

Package leaflet: Information for the patient

Azithromycin ABR 500 mg capsules, hard

Azithromycin ABR

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Azithromycin ABR is and what it is used for
2. What you need to know before you use Azithromycin ABR
3. How to use Azithromycin ABR
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1. What Azithromycin ABR is and what it is used for

Azithromycin ABR contains the macrolide antibiotic Azithromycin ABR. It is active against a large number of pathogens causing some common diseases in humans.

It is used in adults and children to treat infections caused by Azithromycin ABR sensitive bacteria and other microorganisms, such as:

- inflammation of the throat and tonsils, sinuses, middle ear;
- bronchitis, some types of pneumonia;
- skin and soft tissue infections: moderate form of acne, erythema chronica migraine (first stage of Lyme disease), red wind (erysipelas), bacterial skin infections (impetigo, secondary pyoderma);
- sexually transmitted diseases caused by a micro-organism called chlamydia.

2. What you need to know before you use Azithromycin ABR

Do not take Azithromycin ABR

- if you are allergic to Azithromycin ABR or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to erythromycin or other antibiotics in the macrolide and ketolide group.

Warnings and precautions

Talk to your doctor or pharmacist before taking Azithromycin ABR.

You should talk to your doctor if:

- you have or have had liver disease in the past.
Your doctor will decide whether it is necessary to monitor the condition of your liver or to stop treatment with this medicine.
- you have had diarrhea when taking antibiotics.

If you develop diarrhoea or loose stools during or after treatment with this medicine, contact your doctor and do not take any other medicines before consulting your doctor. Tell your doctor if the diarrhoea persists.

- you have or have had kidney disease in the past.
- you have heart problems or complaints.

Tell your doctor immediately if you feel your heart beating in your chest or other similar symptoms, or get dizzy or faint while taking this medicine.

- You have myasthenia gravis (a condition that causes some muscles to become weak).
- You are currently taking medicines to treat migraine containing ergot derivatives, for example ergotamine. These medicines should not be taken with Azithromycin ABR at the same time, as there is a possibility of the so called ergotism (appearance of bruising on the limbs, limping).

It is important to know that serious allergic reactions (rarely life-threatening) such as swelling of the face, lips, tongue and/or throat, shortness of breath, wheezing may occasionally occur with treatment with this medicine.

Some may reoccur because of prolonged drug retention in tissues.

If you experience or suspect allergic reactions, stop taking the medicine **immediately** and contact your doctor.

Azithromycin ABR capsules are not suitable for use in children under 45 kg due to inability to accurate dosing.

Other medicines and Azithromycin ABR

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

It is especially important to tell your doctor if you are taking:

- medicines that can affect heart rhythm and conduction (lead to prolongation of the QT interval in the cardiogram)

Serious and difficult-to-treat arrhythmia may occur.

- medicines to reduce the acidity of the stomach, etc. antacid products

The time between the individual intake should be no less than 2 hours.

- cyclosporine (suppresses rejection of organ or bone marrow after transplantation)

The physician needs to evaluate the benefit of co-administration of Azithromycin ABR with ciclosporin. In patients where it is necessary, plasma levels of cyclosporine should be monitored and, if required, the dose adjusted.

- warfarin, coumarin anticoagulants (reduce blood clotting)

There is an increased risk of bleeding during concomitant administration of Azithromycin ABR.

Your doctor may decide that prothrombin time or other laboratory parameters should be controlled.

- digoxin (used to treat heart disease) and colchicine (used to treat gout and familial Mediterranean fever)

The levels of digoxin and colchicine in the blood with concomitant administration of Azithromycin ABR may increase.

- ergotamine and other ergot derivatives

It is possible to develop an ergot with limb bruising, limping (see Warnings and Precautions).

- nelfinavir

Co-administration with Azithromycin ABR results in an increase in the Azithromycin ABR concentration.

- rifabutin (antibiotic)

It is possible to reduce the number of white blood cells.

Azithromycin ABR with food, drinks and alcohol

Azithromycin ABR should be taken at least 1 hour before or 2 hours after a meal.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There are insufficient and well-controlled studies in pregnant women. During pregnancy, Azithromycin ABR should be used only in the absence of another alternative.

It is not known whether Azithromycin ABR is excreted in breast milk. Azithromycin ABR should therefore be used in breast-feeding women only if there is no other alternative.

Your doctor will consider whether you may be treated with Azithromycin ABR if you are pregnant or breast-feeding. He/she will evaluate the benefit to your health and risk for your baby.

Driving and using machines

There is no evidence of an adverse effect of Azithromycin ABR on the ability to drive and use machines.

Azithromycin ABR contains lactose monohydrate and azorubine

This product contains lactose (milk sugar) as an excipient and is therefore unsuitable for people with congenital or acquired intolerance to some sugars. If you have been told by your doctor that you have such intolerance, consult with your doctor before taking this product.

The gelatin capsule contains azorubin, carmoisine (E122), which can cause allergic reactions.

3. How to take Azithromycin ABR

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and children under 45 kg body weight is:

- 1 capsule daily for 3 days for inflammation of the throat, tonsils, middle ear, bronchitis, pneumonia.
- 2 capsules as a single dose for sexually transmitted diseases caused by the chlamydia microorganism.

Your doctor will determine the appropriate dose and regimen for treating your acne or other infections of the skin and soft tissues.

Azithromycin ABR capsules are not suitable for use in children under 45 kg due to inability of accurate dosing.

If you have kidney or liver disease, your doctor may prescribe treatment with doses other than those indicated.

Method of administration

Azithromycin ABR capsules should be taken as a whole, once a day. As with some other antibiotics, the product should be taken at least one hour before or two hours after a meal.

If you take more Azithromycin ABR than you should

If you have taken more than the prescribed dose, contact your doctor immediately or go to the nearest hospital.

The usual symptoms of an overdose of antibiotics in this group include reversible hearing loss, nausea, vomiting and diarrhoea.

Your doctor will decide if you need any treatment if you have taken more than the prescribed dose.

If you forget to take Azithromycin ABR

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for forgotten dose. Take the next dose at the usual time.

If you stop taking Azithromycin ABR

Do not stop taking your capsules even if you feel better until your doctor tells you to stop. If you stop taking the medicine too soon, the infection may resume or your condition may get worse.

If you have any further questions on the use of this medicine, talk to your doctor, pharmacist or nurse.

4. Possible side effects

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

Contact your doctor **immediately** if you experience any of the following:

- sudden wheezing, difficulty in breathing, swelling of the eyelids, face or lips, rash and itching (especially all over the body);
- severe or prolonged diarrhea that contains blood or mucus during or after cessation of antibiotic treatment, as this may be a sign of a serious inflammation of the intestine;
- severe skin rash, accompanied by redness and formation of flakes and blisters;
- rapid or uneven heartbeats;
- low blood pressure;
- serious skin reactions:
 - blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome);
 - blistering of the skin, such as a severe skin reaction (toxic epidermal necrolysis);
 - skin rash of small itchy red pimples, accompanied by other common symptoms such as fever, swollen glands and increased number of eosinophils (a type of white blood cell) (drug reaction with eosinophilia and systemic symptoms (DRESS));
 - Skin eruption characterized by rapid onset of areas of red skin streaked with small pustules (small blisters filled with white/yellow fluid) (Acute Generalized Eczematous Pustulosis (AGEP)).

Stop taking Azithromycin ABR if you develop these skin symptoms and contact your doctor or seek immediate medical attention.

The following side effects are possible with Azithromycin ABR:

Very common (may affect more than 1 in 10 people taking the product) - abdominal pain, diarrhoea, nausea, increased flatulence and bloating.

Common (may affect at least 1 in 100 and less than 1 in 10 people taking the product) - transient loss of hearing, vomiting, indigestion, rash, itching, loss of appetite, dizziness, headache, tingling of the hands and feet, change in taste, impaired vision, joint pain, fatigue, decreased number of lymphocytes (a type of white blood cell), increased number of eosinophils (a type of white blood cell), decreased bicarbonate level in the blood.

Uncommon (may affect at least 1 in every 1000 and less than 1 in 100 people taking the product) - fungal infections in the mouth and vagina, decrease in the number of all white blood cells, severe allergic reaction that causes swelling of the face or throat, nervousness, decreased sensitivity to touch, drowsiness, insomnia, impaired hearing, ringing in the ears, shaking, gastritis, constipation, liver inflammation, Stevens-Johnson syndrome (a severe disease accompanied by blistering of the skin, mouth, eyes and genital organs), photosensitivity (increased skin sensitivity to sunlight), urticaria (hives), chest pain, oedema, malaise, weakness, elevated values of some laboratory blood tests (liver enzymes, bilirubin, urea, creatinine), altered potassium levels in the blood .

Rare (may affect at least one in 10,000 and less than one in every 1,000 people taking the product) - anxiety, dizziness or vertigo, liver function disorder, skin eruption characterized by rapid onset of red skin with small pustules (small blisters filled with white/yellow fluid), skin rash of small itchy red pimples accompanied by other common symptoms such as fever, swollen glands, and eosinophils (a type of white blood cell).

Not known (frequency can not be estimated from the available data) - aggression or anxiety, hyperactivity, muscle weakness, low blood pressure, heart rhythm abnormalities, loss or disturbance of the sense of smell, loss of taste, discolouration of the tongue, inflammation of the pancreas, abdominal pain accompanied by prolonged diarrhoea and fever, pseudomembranous colitis, kidney inflammation or kidney failure, jaundice or hepatic failure (sometimes life-threatening), reduced red blood cell count and or platelets, severe skin reactions with the formation of flakes and blistering of the skin (toxic epidermal necrolysis, erythema multiforme), changes in the electrocardiogram.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azithromycin ABR

Keep this medicine out of the sight and reach of children.
Do not store above 25 °C.

Do not use Azithromycin ABR after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Azithromycin ABR if you notice changes in the appearance of the capsules.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Azithromycin ABR contains

- The active substance in one capsule is Azithromycin ABR dihydrate, equivalent to Azithromycin ABR 500 mg
- The other ingredients are: sodium lauryl sulfate, lactose, monohydrate/maize starch (85:15), magnesium stearate.
The gelatin capsule contains titanium dioxide (colorant E171), gelatin, azorubine/carmoisine (colorant E122).

What Azithromycin ABR looks like and contents of the pack

Hard gelatin capsules.

3 (three) capsules in a blister.

1 (one) blister with a package leaflet: information for the patient in a carton box.

Marketing Authorisation Holder

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Manufacturer

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For more information about this product, please contact the local representative of the Marketing Authorisation Holder:

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