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

The medicine is dispensed with a doctor's prescription only

ROVAMYCINE

Film-coated Tablets, 1.5 M.I.U

SANOFI

Active ingredient: Spiramycin 1.5 M.I.U.

Inactive ingredients – 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.

Keep this leaflet; you may need to read it again.

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.

This medicine is not intended for children below the age of 6, due to the risk of choking.

1. WHAT IS THE MEDICINE INTENDED FOR?

To treat:

- **Respiratory tract infections**
- **Infections caused by the Chlamydia bacterium**
- **Infections caused by the *Cryptosporidium* parasite**
- **Pregnant women with a toxoplasmosis infection**

Therapeutic group: a macrolide antibiotic

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient, to other antibiotics from the macrolide group or to any of the additional ingredients contained in the medicine (see section 6).
- your child is under 6 years of age, due to risk of choking on the tablet.

Special warnings regarding use of the medicine:

Before treatment with Rovamycine, tell the doctor if you:

- have or have had in the past, heart problems: caution should be exercised with this type of medicines if you were born with or if you have a family history of QT interval prolongation (observed on electrocardiogram [ECG]), if you have a blood electrolyte imbalance (particularly low blood potassium or magnesium levels), if you have a very slow heart rate (bradycardia), if you have a weak heart (heart failure), if you have a history of heart attack (myocardial infarction), if you are a woman, or if you are elderly, or if you are taking other medicines hat may cause certain abnormal changes in the ECG (see section **Drug interactions**).
- have a rare hereditary disease which affects the number of red blood cells in your body and causes tiredness, paleness or breathing difficulties (a disease called G6PD enzyme deficiency).
- are sensitive to any food or medicine.

At the beginning of treatment, tell the doctor immediately if:

You are suffering from redness all over your body with pustules and fever. This might be a sign of a serious reaction called acute generalized exanthematous pustulosis (see also Section **4 Side effects**). If this occurs, it is important that you tell your doctor immediately, as you will need to stop the treatment. If you have this kind of reaction, never take any medicine containing spiramycin again, whether alone or combined with another active substance.

During treatment:

Cases of severe skin reactions with rash accompanied by blisters and peeling of the skin, which may rapidly spread over the whole body and be life-threatening to the patient (toxic epidermal necrolysis, Stevens-Johnson syndrome) have been reported with Rovamycine use. Discontinue treatment immediately and tell your doctor if such effects occur.

Children and adolescents:

This preparation is only intended for use in adults and in children over 6 years of age.

Drug interactions:

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

Use during pregnancy and breastfeeding:

Consult your doctor before taking the medicine if you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy.

If necessary, this medicine can be used during pregnancy. Do not use this medicine during pregnancy unless your doctor has told you to do so.

The active ingredient (spiramycin) passes into breast milk. Breastfeeding is not recommended during the course of treatment with this medicine. Spiramycin may cause digestive disturbances in newborns.

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. The preparation is only intended for use in adults and children over 6 years of age.

Do not exceed the recommended dosage.

Treatment duration:

To ensure efficiency of the treatment, use this antibiotic at the prescribed dosage and for the length of time determined by the doctor.

Method of administration:

There is no information about halving, crushing or pulverizing the tablet.

Swallow the medicine with a glass of water.

If you accidentally took a higher dosage, 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 medicine with you. Depending on your symptoms, treatment or monitoring may be necessary.

If you took a higher dosage, you may suffer from effects such as nausea, vomiting, diarrhea, heart rate disorders.

If you forgot to take the medicine at the required time, do not take a double dose to make up for the forgotten dose. Take the next dose at the regular time and consult a 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.

If the fever or other symptoms have disappeared, this does not mean that you have completely recovered. If you feel tired, it is not as a result of the treatment but due to the infection itself. Lowering the dosage or discontinuing treatment will not improve this feeling and will delay your recovery.

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 Rovamycine may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

The frequency of side effects is generally categorized as follows:

Very common: affect more than 1 patient in 10

Common: affect 1 to 10 in 100 patients

Uncommon: affect 1 to 10 in 1,000 patients

Rare: affect 1 to 10 in 10,00 patients

Very rare: affect less than 1 in 10,00 patients

Unknown (cannot be estimated from the available data)

Discontinue use and refer to a doctor immediately if any of the following signs appear:

Common:

- Patch-like rash, which is a sign of allergic reaction.

Unknown:

- Redness all over the body, accompanied by pustules and fever. These may be signs of a severe reaction called acute generalized exanthematous pustulosis. This effect typically occurs at the beginning of the treatment. If you experience this effect, you must never take medicines containing spiramycin again.
- Allergy. Signs of an allergy include urticaria (skin rash similar to that caused by a nettle sting), itching, sudden swelling of the face and neck (angioedema), sudden malaise with a sharp drop in blood pressure (anaphylactic shock).
- A rash accompanied by blisters with peeling of the skin, which may rapidly spread over the entire body and be life-threatening to the patient (toxic epidermal necrolysis, Stevens-Johnson syndrome). If you experience this effect, never take any medicine containing spiramycin again.

Additional side effects:

Very common:

- A brief tingling or stinging sensation that occurs occasionally.

Common:

- abdominal pain, nausea, vomiting, diarrhea, pseudomembranous colitis (an intestinal disease with symptoms that generally include diarrhea and abdominal pain)
- transient disturbance in sense of taste.

Very rare:

- Changes in liver function tests.

Unknown:

- QT interval prolongation (a disturbance which can be observed in an electrocardiogram), heart rate that is too rapid, too slow or irregular (ventricular fibrillation), abnormally rapid heart rate (ventricular tachycardia), severe heart rate disturbances (torsades de pointes) (see section **2 Before using the medicine**).
- inflammation of the small blood vessels characterized by purple spots on the skin (vasculitis)
- hepatitis (liver inflammation)
- leukopenia (decreased white blood cell count), neutropenia (insufficient quantity of certain white blood cells), hemolytic anemia (destruction of red blood cells).

If a side effect occurs, if one of the side effect worsens, or if you are suffering 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 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.

Storage conditions:

Do not store at a temperature exceeding 25°C.

Do not throw away medicines into wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Inactive ingredients:

Microcrystalline cellulose, Gelifiable maize starch, Hydroxypropylcellulose, Sodium croscarmellose, Hypromellose, Magnesium stearate, Macrogol 6000, Titanium dioxide, Anhydrous colloidal silica.

- **What the medicine looks like and the contents of the package:** Film-coated, round, biconvex, white to creamy-white colored tablets, with RPR 107 imprinted on one side.
- **Pack size:** Each pack contains 16 tablets.
- **Registration holder and address:** sanofi-aventis Israel ltd., P.O.B. 8090 Netanya 4250499.
- **Name of Manufacturer and its address:** Sanofi S.p.A., Scoppito, Italy.
- This leaflet does not contain all of the information about the preparation. If you have any question or are not sure about something, please refer to the doctor.
- Revised in September 2020.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 0465923868.