

PACKAGE LEAFLET: INFORMATION FOR THE USER

AZITROM-REPLEK **Azithromycin** **500 mg film-coated tablets**

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What AZITROM-REPLEK is and what it is used for

AZITROM-REPLEK belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to treat infections caused by micro-organisms like bacteria.

AZITROM-REPLEK is used for the treatment of certain infections caused by bacteria that are sensitive to it, such as:

- Chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis).
- Ear infections.
- Skin and soft tissue infections, with exception of infected burn wounds e.g. - infection of the tube that carries urine from the bladder (urethra) or the neck of the womb (cervix) caused by *Chlamidia trachomatis* (bacteria).

2. Before you take AZITROM-REPLEK

Do not take AZITROM-REPLEK if:

- You are allergic to azithromycin dihydrate, erythromycin or any macrolide or ketolide antibiotic.
- You are allergic to any of the other ingredients of this medicine listed in section 6.

Take special care with AZITROM-REPLEK

Check with your doctor or pharmacist before taking your medicine if:

- You have severe liver or kidney problems.
- You have severe heart problems or problems with your heart beat such as long QT syndrome (shown on an electrocardiogram or ECG machine).
- Your blood levels of potassium or magnesium are too low.
- You develop signs of another infection.
- You are taking any ergot derivatives such as ergotamine (to treat migraine) as these medicines should not be taken together with azithromycin (see section "Taking other medicines").
- You have a certain type of muscle weakness called myasthenia gravis.
- You have nervous (neurological) or mental (psychiatric) problems.

Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Antacids - used for heartburn and indigestion. Azithromycin should be taken at least 1 hour before or 2 hours after the antacid.
- Ergotamine - (used for migraine) should not be taken at the same time as serious side effects may develop (with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain).
- Warfarin or similar medicines - used to thin the blood. Azithromycin can thin the blood even more.
- Cisapride - (used to treat stomach problems) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine).
- Terfenadine - (used to treat hay fever) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine).
- Zidovudine or nelfinavir - used to treat HIV infections. Taking nelfinavir with azithromycin may mean that you get more of the side effects listed in this leaflet.
- Rifabutin - used to treat tuberculosis (TB).
- Quinidine - used to treat heart rhythm problems.
- Cyclosporin - used to stop your body rejecting an organ transplant. Your doctor will regularly check your blood levels of cyclosporin and may change your dose.

Tell your doctor or pharmacist if you are taking any of the following medicines. Azithromycin can make the effects of these other medicines stronger. Your doctor may change your dose:

- Triazolam, midazolam (sedatives).
- Alfentanil - a painkiller used e.g. during operations.
- Theophylline - used for breathing problems such as asthma and chronic obstructive pulmonary disease (COPD).
- Digoxin - used to treat heart problems.
- Astemizol - used to treat hay fever.
- Pimozide - used to treat mental health problems.

Taking AZITROM-REPLEK with food and drink

This medicine can be taken with or without food.

Pregnancy and breast-feeding

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 taking this medicine.

There is insufficient information available about the use of azithromycin during pregnancy. Therefore you should not use AZITROM-REPLEK during pregnancy, unless explicitly advised by your doctor.

Azithromycin is partially passed through the mother's milk, therefore AZITROM-REPLEK should not be used if you are breastfeeding.

Driving and using machines

There are no data available about the influence of azithromycin on the ability to drive or operate machines.

However azithromycin tablets may cause dizziness and seizures so make sure you are not affected before driving or operating machinery.

3. How to take AZITROM-REPLEK

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

For adults and young people with a body weight of 45 kg or over

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

For infections of the neck of the womb and urethra caused by Chlamydia trachomatis

One dose of 1000 mg, to be taken one time.

Children and adolescents under 45 kg

The tablets are not recommended. Young people with a body weight of less than 45 kg should use other forms of this medicine.

Patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

Dosage for elderly

For elderly the same dosage as for adults applies.

Administration

The tablets should be taken with $\frac{1}{2}$ glass of water.

If you take more AZITROM-REPLEK than you should

If you have taken too much AZITROM-REPLEK, contact your doctor, pharmacist or go to your nearest hospital at once.

Symptoms of overdose are loss of hearing, feeling sick or being sick and diarrhoea. In case of overdosage admission into hospital may be necessary.

If you forget to take AZITROM-REPLEK

If you forget to take AZITROM-REPLEK, take your dose as soon as possible. If it is almost time for the next dose, just skip that dose and take the next one when it is due. If in doubt, please contact your doctor or pharmacist. If you have to skip a dose, still take all of your tablets. This means that you will finish your course a day later.

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

If you stop taking AZITROM-REPLEK

Never stop the treatment with AZITROM-REPLEK on your own, but first discuss this with your doctor. If the prescribed treatment is not completely finished, the infection may come back again.

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

4. Possible side effects

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

If you have any of the following symptoms of a severe allergic reaction stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden difficulty in breathing, speaking and swallowing.
- Swelling of the lips, tongue, face and neck.
- Extreme dizziness or collapse.
- Severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs.

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

- Diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation. This is something that can rarely happen after taking antibiotics.

- Yellowing of the skin or whites of the eyes caused by liver problems.
- Inflammation of the pancreas, which causes severe pain in the abdomen and back.
- Increased or reduced urine output, or traces of blood in your urine.
- Skin rash caused by sensitivity to sunlight.
- Unusual bruising or bleeding.
- Irregular heart beat.

These are all serious side effects. You may need urgent medical attention. Serious side effects are uncommon (may affect up to 1 in 100 people) or the frequency cannot be estimated from the available data.

Other side effects include:

Very common (may affect more than 1 in 10 people):

- Diarrhoea.
- Abdominal pain.
- Feeling sick (nausea).
- Loose wind (flatulence).

Common (may affect up to 1 in 10 people)

- Lack of appetite (anorexia).
- Feeling dizzy.
- Headache.
- Sensation of pins and needles or numbness (paraesthesia).
- Changes in your sense of taste and smell.
- Visual impairment.
- Deafness.
- Being sick (vomiting), stomach pain or cramps, loss of appetite, problems digesting your food.
- Skin rashes and itching.
- Joint pain (arthralgia).
- Fatigue.
- Change in the quantity of the white blood cells and the concentration of bicarbonate in the blood.

Uncommon (may affect up to 1 in 100 people):

- Thrush (candidiasis) - a fungal infection.
- Inflammation inside your vagina (vaginitis).
- Reduction in the number of white blood cells.
- Angioedema.
- Hypersensitivity.
- Nervousness.
- Reduced sense of touch (hypoesthesia).
- Feeling drowsy (somnolence).
- Having difficulty sleeping (insomnia).
- Hearing loss or ringing in your ears.
- Palpitations.
- Inflammation of the lining of the stomach (gastritis).
- Constipation.
- Liver problems such as hepatitis.
- Allergic skin reactions such as being sensitive to sunlight, red, flaking and swollen skin.
- Urticaria.
- Chest pain.
- Swelling (oedema).

- Malaise.
- Weakness.
- Change in liver enzyme levels and blood levels.

Rare (may affect up to 1 in 1,000 people):

- Feeling agitated, feeling of unreality to the self and own feeling.
- Spinning sensation (vertigo).
- Abnormal hepatic function.
- Allergic skin reactions.
- Kidney problems.

Not known (frequency cannot be estimated from the available data):

- Gut (colon) infection (pseudomembranous colitis).
- Reduced number of red blood cells due to destruction (haemolytic anaemia); reduction in number of platelets.
- Anaphylactic reaction.
- Feeling angry, aggressive.
- Fainting (syncope).
- Fits (convulsions).
- Feeling hyperactive.
- Change in your sense of smell (anosmia, parosmia).
- Change in your sense of taste (ageusia).
- Exacerbation or aggravation of muscle weakness (myasthenia gravis).
- Rapid (ventricular tachycardia) or irregular heart beat, sometimes being life-threatening, changes of the heart rhythm found by an electro-cardiogram (QT prolongation and torsade de pointes).
- Low blood pressure.
- Inflammation of the pancreas (pancreatitis).
- Your tongue and teeth changes colour.
- Allergic skin reactions.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store AZITROM-REPLEK

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use your medicine after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

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.

6. Further information

What AZITROM-REPLEK contains

Each film coated tablet contains azithromycin dihydrate equivalent to 500 mg azithromycin.

The other ingredients are: starch pregelatinized, copovidone, low-substituted hydroxypropyl cellulose, calcium hydrogen phosphate anhydrous, crospovidone, talc, magnesium stearate, sodium laurilsulphate, hypromellose, macrogol 6000, titanium dioxide, dimeticone.

What AZITROM-REPLEK looks like and contents of the pack

AZITROM-REPLEK 500 mg film-coated tablets are uniform, oblong, biconvex, white film-coated tablets, with score line on one side.

Pack size:

Box with 3 film coated tablets of 500 mg in blister.

Dispensing status

Prescription only medicine (POM).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: REPLEK FARM Ltd.-Skopje, 188 Kozle str., 1000 Skopje, Republic of Macedonia

Manufacturer: REPLEK FARM Ltd.-Skopje, 188 Kozle str., 1000 Skopje, Republic of Macedonia

Date of last revision of the text

05/2016