can further thin the blood
- Hydroxychloroquine (used for the treatment of rheumatic diseases or malaria): can cause heart problems.
- cisapride - (used for the treatment of stomach issues) or terfenadine - (used for the treatment of hay fever) should not be taken simultaneously as it can cause serious heart problems (visible on an electrocardiogram or ECG)
- zidovudine or nelfinavir - used for the treatment of HIV infections. Simultaneous use of nelfinavir and Azithromycin Aurobindo may lead to more of the side effects listed in this leaflet
- rifabutin - used for the treatment of tuberculosis (TB)
- quinidine - used for the treatment of heart rhythm disorders
- ciclosporin - used to prevent rejection after an organ transplant. Your doctor will regularly check the ciclosporin level in your blood and adjust the dose if necessary.

Tell your doctor or pharmacist if you are using any of the following agents. Azithromycin Aurobindo can enhance the effects of these agents. Your doctor will adjust the dosage if necessary:

- theophylline - used for breathing problems such as asthma and chronic obstructive pulmonary disease (COPD)
- digoxin - used for the treatment of heart problems
- pimozone - used for the treatment of psychiatric problems.

What should you pay attention to with food and drink?

This medicine can be taken with or without food.

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.

There is insufficient data on the use of azithromycin during pregnancy.

Therefore you should not use this medicine during pregnancy unless explicitly advised by your doctor.

Azithromycin partially passes into breast milk, therefore breastfeeding should not be given during treatment with this medicine.

Driving and using machines

There is no known data on the effect of azithromycin on driving ability or the ability to operate machines. When performing these activities, you should consider that dizziness and seizures may occur with the use of azithromycin.

Azithromycin Aurobindo contains lactose

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

Sodium

Sodium

it is essentially "sodium-free."

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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.

The recommended dose

Adults, children, and adolescents weighing 45 kg or more

500 mg once daily for three days with a total dose of 1500 mg. Your doctor may decide to prescribe the total dose of 1500 mg over a period of 5 days, with 500 mg on the first day and a tablet of 250 mg on days 2 to 5.

Infections of the cervix and urethra caused by Chlamydia trachomatis
A single dose of 1000 mg, to be taken at once.

Children and adolescents weighing less than 45 kg:
The tablets are not recommended. Young people weighing less than 45 kg should use azithromycin in another form.

Patients with kidney or liver problems
You should tell your doctor that you have kidney or liver problems, as it may be necessary for your doctor to adjust the dosage.

Dosage in the elderly
For the elderly, the same dose as for adults can be applied.

The tablet can be divided into equal doses.

Method of administration
The tablets should be taken with ½ glass of water.
The tablets can be taken with or without food.

Have you used too much of this medicine?
If you have taken too much of this medicine, contact your doctor or pharmacist immediately or go to the nearest hospital.

Symptoms of overdose include hearing loss, feeling sick or being sick, vomiting, and diarrhea. In case of overdose, hospitalization may be necessary.

Have you forgotten to use this medicine?
If you have forgotten to take this medicine, do so as soon as possible. However, if it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule. Always consult your doctor or pharmacist if in doubt. Even if you have missed a dose, you must still take all the tablets. This means that the course will last one day longer.

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

If you stop using this medicine
Never stop the treatment with Azithromycin Aurobindo on your own, but consult your doctor first. If the prescribed course is not completed, 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 is affected by it.

If you experience any of the following symptoms of a severe allergic reaction, stop using this medicine and contact your doctor immediately or go to the emergency department of the nearest hospital.

- sudden difficulty breathing, talking, or swallowing
- swelling of the lips, tongue, face, and throat
- severe dizziness or fainting (collapse)
- severe or itchy skin rash, especially if blistering occurs and the eyes, mouth, or genitals are painful.

If you experience any of the following side effects, contact your doctor as soon as possible:

- diarrhea that is severe, persistent, or contains blood, with stomach pain and fever. This may be a sign of a serious bowel inflammation. This can sometimes occur with the use of antibiotics
- yellowing of the skin or whites of the eyes caused by liver problems
- inflammation of the pancreas, causing severe pain in the abdomen and back
- increased or decreased urine output, or traces of blood in the urine.
- skin rash caused by sensitivity to sunlight
- unusual bruising or bleeding
- irregular heartbeat.

These are all serious side effects. You may need urgent medical attention.

Serious side effects are rare (occur in less than 1 in 100 users) or the frequency cannot be determined from the available data.

Other side effects include:

Very common (occur in more than 1 in 10 users)

- diarrhea.

Common (occur in less than 1 in 10 users)

- headache
- nausea (vomiting)
- stomach pain or cramps
- loss of appetite change in the number of white blood cells and the concentration of bicarbonate in the blood.

Uncommon (occur in less than 1 in 100 users)

- thrush (candidiasis) - a fungal infection
- fungal infection
- bacterial infection
- inflammation of the throat (pharyngitis)
- shortness of breath, chest pain, shortness of breath and coughing (respiratory disorder)
- inflammation of the nasal mucosa (rhinitis)
- stomach flu (gastroenteritis)
- inflammation in your vagina (vaginitis)
- pneumonia

- reduction in the number of white blood cells
- angioedema
- hypersensitivity
- lack of appetite (anorexia)
- nervousness
- drowsiness (sleepiness)
- changes in your sense of taste
- feeling of tingling or numbness (paresthesia)
- visual impairment
- having sleep problems (insomnia)
- ear disorder
- dizziness
- spinning sensation (vertigo)
- palpitations
- hot flashes
- shortness of breath
- nosebleed
- inflammation of the stomach lining (gastritis)
- constipation
- passing wind (flatulence)
- difficulty swallowing
- swollen abdomen
- dry mouth
- belching
- mouth ulcer
- increased saliva production
- skin rash
- itching
- inflammation of the skin (dermatitis)
- dry skin
- excessive sweating
- pain, swelling, and reduced movement in the joints (osteoarthritis)
- muscle pain
- back pain
- neck pain
- increase in blood urea level
- painful or difficult urination
- pain in the upper back (kidney pain)
- breakthrough bleeding (spotting)
- testicular disorder
- skin rash with severe itching and bumps (hives, welts)
- chest pain
- facial swelling
- fever
- pain
- fluid retention in the arms and legs (peripheral edema)
- fluid retention in tissue (edema)

- general feeling of discomfort (feeling unwell)
- fatigue
- weakness (asthenia)
- changes in liver enzymes and blood values
- post-procedure complications.

Rare (occur in less than 1 in 1000 users)

- feeling excited, restless (agitation)
- abnormal liver function, yellowing of the skin and whites of the eyes, dark urine, pale stools
- allergic skin reactions such as sensitivity to sunlight
- skin rash characterized by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid).

Unknown (cannot be determined from the available data)

- large intestine infection (pseudomembranous colitis)
- decrease in the number of red blood cells due to destruction (hemolytic anemia)
- decrease in the number of platelets (thrombocytopenia)
- severe allergic reaction (anaphylactic reaction)
- feeling angry or aggressive
- anxiety
- confusion
- perceptions (seeing, hearing, smelling, feeling) of things that are not there (hallucination)
- fainting (syncope)
- attack of unconsciousness with muscle twitching (convulsions)
- reduced sense of touch (hypesthesia)
- feeling hyperactive
- change in your sense of smell (anosmia, parosmia)
- change in your sense of taste (ageusia)
- worsening of a certain form of muscle weakness (myasthenia gravis)
- blurred vision
- reduced hearing including hearing loss, tinnitus
- rapid (ventricular tachycardia) or irregular heartbeat, sometimes life-threatening, changes in heart rhythm found by an electrocardiogram (QT prolongation and torsade de pointes)
- low blood pressure
- inflammation of the pancreas (pancreatitis)
- discoloration of the tongue
- liver failure
- severe allergic skin reactions
- joint pain (arthralgia)
- kidney failure, inflammation in the kidneys.

The following side effects have been reported in preventive treatment against Mycobacterium Avium complex (MAC):

Very common (occur in more than 1 in 10 users)

- diarrhea

- abdominal pain
- feeling sick (nausea)
- flatulence
- abdominal discomfort
- loose stools.

Common (occur in less than 1 in 10 users)

- loss of appetite (anorexia)
- dizziness
- headache
- tingling or numbness (paresthesia)
- changes in sense of smell
- blurred vision
- deafness
- feeling sick (vomiting), stomach pain or cramps, loss of appetite, digestive problems
- skin rash and itching
- joint pain (arthralgia)
- fatigue.

Sometimes (occur in less than 1 in 100 users)

- reduced sense of touch (hypoesthesia)
- hearing loss or ringing in the ears
- palpitations
- liver problems such as hepatitis
- severe form of flushing
- allergic skin reactions such as sensitivity to sunlight, red, scaly and swollen skin
- general feeling of discomfort (feeling unwell)
- weakness (asthenia).

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, www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the packaging after "Exp". It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

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 PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is azithromycin dihydrate.
Azithromycin Aurobindo 250 mg: Each film-coated tablet contains 250 mg azithromycin (as dihydrate).
Azithromycin Aurobindo 500 mg: Each film-coated tablet contains 500 mg azithromycin (as dihydrate).
- The other substances in this medicine are:
Tablet core: calcium hydrogen phosphate, pregelatinized starch (maize starch), sodium croscarmellose, sodium lauryl sulfate, magnesium stearate.
Tablet coating: lactose monohydrate, hypromellose, titanium dioxide (E 171), triacetin.

What does Azithromycin Aurobindo look like and what is in a package?

Film-coated tablet.

Azithromycin Aurobindo 250 mg, film-coated tablets:

White to off-white, oblong, film-coated biconvex tablets, with the inscription "66" on one side and "D" on the other side. The size is 13.5 mm x 6.6 mm.

Azithromycin Aurobindo 500 mg, film-coated tablets:

White to off-white, oval, film-coated biconvex tablets with the inscription "6" and "7" on either side of the score line on one side and "D" on the other side. The size is 17.1 mm x 8.5 mm.

Azithromycin Aurobindo film-coated tablets are available in clear PVC-Aluminium blister packs. Blister packs: 2, 3, 4, 6, and 12 film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN, Baarn

Manufacturer

APL Swift Services Limited

HF26, Hal Far

Industrial Estate, Hal Far

Birzebbugia, BBG 3000

Malta

Registered under:

RVG 117669 - Azithromycin Aurobindo 250 mg, film-coated tablets.

RVG 117670 - Azithromycin Aurobindo 500 mg, film-coated tablets.

This medicine is registered in EEA member states under the following names:

Belgium: Azithromycin AB 250 mg/500 mg film-coated tablets

Czech Republic: Azithromycin Aurovitas 250 mg/500 mg potahované tablety

Netherlands: Azithromycin Aurobindo 250 mg/500 mg, film-coated tablets

Portugal: Azitromicina Aurovitas

Poland: Azithromycin Aurovitas

Spain: Azitromicina Aurovitas 500 mg comprimidos recubiertos con película EFG

This leaflet was last approved in May 2023

More information about this medicine is available on the website of the Medicines Evaluation Board www.cbg-meb.nl.

Transtoyou