PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Roxo 150
Tablets

Active ingredient:
Each tablet contains:
Roxithromycin 150 mg
Inactive and allergenic ingredients in the preparation – see section 6 (Further information) and section 2 (Before using the medicine).
Read the leaflet carefully in its entirety before using the medicine. Keep this leaflet; you may need to read it again.
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 you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?
The medicine is intended for the treatment of infections caused by bacteria susceptible to roxithromycin, such as infections of the respiratory tract, including nose, ear and throat, infections of the skin and genitals.
Therapeutic group: Macrolide antibiotic.

2. BEFORE USING THE MEDICINE

Do not use the medicine:
- If you are sensitive (allergic) to roxithromycin or to any of the additional ingredients contained in the medicine (see section 6 "Further information"), or to another macrolide antibiotic (e.g., erythromycin).
- If you are being treated concomitantly with ergot derivatives (for treatment of migraine), such as ergotamine and dihydroergotamine.
- If you are being treated concomitantly with colchicine (to treat gout).
- If you are being treated concomitantly with medicines such as: cisapride (for treatment of reflux [gastroesophageal reflux]), pimozide (a neuroleptic medicine) or medicines for treatment of allergies containing terfenadine or astemizole.
- When you are breastfeeding and your baby is being treated with the medicine cisapride (see **Pregnancy and breastfeeding** section).

If you are taking other medicines, confirm that there is no contraindication for combined use with **Roxo 150** (see **Drug interactions**).
If you are uncertain about any matter, consult a doctor or pharmacist.

Special warnings regarding use of the medicine
Before treatment with Roxo 150, tell the doctor if:
- You have an intolerance to certain sugars.
- You are pregnant or breastfeeding.
- You are suffering, or have suffered in the past, from:
  - Liver failure or any other liver disease – liver function should be monitored. The doctor will assess the treatment and may decide to adjust the treatment to your condition.
  - Prolongation of the QT interval (changes in heart activity that are diagnosed by ECG).
  - Bradycardia (slow heart rate).
  - Uncontrolled hypokalemia (lower blood potassium level than normal) or uncontrolled hypomagnesemia (a lower blood magnesium level than normal).
- You are being treated with ergot alkaloids, which may prolong the QT interval (see **Drug interactions**).
- You are suffering from a neuromuscular disease called myasthenia, since this medicine may worsen your disease.
- You are suffering from diarrhea during or after treatment with **Roxo 150**, especially if the diarrhea is severe, prolonged or bloody (risk of pseudomembranous enterocolitis) (see section 4 **Side effects**).

Significant narrowing of blood vessels, with possible damage to the tissues of the limbs (necrosis), has been reported for macrolide antibiotics taken together with certain medicines for treatment of migraine (ergotamine and dihydroergotamine). Before using **Roxo 150**, make sure that you are not using these medicines (see **Drug interactions**).
If a widespread, especially severe skin rash appears, with skin blistering or peeling, together with flu-like signs and fever (Stevens-Johnson syndrome), or a general unwell feeling, fever, chills and muscle aches (toxic epidermal necrolysis), or a red and scaly rash with patches and blisters (acute generalized exanthematous pustulosis), refer to a doctor immediately since these skin effects may be life-threatening. If symptoms like this develop, stop using **Roxo 150**.
Before receiving a prescription for **Roxo 150**, be sure you are not using certain medicines (see **Drug interactions**).
Monitoring of liver function, kidney function and blood count is recommended in the case of prolonged treatment (more than two weeks).
There is no need for dosage adjustments for elderly patients or patients with kidney diseases (kidney failure).
If you are sensitive to any type of food or medicine, inform the doctor before taking the medicine.
If you are uncertain about a specific matter, consult a doctor or pharmacist.

Children and adolescents
This medicine is not usually intended for infants and children.

Tests and follow-up
Blood tests and liver function tests should be performed in cases of prolonged treatment or high dosages.
Liver function should be monitored in patients suffering from a liver function problem and who are taking the medicine.
ECG monitoring should be performed in patients suffering from heart rate problems (e.g., prolongation of the QT interval in ECG).
ECG monitoring and, if possible, blood disopyramide or glycoside levels should be monitored when roxithromycin is concomitantly taken with disopyramide or digoxin and other glycosides for heart treatment.
When taken concomitantly with anticoagulants, INR monitoring should be performed.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not use **Roxo 150** if you are already taking:
- colchicine (to treat gout)
- ergotamine or dihydroergotamine (to treat migraine)
- cisapride (to treat reflux [gastroesophageal reflux])

Unless instructed otherwise by your doctor, do not use this medicine concomitantly with the following medicines: dopaminergic ergot alkaloids such as bromocriptine and pergolide (primarily used to treat Parkinson's disease) or cabergoline or lisuride (primarily used to prevent the secretion of breast milk).
It is especially important to inform the doctor or pharmacist if you are taking:
ciclosporin, digoxin, glycosides to treat heart problems, class I and class III antiarrhythmics, midazolam, theophylline, oral anticoagulants such as warfarin (coumadin), medicines to lower cholesterol level (atorvastatin, simvastatin).
Your doctor may ask you to monitor for specific symptoms and to perform blood tests if roxithromycin is taken together with other medicines, especially with medicines that may prolong the QT interval, such as:
- certain antiarrhythmics (e.g., quinidine, procainamide, disopyramide, dofetilide, amiodarone).
- certain antidepressants (e.g., citalopram).
- certain medicines used to treat mood or behavior disturbances (e.g., phenothiazines, pimozide).
- certain antibiotics that belong to a group of medicines called fluoroquinolones (e.g., moxifloxacin).
- certain medicines used to treat fungal and parasitic infections (e.g., fluconazole, pentamidine).
- certain antivirals (e.g., telaprevir).
- methadone (a medicine used to treat addiction to certain drugs).

(See section **Special warnings regarding use of the medicine**). Combined use with these medicines may cause cardiac side effects.

Use of the medicine and food
Swallow the medicine with water about one hour before a meal or on an empty stomach.
If gastrointestinal side effects occur – take the medicine with or after a meal.

Pregnancy and breastfeeding
Do not use the medicine without consulting a doctor if you are pregnant, think you may be pregnant, are planning a pregnancy or are breastfeeding.
If you discover that you are pregnant during the course of treatment, consult your doctor, since only he can decide if there is a need to continue the treatment.
It has been found that most macrolides are secreted into breast milk, at equal to or higher concentrations than in the mother's blood. Nonetheless, the amount of medicine absorbed by the newborn is low. If the infant has symptoms of digestive problems (diarrhea, fungal infection), stop breastfeeding. If these symptoms occur, stop breastfeeding and consult the doctor quickly.
Do not use this medicine if you are breastfeeding and the infant is taking cisapride (a medicine for certain digestion disturbances), due to concern for potential interaction that can cause heart rhythm disorders (torsades de pointes) (see section 2 **Before using the medicine** under the heading **Do not use the medicine**).
Tell your doctor or pharmacist if you are taking, have recently taken, or may take any other medicine.

Driving and operating machinery
Vision disturbances and blurred vision may affect the ability to drive and operate machinery.
Use of this medicine may cause dizziness which may cause danger when driving and operation of certain machinery.

Important information regarding some of the ingredients of the medicine
The medicine contains 0.9 mg dextrose and therefore, do not use it if you are suffering from problems in absorbing glucose and galactose.

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. **Do not exceed the recommended dose or the recommended duration of treatment.**
If necessary, the tablets can be halved for immediate use. There is no information about crushing or chewing the tablet.
If you forgot to take the medicine at the designated time, do not take a double dose to compensate for the forgotten dose.
If you accidentally took a higher dosage or if a child has 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. Do not induce vomiting unless explicitly instructed to do so 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.
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 **Roxo 150** 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 a doctor immediately if any of the following signs occur:
- **Digestive disorders:**
  The following effects are common: diarrhea, nausea, vomiting, stomach pain.
  Pain in the upper digestive system, digestive disorders, lack of appetite, pancreatitis and bloody diarrhea have also been reported (see section **Special warnings regarding use of the medicine**).
- **Cardiac disorders:**
  Prolongation of the QT interval, heart rhythm disorders, cardiac arrest.
- **Nervous system disorders:**
  The following effects are common: dizziness, headaches, tiredness, numbness/sensation changes, loss of or change in senses of taste and smell.
- **Ear disorders:**
  Impaired hearing, temporary hearing loss, dizziness (vertigo), abnormal buzzing or whistling sensation in the ears (tinnitus).
- **Eye symptoms may occur:**
  The frequency of these symptoms is unknown (cannot be estimated from the existing data): vision disturbances, vision problems (blurred vision).
- **Liver disorders:**
  Increase in liver enzymes (transaminases and basic phosphatase), hepatitis (liver damage possibly manifested by jaundice).
- **Allergic effects:**
  Skin rash is common.
  The following effects are uncommon: hives (red itchy patches on the skin), blisters on the skin (see section **Special warnings regarding use of the medicine**).
  Purpura (bruising or small red marks on the skin) and severe allergic reactions such as angioedema (sudden swelling of the face and neck), difficulty breathing and anaphylactic shock have also been reported.
  Widespread severe skin rash, including: skin blistering or peeling, as well as signs of flu and fever (Stevens-Johnson syndrome) or a general unwell feeling, fever, chills and muscle aches (toxic epidermal necrolysis) – unknown frequency.
  Bronchospasm – unknown frequency.
  Severe skin effects, such as red, scaly rash with patches and blisters (exanthematous pustulosis) have been reported.
  The frequency of these side effects is unknown (cannot be estimated from the available data).

Refer to a doctor if any of the following signs occur:
- **Blood and lymphatic system disorders:**
  The following effects are uncommon: high levels of certain white blood cells (eosinophilia), reduced levels of blood platelets (thrombocytopenia) and of certain white blood cells (neutropenia, agranulocytosis).
- Superinfection (in long-term use) with severe inflammation of the bowel (pseudomembranous enterocolitis).
- **Psychiatric disorders:**
  Hallucinations, confusion.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect 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), 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 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.
- Storage conditions: Store the medicine at a temperature below 25°C and in a dry 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, poloxamer 188, opadry Y-1-7000 (white), dextrose.
What the medicine looks like and the contents of the package:
Roxo 150 is packaged in trays (blisters) inserted into a carton package. **Roxo 150** comes in package sizes of 2, 5, 10, 14, 15, 20 and 30 tablets.
Not all package sizes may be marketed.
Roxo 150 tablets are white, film-coated, round, biconvex, with a break line on one side.
This leaflet does not contain all the information about the preparation. If you have any question, or are uncertain about something, please refer to the doctor.
Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.
Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 134 98 30273 01
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