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

This medicine is dispensed with a doctor's prescription only.

KARIN 250 KARIN 500

Film-coated tablets 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 ingredients, please see section 6 "Further Information".

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 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 in patients being

1. WHAT IS THIS MEDICINE INTENDED FOR?

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

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 Helicobacter pylori infection.

This antibiotic stops development of bacteria that cause

Therapeutic group: Macrolide antibiotics.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to clarithromycin, to any of the other ingredients contained in the medicine (see section 6 "Further Information") or to other medicines from this group (macrolide antibiotics) such as erythromycin or azithromycin
- you have a history of jaundice or any other liver problem after using clarithromycin.
- you are taking astemizole or terfenadine (medicines for hay fever or allergy), cisapride (for stomach disorders), pimozide (for mental problems) Combination of these medicines with Karin may cause heart rhythm disturbances.
- you are taking eletriptan tablets, ergotamine tablets inhaler or dihydroergotamine tablets (for migraine).
- you are taking eplerenone (to treat heart failure). you are taking ticagrelor, ivabradine or ranolazine (to
- treat stable angina pectoris). you are taking medicines from the statins group, such as lovastatin, simvastatin, pravastatin, atorvastatin
- or rosuvastatin [HMG-CoA reductase inhibitors used to lower blood levels of cholesterol and triglycerides (types of fat)]. you are taking colchicine and are being concomitantly
- treated for liver or kidney problems.
- you have low blood potassium level (a condition called hypokalemia).
- you have liver and/or kidney problems.
- you or someone from your family are suffering, or have

suffered in the past, from heart rhythm disturbances (such as ventricular rhythm disturbances including "Torsades de pointes"), or an ECG abnormality called "long QT syndrome"

Special warnings regarding use of the medicine:

- Before treatment with Karin, tell the doctor if: vou have heart problems.
- you suffered in the past from impaired function of the liver and/or kidney.
- you are suffering from fungal infections (e.g., thrush) or you have a tendency to develop such infections
- you are pregnant, think you may be pregnant or are breastfeeding.
- you are taking theophylline (for asthma) carbamazepine, phenytoin (for epilepsy and seizures), digoxin (for the heart). In combined treatment the plasma concentration of these medicines should be monitored.
- you are suffering from myasthenia gravis (a disorder that causes muscle weakness).
- you are taking colchicine (to treat gout), as combination of these medicines may cause severe side effects.
- you are sensitive to any food or medicine. If the symptoms do not improve within a few days or they worsen, consult your doctor.
- Prolonged use of the medicine may cause a resistant bacterial/fungal infection.
- If you are due to undergo surgery or another procedure under anesthesia, inform the doctor beforehand that you are taking this medicine.
- Karin may cause a heart rate disorder called "prolongation of the QT interval". This disorder may be severe (and in rare cases even fatal) and manifested by rapid/abnormal heart rhythm and other signs (e.g. severe dizziness, fainting) that require immediate medical intervention. The risk of such a heart rate disorder may rise if you are suffering from certain background diseases, from low blood potassium or magnesium levels, from medical conditions such as: severe sweating, diarrhea, vomiting, if you are taking diuretics or other medicines that may affect the heart rate (see section "Do not use this medicine if" and "If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist").
- If you develop severe or prolonged diarrhea during or after treatment with Karin, tell the doctor immediately, as this may be a symptom of a severe intestinal infection.
- If you develop any symptoms that may suggest impaired liver function, such as loss of appetite. vellowing of the skin or the whites of the eyes, dark urine, itching or tender abdomen, stop taking the medicine and tell the doctor immediately.
- Although most antibiotics apparently have no effect on hormonal contraceptives (such as birth control pills). certain antibiotics may reduce their contraceptive effectiveness. Consult with the doctor or pharmacist if you need to use additional contraceptives during ne course of treatment with the medicine.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

· digoxin (see section "Before treatment with Karin, tell the doctor if"), disopyramide, quinidine, amiodarone, dofetilide, sotalol, procainamide, propafenone (for heart diseases) - you may need to undergo blood tests and tests to monitor heart activity

- · thioridazine (antipsychotic).
- · anticoagulants (e.g., warfarin or any other blood thinner) - you may need to perform blood coagulation tests
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy) - see section "Before treatment with
- Karin, tell the doctor if". colchicine (for treatment of gout) - see section "Refore treatment with **Karin**, tell the doctor if".
- medicines to lower blood glucose levels, such as: nateglinide, pioglitazone, repaglinide, rosiglitazone
- theophylline, aminophylline (medicines for lung diseases, such as: asthma) - see section "Before treatment with Karin, tell the doctor if".
- midazolam, alprazolam, triazolam (sedatives and/or hypnotics).
- cilostazol (for blood circulation problems).
- omeprazole (for heartburn and peptic ulcers, unless prescribed to treat Helicobacter pylori).
- corticosteroids such as methylprednisolone.
- vinblastine (to treat cancer).
- ciclosporin, sirolimus, tacrolimus (immunosuppressants used, for example, to prevent transplant rejection).
- efavirenz, delavirdine, nevirapine, zidovudine, etravirine, protease inhibitors such as: ritonavir. atazanavir, saguinavir (antiviral medicines used to treat AIDS)
- rifabutin rifampicin rifapentine fluconazole itraconazole (to treat different infections).
- aprepitant (to prevent vomiting during chemotherapy).
- tolterodine (to treat irritable bladder)
- calcium channel blockers such as: verapamil. amlodipine, diltiazem (to treat hypertension).
- sildenafil, vardenafil, tadalafil (to treat erectile dysfunction in men or pulmonary hypertension high blood pressure in the blood vessels of the lungs).
- Hypericum (St. John's Wort) an herbal preparation used to treat depression.
- cimetidine (for digestive system disorders).
- aminoglycoside antibiotics (e.g., gentamycin, streptomycin, tobramycin, amikacin, netilmicin); macrolide antibiotics (e.g., erythromycin); moxifloxacin and gatifloxacin.
- bromocriptine.
- hexobarbital
- alfentanil and fentanyl (narcotic analgesics). live bacterial vaccinations.
- astemizole or terfenadine (medicines for hay fever or allergy), cisapride (for stomach disturbances), pimozide (for mental problems) - see section "Do not use this medicine if".
- eletriptan tablets, ergotamine tablets/inhaler or dihydroergotamine tablets (for migraine) - see section "Do not use this medicine if".
- medicines from the statins group such as: lovastatin, simvastatin pravastatin atorvastatin or rosuvastatin [HMG-CoA reductase inhibitors used to lower blood levels of cholesterol and triglycerides (types of fat)] - see section "Do not use this medicine if"
- eplerenone (to treat heart failure) see section "Do not use this medicine if".
- ticagrelor, ivabradine or ranglazine (to treat stable angina pectoris) - see section "Do not use this medicine if".

Use of the medicine and food:

his medicine can be taken with or without food. ■ Pregnancy and breastfeeding:

There is no information regarding the safety of this medicine in pregnant or breastfeeding women. If you are pregnant, think you may be pregnant or are breastfeeding, consult the doctor before starting treatment.

■ Driving and use of machinery:

Use of this medicine may cause dizziness, vertigo, confusion, spatial disorientation or impaired alertness. If the tablets cause these effects, do not drive a car, operate machines or engage in any activity that requires alertness. As for children - caution them against riding bicycles and playing near the road and the like.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined

by your doctor only.
In elderly patients with severe kidney failure, the doctor may adjust the dosages.

Do not exceed the recommended dose.

Swallow the medicine with at least half a glass of water. Do not chew. If necessary, the tablet can be halved or crushed

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

If you forget to take the medicine, 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 with the doctor or pharmacist 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

If any of the following symptoms occur, stop using the medicine and refer to the doctor immediately:

- Severe and/or prolonged diarrhea, with abdominal cramps or pains, that can be with blood or mucus (may be a symptom of a severe bacterial infection). Diarrhea may also occur in the two months following completion of treatment with clarithromycin - also refer to the doctor in such a case. Do not take antidiarrheals or narcotic analgesics, as they may worsen the situation
- Rash, breathing difficulties, fainting, loss of consciousness, or swelling of the face and neck; you may have developed an allergic reaction to the medicine
- Yellowing of the skin and/or eyes (jaundice), skin irritation pale stools dark urine tender abdomen or loss of appetite; these signs may indicate a liver function problem.
- DRESS syndrome (a severe disease accompanied by rash, fever and inflammation of the internal organs). Severe skin reaction such as Stevens-Johnson
- syndrome or Toxic Enidermal Necrolysis (a rare allergic reaction causing severe illness accompanied by blistering of the skin, mouth, lips, eyes and genitals). Purple spots on the skin, joint pains, problems in the
- digestive system and kidney (that may be indicative of a disease called Henoch-Schonlein purpura).
- Muscle pains and weakness (rhabdomyolysis -

a condition that causes breakdown of the muscle tissue that can lead to kidney damage).

If any of the following symptoms occur, refer to a doctor immediately:

- Hearing loss, changes in mood and mental state.
- · Severe dizziness, fainting, rapid/abnormal heart rhythm.
- New signs of infection (e.g., fever, prolonged sore throat), muscle weakness, prolonged nausea or vomiting, acute abdominal pain, change in the amount of urine

If any of the following symptoms occur, refer to a doctor:

· White spots in the oral cavity, change in vaginal discharges or other new symptoms that may indicate oral or vaginal thrush (as prolonged or repeated use of the medicine may increase the risk of such infections)

Additional side effects: Common side effects (effects that occur in 1-10 in

100 users): Headache.

- Change in sense of taste.
- Skin rash.
- Sleeping difficulties.
- Diarrhea, nausea, vomiting, abdominal pains, dvsnensia
- Changes in liver function.
- Increased sweating.

Flushing.

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

- · Swelling, itching, or redness of the skin, brown scales.
- Fungal infections of the skin.
- Dermatitis, urticaria.
- Oral or vaginal thrush Decreased white blood cell count that may increase the risk of infections.
- Changes in platelet levels (may increase the risk of bruising, bleeding or blood clots).
- Loss of or decreased appetite, anorexia, heartburn, abdominal bloating, constipation, flatulence, belchina
- Anal pain Inflammation of the wall of the stomach or of the
- esophagus.
- Pancreatitis Anxiety, nervousness, screaming, fainting, loss of consciousness, drowsiness, tiredness, dizziness,
- Muscle stiffness or spasms
- Movement disturbances, involuntary movements of
- the tongue, face, lips or extremities Ringing/buzzing in the ears, hearing loss.
- Vertigo. Tingling or paresthesia in the extremities.
- Hematomas, nosebleed. Pulmonary blood clot.
- Inflammation of the mouth or tongue. Dry mouth.
- Mouth pain · Joint pains or muscle pains, loss of muscle mass. If you are suffering from myasthenia gravis (a condition in which muscles weaken and tire easily) or from rhabdomyolysis (a condition in which muscle tissue
- breaks down), treatment with clarithromycin may worsen your symptoms.
- Chest pains, changes in heart rhythm, palpitations. Cardiac arrest.
- Breathing problems (asthma).
- Liver inflammation or bile duct obstruction (can be manifested by vellowing of the skin, dark urine, pale stools, skin irritation), increased liver enzyme levels.

- · Impaired kidney function such as: increased secretion of proteins by the kidney or increased levels of kidney enzymes, increased blood creatinine and urea levels. inflammation of the kidney (can be manifested by tiredness, swelling and puffiness of the face, abdomen, thighs or ankles) and problems passing urine.
- Fever, chills, weakness.
- · General feeling of discomfort.
- Abnormal blood test results.

Side effects whose frequency is unknown (effects whose frequency has not been determined):

- Infection in the large intestine
- Infection of the skin or in the skin folds.
- · Low blood sugar levels that may cause fainting. Psychotic disturbances, mania, confusion. hallucinations, change in perception of reality, spatial disorientation, panic, depression, nightmares (bad
- Convulsions

dreams).

- Change or loss of sense of taste and/or smell.
- Paresthesia/tingling of the skin.
- Deafness.
- · Bleeding (hemorrhage).
- Discoloration of the tongue and teeth (very rare - generally reversible by a professional dental cleaning).
- Liver failure jaundice
- DRESS (a severe disease accompanied by rash, fever, and inflammation of the internal organs)
- Muscle diseases, breakdown of muscle tissue.

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

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 of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the

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 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

Karin is packaged in trays (blister) that are inserted into a carton box. Each package contains 14 tablets. Karin are pink, oval, film-coated tablets with a score

Manufacture and address: Unipharm Ltd.,

License holder: Unipharm Ltd., P.O.B. 21429 Tel Aviv 6121301 This leaflet was checked and approved by the Ministry

Registration number of the medicine in the National Drug Registry of the Ministry of Health: Karin 250: 104 96 28719 00

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"Mavo Carmel" Industrial Park



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