

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Azithromycin Inovamed 250 mg Capsules

Each capsule contains:

Azithromycin (as dihydrate) 250 mg

Inactive and allergenic ingredients in the preparation – see section 6 “Further information” and section 2 “Important information about some of the ingredients in this medicine”.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

Azithromycin Inovamed 250 mg capsules is intended for children weighing more than 45 kg.

1) WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of infections caused by bacteria susceptible to the medicine in the respiratory tract (bronchitis, pneumonia, sinusitis, pharyngitis and tonsillitis), skin and soft tissues, ears and genital infections due to *Chlamydia trachomatis*.

Therapeutic group:

Macrolide antibiotic.

2) BEFORE USING THE MEDICINE

Do not use the medicine if:

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| X you are sensitive (allergic) to the active ingredient (azithromycin) or any of the additional ingredients contained in the medicine that are listed in section 6. |
| X you have a history of allergic reaction to the preparation or to erythromycin or to any other antibiotic from the macrolide or ketolide group. |
| X you have suffered in the past from jaundice resulting from bile flow obstruction in the liver (cholestatic jaundice) or from impaired liver function that occurred following the use of azithromycin. |

Special warnings regarding use of this medicine

Do not use the medicine without consulting a doctor before starting treatment if you:

- have pneumonia.
- have cystic fibrosis.
- have known or suspected bacterial infection in the blood.
- have a disease that causes muscle weakness (myasthenia gravis).
- have liver or kidney function problems.
- have an irregular heartbeat, particularly from a problem called “QT prolongation”.
- have any other medical problems.
- are pregnant or breastfeeding, planning to become pregnant or to breastfeed – see “Pregnancy and breastfeeding” section.

Children and adolescents

Azithromycin Inovamed 250 mg capsules is intended for children weighing more than 45 kg.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular if you are taking:

- digoxin.
- antacids containing aluminum or magnesium.
- anticoagulants (e.g., warfarin) – you should be monitored for coagulation indices.
- nelfinavir (for treatment of AIDS) – since the combination may increase the levels of azithromycin in the blood.
- phenytoin.
- colchicine.
- hydroxychloroquine or chloroquine. Taking these medicines together with Azithromycin Inovamed 250 mg may increase the chance of developing side effects that affect the heart.

Use of the medicine and food

Take one hour before a meal or two hours after a meal.

Pregnancy and breastfeeding

Do not use the medicine without consulting a doctor before starting treatment if you are pregnant or planning to become pregnant. It is not known whether azithromycin will harm your unborn baby.

Do not use the medicine without consulting a doctor before starting treatment if you are breastfeeding or planning to breastfeed. Azithromycin Inovamed 250 mg has been reported to pass into breast milk. Consult with the doctor regarding the best way to feed your baby while being treated with Azithromycin Inovamed 250 mg.

Important information about some of the ingredients in this medicine

This medicine contains less than 23 mg sodium per capsule, and is therefore considered to be sodium-free.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen with the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Adults:

The dosage recommended for the treatment of sexually transmitted diseases caused by *Chlamydia trachomatis* is 1000 mg as a single dose.

For all other indications, the recommended dosage is 500 mg once a day for 3 days. An alternative dosage method is dividing it over 5 days, with 500 mg taken once on the first day, and 250 mg taken once a day on days 2 to 5.

Children:

For children over 45 kg body weight and adults, including elderly patients, the recommended dosage is 500 mg once a day for 3 days.

For noncomplicated infections in the genitals caused by *Chlamydia trachomatis*, the recommended dosage is 1000 mg as a single dose. In general, the total dosage for treatment of children is 30 mg/kg - divided as 10 mg/kg once a day for 3 days or divided over 5 days, as 10 mg/kg once a day on the first day, and 5 mg/kg once a day on days 2-5.

As an alternative to this dosage, children with an acute middle ear infection can be treated with a single dose of 30 mg/kg.

For streptococcal pharyngitis: The recommended dosage is 10 mg/kg or 20 mg/kg once a day for 3 days.

Do not exceed a daily dosage of 500 mg per day.

Azithromycin Inovamed 250 mg capsules is intended for children weighing more than 45 kg. It should be noted that for patients who need to be treated with dosages that can not be achieved with Azithromycin Inovamed 250 mg capsules, there are preparations in other delivery forms (e.g., suspension) which contain the active ingredient azithromycin, from other companies. In such cases, consult the doctor and read the patient leaflet of these preparations.

Special populations:

Elderly: The recommended dosage for adults is also given to elderly patients. Elderly patients may be more susceptible compared to younger patients, to develop Torsade de pointes - a ventricular rhythm disturbance.

Kidney function disturbances: There is no need for dosage adjustments for mild to moderate kidney function disturbances (GFR 10-80 ml/min). Exercise caution if administering to patients with a severe kidney function disturbance (GFR < 10 ml/min).

Liver function disturbances: The same dosage used for patients with normal liver function can be used for patients with mild to moderate liver dysfunction. Since azithromycin is metabolized in the liver and is excreted via the bile, the medicine should not be given to patients with severe liver disease.

Take the capsule whole. Do not open and disperse the contents of the capsule, as the effect of this mode of administration has not been assessed.

Do not give capsules to children weighing less than 45 kg.

Do not exceed the recommended dosage.

If you accidentally took a higher dose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take this medicine at the intended time, take a dose as soon as you remember. However, if it is time for your next dose, skip the forgotten dose and take the next dose as usual. Do not under any circumstances take a double dose to make up for the forgotten dose!

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor.

Do not skip a dose of Azithromycin Inovamed 250 mg or stop taking the medicine, even if you start to feel better, until the treatment is completed, except in cases in which you have a serious allergic reaction or your doctor has instructed you to stop taking the medicine (see section 4 “Side Effects”). **If you skip taking doses or fail to complete the entire treatment with Azithromycin Inovamed 250 mg,** the result may be that the treatment is not sufficiently effective and that it will be more difficult to treat your infection. Completing the entire treatment will lower the risk of the bacteria developing resistance to Azithromycin Inovamed 250 mg.

If the bacteria develop resistance to Azithromycin Inovamed 250 mg, then Azithromycin Inovamed 250 mg and other antibiotic medicines may not be effective in the future.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS

As with any medicine, use of Azithromycin Inovamed 250 mg may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Serious side effects

Stop treatment and contact the doctor immediately in the event of:

- a serious allergic reaction. Allergic reactions can occur after taking azithromycin, the active ingredient in Azithromycin Inovamed 250 mg, even after taking only one dose. Stop treatment and contact the doctor immediately if you experience one or more of the following symptoms:
 - difficulty breathing or swallowing
 - swelling of the lips, tongue or face
 - throat tightness, hoarseness
 - rapid heartbeat
 - fainting
 - skin rash (hives)
 - new onset of fever and swollen lymph nodes

Stop using Azithromycin Inovamed 250 mg at the first sign of skin rash, and contact the doctor immediately. A rash may be a sign of a more serious reaction to Azithromycin Inovamed 250 mg.

- Liver damage (hepatotoxicity). Stop using the medicine and contact the doctor immediately in the event of yellowing of the skin or white part of the eyes, dark-colored urine, nausea or vomiting, abdominal pain or tenderness, fever, weakness, itching, excessive fatigue, loss of appetite, change in the color of bowel movements. These can be signs of a serious reaction to Azithromycin Inovamed 250 mg (hepatotoxicity).

Contact the doctor immediately in the event of:

- Serious heart rhythm changes that may be life-threatening, including cardiac arrest (heart stops beating), prolongation of the QT interval, torsades de pointes – ventricular rhythm disturbance, a feeling that your heart is pounding or speeding up (palpitations), chest discomfort or irregular heartbeat. Contact the doctor immediately if you or your child experience a rapid or irregular heartbeat, get dizzy or faint. Azithromycin Inovamed 250 mg may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and be very dangerous. The risk of this is higher among the elderly, in patients with a family history of prolonged QT interval, in patients with a low blood potassium level and in patients taking certain medicines to control the heart rhythm (antiarrhythmics).
- Worsening of myasthenia gravis (a disease that causes muscle weakness). Antibiotics like Azithromycin Inovamed 250 mg may worsen myasthenia gravis symptoms, including muscle weakness and breathing problems.
- Watery diarrhea, prolonged diarrhea or bloody stools. You may experience cramping and fever. These may occur after you have completed the treatment with Azithromycin Inovamed 250 mg.

Common side effects:

The most common side effects of Azithromycin Inovamed 250 mg are:

- loose stools or diarrhea
- nausea
- abdominal pain
- vomiting
- vaginal inflammation
- rash
- indigestion
- headaches

Additional side effects:

Chest pain, rapid heartbeat, flatulence, black stools, jaundice, kidney inflammation, fungal infection, dizziness, vertigo, somnolence, fatigue, itchiness, photosensitivity, subcutaneous swelling, constipation, anorexia, inflammation of the small intestine, gastritis, anemia, reduced white blood cell (leukocyte) count, agitation, nervousness, insomnia, fever, facial edema, malaise, pain, cough, pharyngitis, runny nose, eczema, sweating, inflammation of the eye.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking the link “Report side effects of drug treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5) HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C, in the original packaging.

6) FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Cellulose microcrystalline, maize starch, magnesium stearate, sodium laurilsulfate.

Hard gelatin capsule: gelatin, titanium dioxide, edible black color printing ink (Shellac E904, black iron oxide E172, potassium hydroxide E525).

What the medicine looks like and the contents of the package: Capsule with opaque white cap and body, imprinted in black with “250” on cap and body.

The capsules are packaged in blister packs, which are packaged in carton boxes.

The medicine is supplied in the following packaging as detailed: Carton packages containing trays/blister packs with 2, 4 or 6 capsules. The number of blister packs in each package may vary depending on the package size. The number of capsules in the package appears on the carton package. Not all package sizes may be marketed.

Registration holder: Inovamed Ltd., P.O.B. 62, Even Yehuda.

Manufacturer: Jubilant Generics, Noida, Uttar Pradesh, India. Revised in July 2024.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 160 55 35154.