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

RULID 150 mg Film-coated Tablets

SANOFI

Active ingredient: each tablet contains roxithromycin 150 mg.
Inactive ingredients – see section 6.
Read this 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.
If a side effect worsens or if you experience a side effect not mentioned in this leaflet, please refer to a doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

This 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, skin infections, and infections of the 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), or to other antibiotics of the macrolides group (e.g., erythromycin).
- you are being treated concomitantly with ergot derivatives (for treatment of migraine), such as ergotamine and dihydroergotamine.
- you are being treated concomitantly with colchicine (to treat gout).
- you are being treated concomitantly with medicines such as: cisapride (for treatment of reflux [gastroesophageal reflux]), pimozide (a neuroleptic preparation), or antiallergics 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 to their combined use with Rulid (see **Drug interactions**).
If you are uncertain about any issue, consult the doctor or pharmacist.

Special warnings regarding use of the medicine

Before treatment with Rulid, 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, diagnosed by E.C.G).
  - bradycardia (slow heart rate)
  - uncorrected hypokalemia (sub-normal blood potassium levels) or uncorrected hypomagnesemia (sub-normal blood magnesium levels).
- you are being treated with medicines that are 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 following treatment with Rulid, especially if the diarrhea is severe, prolonged or bloody (risk of pseudomembranous enterocolitis) (see section 4 **Side effects**).

Significant narrowing of the blood vessels with possible damage to the tissues of the extremities (necrosis), has been reported for macrolide antibiotics taken together with certain medicines for treatment of migraine (ergotamine and dihydroergotamine). Before using Rulid, make sure that you are not taking these medicines (see **Drug interactions**).
If a widespread, extremely severe skin rash occurs, including skin blistering or peeling, with flu-like symptoms and fever (Stevens-Johnson syndrome), generally feeling unwell, fever, chills and muscle aches (toxic epidermal necrolysis), or red and scaly rash with spots and blisters (acute generalized exanthematous pustulosis), refer to a doctor immediately since these skin effects may be life-threatening. If these symptoms occur, stop using Rulid.
Before receiving a prescription for Rulid, make sure that you are not using certain medicines (see **Drug interactions**).
Monitoring of liver and kidney function and a blood count are recommended in 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 food or medicine, inform the doctor before using the medicine.
If you are uncertain about any issue, consult the doctor or pharmacist.

Children

This medicine is not usually intended for babies 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 this medicine.
E.C.G. monitoring should be performed in patients suffering from heart rate problems (e.g., prolongation of the QT interval in an E.C.G.).
E.C.G. monitoring, and, if possible, blood dysopyramide 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 Rulid if you are already taking:
- colchicine (for treatment of gout)
- ergotamine or dihydroergotamine (for treatment of migraine)
- cisapride (for treatment of 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 certain symptoms and perform blood tests if roxythromycin is taken together with other medicines, especially with medicines that may prolong the QT interval, such as:
- Certain medicines for heart rate disturbances (e.g., quinidine, procainamide, disopyramide, dofetilide, amiodarone)
- Certain antidepressants (e.g., citalopram)
- Certain medicines used to treat some mood or behavioral disturbances (e.g., phenothiazines, pimozide)
- Certain antibiotics belonging to a group of medicines called fluoroquinolones (e.g., moxifloxacin)
- Certain medicines used to treat fungal or parasitic infections (e.g., fluconazole, pentamidine)
- Certain antivirals (e.g., telaprevir)
- Methadone (a medicine used to treat addiction to certain drugs) (see **Special warnings regarding use of the medicine** section)

Concomitant use with these medicines may lead to cardiac side effects.

Use of the medicine and food

Do not chew! 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 during treatment that you are pregnant, consult with your doctor, since only he can decide if there is a need to continue treatment.

It has been shown that most macrolides are secreted into breast milk, at equal or higher concentrations than those found in the mother's blood. Nevertheless, the amount of medicine absorbed by the newborn is low. Stop breastfeeding if the infant shows signs of digestion problems (diarrhea, fungal infection). If these symptoms occur, stop breastfeeding and consult a doctor quickly.

Do not use this medicine if you are breastfeeding an infant taking cisapride (a medicine for certain digestive disturbances), due to risk of potential interaction that can cause heart disturbances (Torsades de pointes). (See section **2 Before using the medicine**, under the heading **Do not use the medicine if:**).

Tell your doctor or pharmacist if you are taking, have recently taken or may take any other medicine.

Driving and operating machinery

Visual disturbances and blurred vision may affect your ability to drive and operate machinery.

Use of this medicine may cause dizziness, which may pose danger when driving or operating certain machinery.

Important information about some of the ingredients of the medicine

This medicine contains 1.12 mg glucose and therefore, do not use it if you are suffering from a glucose and galactose malabsorption syndrome.

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 regarding 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 dosage or recommended duration of treatment.

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, do not take a double dose to compensate for 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, and even then, it should be done gradually.

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 Rulid 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 upon onset of any of the following signs:

- **Digestive disorders may occur:**
  The following effects are common: nausea, vomiting, stomach pain, diarrhea.
  Pains 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 rate disorders, cardiac arrest.
- **Nervous system disorders:**
  The following effects are common: dizziness, headaches, tiredness, lack of/change in sensation, loss of or change in senses of taste and smell.
- **Ear disorders:** temporary deafness, impaired hearing, dizziness (vertigo), abnormal buzzing or whistling sensation in the ears (tinnitus).
- **Ocular symptoms may occur;** however, the frequency of such symptoms is not known (cannot be estimated from the available data): visual disturbances, eyesight problems (blurred vision).
- **Liver disorders:** increase in liver enzymes (transaminases and alkaline phosphatase), hepatitis (liver damage possibly causing jaundice).
- **Allergic reactions that may occur:**
  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.
  Serious widespread skin rash that includes: skin blistering or peeling, as well as signs of flu and fever (Stevens-Johnson syndrome) or generally feeling unwell, fever, chills and muscle aches (toxic epidermal necrolysis) – unknown frequency.
  Bronchospasm – unknown frequency.
  Serious skin reactions, such as a red, squamous rash with spots and blisters (exanthematous pustulosis), have been reported. The frequency of these side effects is not known (cannot be estimated from the available data).

If any of the following signs occurs, refer to the doctor immediately:

- **Blood and lymphatic system disorders:**
  The following effects are uncommon: high levels of certain white blood cells (eosinophils), low levels of blood platelets (thrombocytopenia) and of certain white blood cells (neutropenia, agranulocytosis).
- Superinfection (in long-term use) with severe inflammation of the colon (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 this leaflet, consult with the doctor.

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

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be stored 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.

Storage conditions: Do not store above 25°C.

6. FURTHER INFORMATION

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

Maize starch, Hydroxypropyl cellulose, Povidone, Hypromellose, Talc, Colloidal anhydrous silica, Magnesium stearate, Anhydrous glucose, Propylene glycol, Titanium dioxide, Poloxamer.

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

Cylindrical, white, biconvex, film-coated tablets, with an imprint on one side.

Each package contains 20 tablets.

This leaflet does not contain all the information about the medicine. If you have any questions or are not sure about anything, please ask your doctor.

License holder: sanofi-aventis Israel ltd., 10 Beni Gaon Street, Netanya 4250499.

Manufacturer: Sanofi Winthrop Industries, France

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 041-78-25741