

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

The medicine is dispensed with a doctor's prescription only

## **KARIN 250**

**Film-coated  
tablets**

## **KARIN 500**

**Film-coated  
tablets**

### **Composition:**

Each film-coated Karin 250 tablet contains:

Clarithromycin 250 mg

Each film-coated Karin 500 tablet contains:

Clarithromycin 500 mg

For the list of inactive and allergenic ingredients in the preparation, see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

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 the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not usually intended for infants under 6 months of age or under 20 months of age in patients being treated for MAC.

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

For treatment of upper respiratory tract infections, lower respiratory tract infections, skin and soft mucosal tissue infections.

For the treatment of MAC (*Mycobacterium avium* complex) infections in AIDS patients.

For combination treatment with proton pump inhibitors (PPI) in patients with an active peptic ulcer associated with a *Helicobacter pylori* infection.

This antibiotic stops development of bacteria that cause infections.

#### **Therapeutic group:**

Macrolide antibiotics.

## 2. BEFORE USING THE MEDICINE

### **Do not use the medicine if:**

- You are sensitive (allergic) to clarithromycin, other macrolide antibiotics or to any of the additional ingredients contained in the medicine (see section 6 “Further Information”).
- You or someone from your family has a history of heart rhythm disturbances (such as ventricular arrhythmias including “Torsades de pointes”), or an ECG abnormality called “long QT syndrome”.
- You have severe liver failure and kidney problems at the same time.
- You have unusually low blood potassium or magnesium levels (hypokalemia or hypomagnesemia).
- You are taking:
  - Ticagrelor (to prevent blood clotting).
  - Ranolazine (to treat angina pectoris).
  - Ivabradine (for heart attack, chest pain or angina pectoris).
  - Ergotamine or dihydroergotamine (medicines to treat migraine).
  - Cisapride and domperidone (for gastrointestinal disturbances).
  - Pimozide (antipsychotic).
  - Terfenadine or astemizole (hay fever, antiallergics).
  - Lovastatin, simvastatin (medicines used to lower cholesterol levels).
  - Colchicine (to treat gout).
  - A medicine containing lomitapide.
- Other medicines which are known to cause serious disturbances in heart rhythm.

### **Special warnings regarding use of the medicine**

#### **Before treatment with Karin, tell the doctor if:**

- You have impaired liver or kidney function.
- You develop severe or prolonged diarrhea (pseudomembranous colitis) during or after treatment with Karin, consult the doctor immediately. Inflammation of the colon (pseudomembranous colitis) has been reported with nearly all antibiotic medicines, including Karin.
- You have, or have had, heart problems.
- You have taken Karin before on several occasions or for a long period of time.

### **Children and adolescents**

This medicine is not usually intended for infants under 6 months of age or under 20 months of age for those treated for MAC.

### **Drug interactions**

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

Certain medicines may affect the effectiveness of Karin or vice-versa. These medicines include:

#### **Karin may increase the effect of the following medicines:**

- Astemizole, terfenadine (antiallergics), pimozide (antipsychotic), cisapride and domperidone (to treat gastrointestinal disturbances), ergotamine,

dihydroergotamine (migraine medicines), ibrutinib (a medicine for chronic lymphocytic leukemia), lovastatin, simvastatin (medicines to lower blood cholesterol levels), ticagrelor (a medicine to prevent blood clots), ranolazine (to treat angina pectoris), colchicine (to treat gout) - see section 2 "Do not use the medicine if".

- Alprazolam, triazolam, midazolam (sedatives and/or hypnotics).
- Digoxin, verapamil, amlodipine, diltiazem (heart medicines).
- Theophylline (antiasthmatic).
- Warfarin or other anticoagulants, e.g., dabigatran, rivaroxaban, apixaban, edoxaban (used to thin the blood).
- Atorvastatin, rosuvastatin (medicines to lower blood cholesterol levels).
- Cyclosporine, sirolimus, tacrolimus (immunosuppressants).
- Carbamazepine, phenytoin, valproate (to treat epilepsy).
- Cilostazol (used to improve circulation in the legs).
- Insulin and other medicines for the treatment of diabetes (such as nateglinide, repaglinide).
- Methylprednisolone (a corticosteroid to treat inflammation).
- Omeprazole (a gastric medicine).
- Sildenafil, tadalafil, vardenafil (to treat impotence).
- Tolterodine (to treat overactive bladder syndrome).
- Vinblastine (for cancer therapy).
- Medicines with a risk to affect hearing, especially antibiotics from the aminoglycosides group, such as gentamicin or neomycin.

This information is also important if you are taking the following medicines:

- Hydroxychloroquine or chloroquine (to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as clarithromycin may increase the chance of abnormal heart rhythm and other serious side effects that affect your heart.
- Corticosteroids, given by mouth, by injection or by inhalation (used to suppress the immune system – useful in treating a wide range of conditions).

**Both the effect of Karin and the effect of the following medicines may be increased when taken together:**

- Atazanavir, saquinavir (medicines to treat HIV).
- Itraconazole (a medicine to treat fungal infections).

If your doctor recommended that you take Karin together with one of the above-mentioned medicines, your doctor may need to monitor you closely.

**The following medicines may reduce the effect of Karin:**

- Rifampicin, rifabutin, rifapentine (antibiotics).
- Efavirenz, etravirine, nevirapine (medicines to treat HIV).
- Phenytoin, carbamazepine, phenobarbital (to treat epilepsy).
- Hypericum (St. John's Wort).

**Please note**

- Ritonavir (antiviral) and fluconazole (a medicine to treat fungal infections) may increase the effect of Karin.

Karin may reduce the effect of zidovudine (antiviral).

In order to avoid this, leave a 4-hour interval between taking these medicines.

- Taking Karin at the same time as digoxin, quinidine, disopyramide or verapamil (heart medicines) or other macrolide antibiotics may cause heart rhythm disturbances.

### **Use of the medicine and food**

The medicine can be taken with or without food.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before taking this medicine.

There is no information about the effect of clarithromycin on human fertility. In rats, fertility studies did not show any evidence of harmful effects.

### **Driving and operating machinery**

Generally, Karin should not affect the ability to drive or operate machinery, but may cause side effects such as dizziness, confusion and disorientation.

If the preparation causes these effects, do not drive, operate machinery or engage in any other activity that endangers you or those around you. Visual impairment and blurred vision may affect the patient's ability to drive or operate machinery.

### **Important information about some of the ingredients of the medicine**

Karin contains less than 1 mmol (23 mg) sodium per tablet, i.e., the tablet is essentially "sodium-free".

## **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use this 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 your doctor only.

Do not exceed the recommended dose.

Swallow 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.

#### **If you accidentally take a higher dosage**

You may experience various side effects in the digestive system such as: diarrhea, nausea, vomiting and abdominal pains.

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 the medicine at the designated time, take the dose as soon as you remember. Do not take a double dose to compensate for a forgotten dose. Do not take more tablets per day than instructed by the doctor.

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 to prevent recurrence of the disease.

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 Karin 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**

If any of the following symptoms occur, stop using the medicine and immediately refer to the doctor or proceed to a hospital emergency room:

#### **Uncommon serious side effects (effects that occur in 1-10 in 1,000 users):**

- Fever, sore throat or mouth ulcers due to infections (signs of low levels of white blood cells).
- Rash, itching, hives, breathlessness or difficult breathing, wheezing or cough, dizziness, light-headedness, changes in levels of consciousness, hypotension, with or without mild generalized itching, skin reddening, facial/throat swelling, blue discoloration of the lips, tongue or skin (signs of a severe allergic reaction).
- Irregular heart rate (change in the electrical activity of the heart).
- Yellowing of the skin and eyes, nausea, loss of appetite, dark urine.

#### **Serious side effects of unknown frequency (effects whose frequency has not yet been determined):**

- Diarrhea, abdominal pain, fever (signs of inflammation of the colon).
- Severe pain in the abdomen and back, caused by inflammation of the pancreas.
- Change in urine output, drowsiness, confusion, and nausea caused by kidney inflammation.
- Severe or itchy skin rash, especially if accompanied by blistering and there is soreness of the eyes, mouth or genitals.
- Unusual bruising or bleeding caused by a low blood platelet level.
- Fast or irregular heart rate.
- Heavy bleeding.
- Abnormal breakdown of muscle tissue, causing pain, fever, red-brown urine.
- Severely decreased urine output.
- Dermatitis bullous, rash, fever, blood alterations (which may be a sign of hypersensitivity syndrome, called DRESS), a red, scaly rash with bumps under the skin and blisters (acute generalized exanthematous pustulosis).

These are all serious side effects. You may need urgent medical attention.

### **Additional side effects:**

Tell your doctor if any of the following side effects bother you.

#### **Common side effects (effects that occur in 1-10 in 100 users):**

- Difficulty falling asleep.
- Headache.
- Change in the senses of taste (for example, metallic or bitter taste).
- Abdominal pain, nausea or vomiting, diarrhea, indigestion, heartburn.
- Abnormal liver function test results.
- Rash.
- Excessive sweating.
- Widening of blood vessels.

#### **Uncommon side effects (effects that occur in 1-10 in 1,000 users):**

- Fungal infections (candidiasis).

- Vaginal infection.
- Low levels of white blood cells, increased number of certain white blood cells.
- Decrease in neutrophils (neutropenia).
- Loss or reduced appetite.
- Anxiety.
- Dizziness, drowsiness, tremor, somnolence, tremors.
- Involuntary muscle movements.
- Impaired hearing.
- Spinning sensation.
- Ringing in the ears (tinnitus).
- Inflammation of the stomach lining, constipation, wind, dry mouth, belching, swelling and bloating of the abdomen.
- Increase of liver enzymes in the blood.
- Malaise, weakness, tiredness.
- Chest pain.
- Chills.
- Muscle spasms, muscle pain or loss of muscle tissue. If your child suffers from myasthenia gravis (a condition in which the muscles become weak and tire easily), treatment with Karin may worsen these symptoms.
- Anal pain.
- Asthma - a lung disease associated with narrowing of air passages, making breathing difficult.
- Nosebleed.
- Blood clot that causes sudden blockage in a lung artery (pulmonary embolism).
- Abnormal increase in kidney and liver function blood test results.
- Abnormal blood test results - high blood levels of the enzyme called alkaline phosphatase, which is indicative of bone health in the body, or high blood levels of the enzyme called lactate dehydrogenase, which is indicative of the health of certain organs in the body.

**Side effects of unknown frequency (effects whose frequency has not yet been determined):**

- Nightmares, loss of bearings, confusion, hallucinations (seeing things that are not there), psychosis (loss of contact with reality), a feeling of loss of identity, mania (feeling of elation or over-excitement), depression.
- Convulsions, loss of sense of taste or smell, tingling and numbness of the skin.
- Deafness.
- Certain bacterial infections of the skin and underlying tissues.
- Disturbed sense of smell, loss of sense of smell or taste.
- Tongue discoloration, tooth discoloration.
- Hemorrhage.
- Acne.
- Muscle pain or weakness.
- Abnormal blood test results - prolonged blood clotting time.
- Abnormal urine color.
- Vision problems (blurred vision).
- Vision impairment.

Karin may affect some laboratory test results. If you have to go to hospital or doctor for blood tests, it is important that you tell the doctor or nurse that you are taking Karin.

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

### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "[Report 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, you can report to "[Unipharm Ltd.](#)".

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

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

## **6. FURTHER INFORMATION**

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

Microcrystalline Cellulose, Pregelatinized Starch, Carmellose Sodium LS, Povidone, Glyceryl Behenate, Magnesium Stearate, Colloidal Silicon Dioxide, Opadry OY-6900 (pink).

What the medicine looks like and the contents of the package:

Karin is packaged in trays (blisters) that are inserted into a carton box.

Each Karin 250 package contains 2, 10, 14, 20 or 28 tablets.

Each Karin 500 package contains 1, 2, 7, 10, 14, 21 or 28 tablets.

Not all package sizes may be marketed.

Karin are pink, oblong, oval, film-coated tablets with a break line on one side.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

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

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Karin 250: 104 96 28719 01

Karin 500: 109 30 29343 01

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