

**Patient leaflet according to Pharmacists' Regulations (Preparations) - 1986**

**This medicinal product is dispensed with a doctor's prescription only**

**Name, form and strength of the medicinal product**

**Azithromycin Inovamed 250 mg**

Capsules

**Each capsule contains:**

Azithromycin (as Dihydrate) 250 mg

Inactive ingredients and allergenics in the preparation are listed in section 6.

**Read this entire leaflet carefully before using this medicinal product.** This leaflet contains concise information about the medicinal product. If you have any additional questions, please contact your physician or pharmacist.

This medicinal product was prescribed as a treatment for 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. This medicinal product is not usually intended for children and babies under 6 months of age.

**1) What is this medicinal product used for?**

Treatment of infections caused by bacteria susceptible to the medicinal product in the respiratory system (bronchitis, pneumonia, sinusitis, laryngitis etc.), skin and soft tissues, ears and infections in the genitals caused by *Chlamydia trachomatis*.

**Therapeutic group:**

Macrolide antibiotic

**2) Before using this medicinal product**

**X** Do not use this medicinal product if:

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|---|---|
| X | If you are sensitive (allergic) to the active ingredient (Azithromycin) or to any of the other ingredients contained in the medicinal product listed in section 6.      |
| X | You have a history of allergic reactions to the medicinal product or to erythromycin or to other antibiotics from the macrolide or ketolide groups.                     |
| X | You have previously suffered from jaundice due to the blockage of bile flow in the liver (cholestatic jaundice) or liver dysfunction following the use of Azithromycin. |

Do not use the medicinal product without consulting your physician before starting the treatment if you:

- Suffer from pneumonia.
- Suffer from cystic fibrosis.
- Suffer or there is a suspicion of bacterial infection in the blood.
- Suffer from a disease that causes muscle weakness (myasthenia gravis).
- Suffer from impaired function of the liver or the kidneys.
- Suffer from irregular heart rhythm mainly due to a problem called "QT segment extension".
- Suffer from other medicinal problems.

**If you are taking or have recently taken any other medicinal products, including non-prescription medicinal products and nutritional supplements, please notify your physician or pharmacist.** In particular, you should notify your physician or pharmacist if you are taking:

- Digoxin.
- Anti-acid medicinal products containing aluminum or magnesium.
- Anti-coagulant medicinal products (e.g. Warfarin) – coagulation indices must be monitored.
- Nelfinavir (AIDS treatment) – since the combination may cause blood Azithromycin levels to rise.
- Phenytoin
- Colchicine

### **Use of the medicinal product and food**

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

### **Pregnancy and breastfeeding**

Do not use the medicinal product without consulting the physician before starting treatment, if you are pregnant or planning to become pregnant. It is unclear whether Azithromycin may cause damage to your fetus.

Do not use the medicinal product without consulting the physician before starting the treatment, if you are breastfeeding or planning to breastfeed. It was reported that Azithromycin infiltrates to mother's milk. Consult your physician on the best way of feeding your baby while being treated with Azithromycin Inovamed 250mg.

## **3) How should you use this medicinal product?**

Always use this medicinal product according to your physician's instruction. Check with your physician or pharmacist if you are not sure. The dosage and treatment method will be determined by your physician only.

The capsules should not be given to children weighing less than 45kg.

### **Do not exceed the recommended dose!**

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

If you took an overdose, or if a child has accidentally swallowed the medicinal product, immediately proceed to a physician or a hospital emergency room and bring this medicinal product package with you.

**If you forgot to take this medicinal product on time, do not take a double dose.** Take the following dose at the regular time and consult your physician.

Adhere to the treatment regimen according to your physician's instructions.

Even if your health has improved, do not stop taking this medicinal product without consulting your physician.

Do not skip a dose of Azithromycin Inovamed 250mg or do not stop taking the medication even if you start to feel better, until completing the entire course of treatment, except if you suffer severe allergic reaction or your physician has instructed you to stop taking the

medicinal product (see section 4 “Side Effects”). If you skip doses or fail to complete the entire course of treatment with Azithromycin Inovamed 250mg, treatment may fail to have the desired influence and your infection may be more difficult to treat. Completion of the entire treatment will reduce the risk of bacteria developing resistance to Azithromycin Inovamed 250 mg.

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

Do not take medications in the dark! Check the label and dose every time you take the medicinal product. Wear glasses if necessary.

If you have additional questions regarding use of the medicinal product, consult your physician or pharmacist.

#### **4) Side effects**

As with any medicinal product, use of this medicinal product may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

#### **Discontinue use and refer to your physician immediately in the following cases:**

- Severe allergic reaction. Allergic reactions may occur following the use of Azithromycin, even after taking a single dose. Stop the treatment and refer to your physician immediately if you notice one or more of the following symptoms:
  - Difficulty in breathing or swallowing.
  - Swelling in lips, tongue or face.
  - Narrowing of throat, hoarseness.
  - Rapid heart rhythm.
  - Fainting.
  - Rash.
  - New appearance of temperature and swelling of the lymph glands.

Immediately upon noticing signs of skin rash, stop the use of Azithromycin Inovamed 250 mg and refer to your physician. Rash may signify a more severe reaction to Azithromycin Inovamed 250 mg.

#### **Contact your physician immediately in the following cases:**

- Liver damage. Stop using the medicinal product and refer to your physician immediately in case of yellowing of the skin or the white of the eye, dark colored urine, nausea or vomiting, abdomen pain or sensitivity to touch, temperature, weakness, itching, fatigue, poor appetite, changes in feces color. They may be the signs of severe reaction to Azithromycin Inovamed 250mg (liver damage).
- Severe changes in heart rhythm (extended QT segment and torsades de pointes – abnormal ventricular rhythm). If you sense a change in your heart rhythm (quick or irregular) or if you feel weak and dizzy, Azithromycin Inovamed 250 mg may cause a rare cardiac condition called QT segment extension. This condition may cause irregular heart rhythm and is extremely dangerous. The risk is higher among the elderly, patients with a family history of QT segment extension, patients with low blood phosphate level, patients taking certain heart rhythm control medications (anti-arrhythmic drugs).

- Worsening of myasthenia gravis (disease that causes muscle weakness). Antibiotics such as Azithromycin may worsen the symptoms of myasthenia gravis, including muscle weakness and respiratory problems.
- Watery diarrhea, continuous diarrhea or blood in feces. You may experience cramps and temperature. They may appear after treatment with Azithromycin Inovamed 250 mg ends.

#### **Common side effects:**

The most common side effects of Azithromycin Inovamed 250 mg are: soft stools or diarrhea, nausea, abdominal pain, vomiting, vaginal inflammation, rash, indigestion, headaches.

#### **Additional side effects:**

Chest pain, rapid heartbeats, flatulence, black stools, jaundice, kidney inflammation, fungal infection, dizziness, vertigo, sleepiness, tiredness, itchiness, sensitivity to light, subcutaneous swelling, constipation, anorexia, inflammation of the small intestine, gastric inflammation, anemia, decreased white blood cell (leukocytes) count, restlessness, nervousness, insomnia, fever, facial edema, malaise, pain, cough, throat inflammation, runny nose, eczema, sweating, eye inflammation.

If any of the side effects worsens or if you are suffering from a side effect not mentioned in this leaflet, consult your physician.

You may report side effects to the Ministry of Health by clicking the link “report side effects from medicinal treatment” in the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) referring you to an online form for reporting side effects, or by entering the following link: <https://sideeffects.health.gov.il>

### **5) How to store this medicinal product?**

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

Do not induce vomiting without being explicitly instructed by your physician to do so.

Do not use this medicinal product after its expiry date displayed on the package. The expiry date refers to the last day of that month.

**Storage conditions:** Store at temperatures below 25°C in the original package

### **6) Additional information**

In addition to the active ingredient, this medicinal product also contains: Cellulose Microcrystalline, Maize Starch, Magnesium Stearate, Sodium Lauryl sulfate.

Hard gelatin capsule: Gelatin, Titanium Dioxide (E = 171), Edible Black Color Printing Ink.

#### **What does this medicinal product look like, and what does the package contain:**

Capsule with white body and cap. “250” is printed in black on the body and cap.

The capsules are packed in blisters placed in cardboard boxes

The medicinal product is supplied in the following package:

Cardboard boxes containing blisters with 2, 4 or 6 capsules. The number of blisters per package depends on the size of the package. The number of capsules per package is written on the cardboard box.

Not all packages may be marketed.

**Registration holder:** Inovamed Ltd., VAT# 513988089, P.O.B. 62, Even Yehuda 40500.

**Manufacturer:** Jubilant Generics, Noida, Uttar Pradesh, India.

This leaflet was checked and approved by the Ministry of Health in May 2018 and was updated in October 2019.

Medicine registration number in the Israel Drug Registry at the Ministry of Health:

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