

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

The medicine is dispensed with a doctor's prescription only

## Zeto 250

### Film-coated tablets

#### Composition:

Each **Zeto 250** film-coated tablet contains: Azithromycin (as Dihydrate) 250 mg

A list of the inactive and allergenic ingredients in the preparation – see section 6.

**Read the 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 for your treatment. 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 medicine is not usually intended for children and infants under 6 months of age.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

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

**Therapeutic group:** Macrolide antibiotic.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (azithromycin) or to any of the additional ingredients contained in the medicine that appear in section 6.
- You have a history of an allergic reaction to the preparation or erythromycin or to any other antibiotic from the macrolide or ketolide group.

- You have suffered in the past from jaundice as a result of obstruction of bile flow in the liver (cholestatic jaundice) or from hepatic dysfunction occurring following azithromycin use.

#### Special warnings regarding use of the medicine

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

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

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

- nelfinavir (for treatment of AIDS), since the combination may increase the levels of azithromycin in the blood.
- anticoagulants (e.g., warfarin) - you should be monitored for coagulation indices.
- digoxin.
- colchicine.
- phenytoin.
- antacids containing aluminum or magnesium.

#### 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 commencing treatment, if you are pregnant or planning to become pregnant. It is not known if **Zeto** will harm your unborn baby.

Do not use the medicine without consulting a doctor before commencing treatment, if you are breastfeeding or

planning to breastfeed. **Zeto** has been reported to pass into breast milk. Consult the doctor regarding the best way to feed your baby during the course of treatment with **Zeto**.

### 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 of the preparation.

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

Take the tablet with a little water. If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

#### Do not exceed the recommended dose!

**If you took an overdose 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 designated 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. Never take a double dose instead of the forgotten dose!

Adhere to the treatment regimen as recommended by the doctor.

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

Do not skip a dose of **Zeto** or stop taking the medicine, even if you start to feel better, until completion of treatment, except in cases in which you are suffering from a severe allergic reaction or your doctor has instructed you to stop taking the medicine (see section 4 "Side effects"). **If you skip taking doses or do not complete the full course of treatment with Zeto,** the treatment may not be adequately effective and it will be more difficult to treat your infection. Completion of the full course of treatment will lower the risk of the bacteria developing resistance to **Zeto**.

If the bacteria develop resistance to **Zeto, Zeto** and other antibiotics may not be effective in the future.

**Do not take medicines in the dark! Check the label and the dose each time you take 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 **Zeto** 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.

#### Serious side effects

**Stop the use and refer to the doctor immediately in the event of:**

- Serious allergic reactions. Allergic reactions can occur after taking azithromycin, the active ingredient in **Zeto**, even after only taking a single dose. Stop treatment and refer to a doctor immediately if you experience one or more of the following symptoms:
  - breathing or swallowing difficulties
  - swelling of the lips, tongue or face
  - throat tightness, hoarseness
  - rapid heartbeat
  - faintness
  - skin rash (urticaria)
  - new onset of fever and swollen lymph nodes

Stop using **Zeto** with the first sign of a skin rash and refer to a doctor immediately. A rash may be a sign of a more serious reaction to **Zeto**.

- Liver damage (hepatotoxicity). Stop using the medicine and refer to a doctor immediately in the event of yellowing of the skin or whites of the eyes, dark-colored urine, nausea or vomiting, abdominal pain or tenderness, fever, weakness, itching, unusual tiredness, loss of appetite, change in the color of stools. These can be signs of a severe reaction to **Zeto** (hepatotoxicity).

**Refer to the doctor immediately in the event of:**

- Serious potentially life-threatening heart rhythm changes, including cardiac arrest, QT interval prolongation, torsades de pointes – ventricular arrhythmia, a sensation that your heart is beating or beating faster (palpitations), chest discomfort or irregular heartbeat.

Refer to a doctor immediately if you or your child experiences fast or irregular heartbeat, dizziness or weakness. **Zeto** may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and can be very dangerous. The risk for this is higher among the elderly, in patients with a family history of QT interval prolongation, in patients with a low blood potassium level, in patients taking certain medicines to control heart rhythm (antiarrhythmics).

- Worsening of myasthenia gravis (a disease that causes muscle weakness). Antibiotics like **Zeto** 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 even occur after you have finished treatment with **Zeto**.

#### Common side effects

The most common side effects of **Zeto** are:

- soft stools or diarrhea
- nausea
- stomach pain
- vomiting
- vaginitis
- rash
- indigestion
- headaches

#### Additional side effects:

Chest pain, rapid heartbeat, wind, black stools, jaundice, kidney inflammation, fungal infection, dizziness, vertigo, sleepiness, tiredness, itching, sensitivity to light, subcutaneous swelling, constipation, anorexia, inflammation of the small intestine, gastritis, anemia, reduced white blood cell (leukocyte) count, restlessness, nervousness, insomnia, fever, facial edema, malaise, pain, cough, laryngitis, runny nose, eczema, sweating, inflammation of the eye.

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

Side effects can be reported to the Ministry of Health by clicking on the link "[Reporting Side Effects of Drug Treatment](#)"

found on the Ministry of Health homepage ([www.health.gov.il](http://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>

Additionally, a report can be made to "Unipharm Ltd."

### 5. HOW SHOULD THE MEDICINE BE STORED?

Store below 25°C and in a place protected from light.

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

### 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Dibasic calcium phosphate (anhydrous), Pregelatinized starch, Magnesium stearate, Colloidal silicon dioxide, Carmellose sodium LS, Sodium lauryl sulphate, Colorant.

**What does the medicine look like and what are the contents of the package:**

**Zeto** tablets are round, biconvex and orange-colored, with a score line on one side.

They are packaged in trays (blisters) inserted into a carton box.

#### Approved package sizes:

In each package of **Zeto 250** there are 2, 6, 10, 12 and 24 tablets.

Not all package sizes may be marketed.

**Registration holder and address:** Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.

**Manufacturer and address:** Unipharm Ltd., "Mevo Carmel" Industrial Park.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

103 83 28422 01

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