

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rodogyl® 0.75 M.I.U. / 125 mg, film-coated tablets

spiramycin, metronidazole

<p>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</p> <ul style="list-style-type: none">Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
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What is in this leaflet:

- What Rodogyl is and what it is used for
- What you need to know before you take Rodogyl
- How to take Rodogyl
- Possible side effects
- How to store Rodogyl
- Contents of the pack and other information

1. WHAT RODOGYL ARE AND WHAT THEY ARE USED FOR

This medicine is a combination of two antibiotics, one belonging to the group of macrolides and the other belonging to the group of imidazoles. The active substances are spiramycin and metronidazole, respectively.

This medicine is for use in adults and children to treat oral and dental infections such as certain tooth abscesses.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RODOGYL

If your doctor has told you that you are intolerant to certain sugars, contact your doctor before taking this medicine.

Contraindications

Do not take Rodogyl:

- if you are allergic to spiramycin and/or metronidazole and/or other antibiotics in the imidazole group (the group of antibiotics that includes metronidazole) or any of the other ingredients of this medicine (listed in section 6).
 - if the patient is a child under 6 years of age, as these are tablets.
- If you are not sure, you must ask your doctor or pharmacist for advice.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rodogyl.

Tell your doctor before taking Rodogyl if you have:

- neurological disorders,
- psychiatric disorders,
- blood disorders,
- ever had meningitis while receiving metronidazole treatment.
- a history of heart problems: you should be careful when taking this type of medicine if: you were born with or have a family history of QT interval prolongation (as shown on an electrocardiogram (ECG)), you have a blood electrolyte imbalance (in particular, low levels of potassium or magnesium in the blood), you have a very slow heart rate (bradycardia), you have a weak heart (heart failure), you have a history of heart attack (myocardial infarction), you are a woman or elderly, or you are taking other medicines that may cause certain abnormalities in your ECG (see “Other medicines and Rodogyl”).
- a personal or family history of glucose-6-phosphate-dehydrogenase deficiency (a hereditary disease of the red blood cells), since the spiramycin contained in Rodogyl may cause hemolysis (destruction of red blood cells).

Tell your doctor immediately if any of the following problems occur **during treatment with Rodogyl:**

- From the first dose, there is a risk of severe and sudden allergic reaction (anaphylactic shock, angioedema) possibly causing the following symptoms: tight chest, dizziness, nausea or fainting, or dizziness on standing up (see “Possible side effects”). If these symptoms occur, stop taking this medicine and immediately contact your doctor as your life might be in danger.
- If, at the start of treatment, you observe redness spreading all over the body with pustules, accompanied by fever, a serious reaction known as acute generalized exanthematous pustulosis should be suspected (see “Possible side effects”); inform your doctor immediately, as treatment must be stopped. If such a reaction occurs, you should never take metronidazole again, either alone or combined with another active substance in the same medicine.
- Some cases of severe skin reactions such as a blistering rash with peeling of the skin which can rapidly spread all over the body and be life-threatening (toxic epidermal necrolysis, Stevens-Johnson syndrome) have been reported with spiramycin/ metronidazole. Tell your doctor immediately if such reaction occurs.

- You should watch out for any potential signs or worsening of nervous disorders such as difficulty coordinating movements, confusion, seizures, difficulty speaking or walking, shakiness, involuntary eye movements, as well as other effects on the hands and feet such as tingling, pins and needles, feeling cold, numbness and reduced sense of touch. These disorders are generally reversible on stopping treatment. If these symptoms occur, it is important that you stop taking the treatment and consult your doctor immediately (see “Possible side effects”).
- From the very first doses of treatment, your behavior may alter and put you at risk, especially if you have had psychiatric problems in the past. If this happens, you should stop taking the medicine and see a doctor (see “Possible side effects”).
- If you have had blood disorders or are receiving high-dose and/or long-term treatment, your doctor may prescribe regular blood tests to check your complete blood count.
- Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with medicines containing metronidazole. If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated and afterwards. Tell your doctor immediately and stop taking this medicine if you develop:
 - stomach pain, anorexia, nausea, vomiting, fever, feeling faint, tiredness, jaundice, dark urine, putty or mastic colored stools or itching.
- Inform the doctor or analysis laboratory that you are taking this medicine if you have to have a medical laboratory test, as taking metronidazole may interfere with some laboratory test results (test for treponema) by triggering a false positive result (e.g. the Nelson test).

Talk to your doctor or pharmacist before taking Rodogyl.

Other medicines and Rodogyl

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

In particular, tell your doctor if you are taking:

- medicines containing alcohol because of the risk of side effects such as redness of the face, feeling hot, vomiting and increased heart rate,
- busulfan (recommended for the treatment of certain types of blood disorders and for the preparation of a bone marrow transplant),
- disulfiram (used to prevent relapse in alcohol-dependent patients).

Rodogyl with food and drink

You should avoid drinking alcohol while taking this medicine due to the risk of side effects such as redness of the face, feeling hot, vomiting and increased heart rate.

If you are not sure, do not hesitate to ask your doctor or pharmacist for advice.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. This medicine can be used during all stages of pregnancy, if necessary.

As metronidazole and spiramycin pass into breast milk, you should avoid taking this medicine during breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You should be aware, particularly if you drive or use machines, that there is a risk of dizziness, confusion, hallucinations, seizures or vision disorders associated with this medicine.

Rodogyl contain 8 mg of sorbitol per tablet.

3. HOW TO TAKE RODOGYL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

As an indication, the usual dosage is as follows:

- Adults and children over 15 years of age: 4 to 6 tablets per day, taken as 2 or 3 doses.
- Children:
 - from 6 to 10 years of age: 2 tablets per day
 - from 10 to 15 years of age: 3 tablets per day taken as 2 or 3 divided doses

Route and method of administration

Oral use.

The tablets must be swallowed with a large glass of water.

The tablets should be taken with meals.

Frequency of administration

Take this medicine 2 or 3 times a day.

Duration of treatment

To be effective, this antibiotic should be used regularly at the prescribed doses, and for as long as your doctor has prescribed. If fever or any other symptoms disappear, this does not mean that you have completely recovered. Any feeling of tiredness is not caused by the antibiotic treatment but by the infection itself. Reducing or stopping your treatment would have no effect on this feeling and would delay your recovery.

If you take more Rodogyl than you should:

Talk to your doctor straight away. Your doctor may decide to prescribe appropriate treatment. Monitoring may be necessary.

If you forget to take Rodogyl

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Digestive disorders

- non-serious digestive disorders: commonly, abdominal pain, stomach pain, nausea, vomiting, diarrhea;
- inflammation of the tongue and dry mouth, inflammation of the mouth, taste disorders, loss of appetite;
- pancreatitis (inflammation of the pancreas), which is reversible on stopping treatment;
- discoloration of the tongue or change in its appearance (can be caused by the growth of a fungus), inflammation of the tongue and dry mouth, inflammation of the mouth, taste disorders, loss of appetite;
- pseudomembranous colitis (intestinal disease with diarrhea and abdominal pain).

Effects on the skin and mucous membranes

- hot flushes with redness of face, itching, skin rashes sometimes accompanied by fever;
- hives (skin rash like the one caused by stinging nettles), sudden allergic swelling of the face and neck (angioedema), allergic shock that can be life-threatening (see “What you need to know before you take Rodogyl”);
- very rare cases of redness spreading all over the body along with pustules and fever (acute generalized exanthematous pustulosis) (see “What you need to know before you take Rodogyl”);
- a blistering rash with peeling of the skin which can rapidly spread to the whole body and be life-threatening (toxic epidermal necrolysis, Stevens-Johnson syndrome). Should this occur, you must never again use medicines containing spiramycin or metronidazole;
- fixed drug eruption: skin rash in the form of itchy, burning, round red patches that leave colored spots and can appear in the same areas if the medicine is taken again.

Nervous system disorders

- nerve damage in the limbs (peripheral sensory neuropathy) that can result in symptoms in the hands and feet such as tingling, pins and needles, feeling cold, numbness, or reduced sense of touch;
- headaches;
- dizziness;
- seizures;
- confusion;
- neurological disorders, known as encephalopathy or cerebellar syndrome, with symptoms including confusion, consciousness disorders, behavioral disorders, difficulty coordinating movements, problems with pronunciation, gait disorders, involuntary eye movements, shakiness. These disorders are generally reversible on stopping treatment and may be associated with changes in MRI scans. Very rare cases of fatal outcome have been reported (see “What you need to know before you take Rodogyl”);
- non-bacterial meningitis.

Psychiatric disorders

- hallucinations;
- personality disorders (paranoia, delirium) that may be accompanied by suicidal thoughts or actions (see “What you need to know before you take Rodogyl”);
- depressive tendency.

Eye disorders

- temporary vision disorders such as blurred vision, double vision, short sightedness, decreased vision, changes in color vision;
- damage/inflammation of the optic nerve.

Blood disorders

- anemia with possible destruction of red blood cells (see “What you need to know before you take Rodogyl”);
- leukopenia (decreased number of white blood cells), neutropenia (insufficient number of certain white blood cells in the blood);
- abnormally low levels of platelets in the blood, abnormally low levels or significant drop in certain white blood cells (neutrophils) in the blood.

Effects on the liver

- elevated liver enzymes (transaminases, alkaline phosphatase);
- very rare cases of serious liver disease (sometimes with jaundice), in particular cases of liver failure requiring a transplant.

Effects on the heart and blood vessels

- QT interval prolongation (an abnormality that can be seen on an electrocardiogram), heart that beats too fast, too slow or irregularly (ventricular arrhythmia), abnormally fast heart rate (ventricular tachycardia), serious heart rhythm disorders (torsades de pointes) (see “What you need to know before you take Rodogyl”).

Immune system disorders

- inflammatory disease of small blood vessels characterized by purplish patches on the skin (vasculitis), potentially life-threatening shock resulting from an allergy (see “What you need to know before you take Rodogyl”).

Other

- reddish-brown colored urine caused by the medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE RODOGYL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rodogyl film-coated tablets contain

• The active substances are:

Spiramycin0.75 M.I.U.
Metronidazole..... 125 mg
For one film-coated tablet.

• The other ingredients are:

Maize starch, povidone K30, croscarmellose sodium, colloidalanhydrous silica, sorbitol, magnesium stearate, microcrystalline cellulose, hypromellose, titanium dioxide (E171), Macrogol 6000.

What Rodogyl look like and contents of the pack

This medicine is supplied as film-coated tablets, boxes of 20.

Marketing Authorization Holder

sanofi-aventis France
82, avenue Raspail
94250 Gentilly, France

Manufacturer

Sanofi S.p.A.
S.S. 17 KM 22
67019 - Scoppito (AQ)
Italy

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<p>HEALTH EDUCATION AND ADVICE</p> <p>WHAT YOU SHOULD KNOW ABOUT ANTIBIOTICS</p> <p>Antibiotics are effective in fighting infections caused by bacteria. They are not effective against infections caused by viruses. Your doctor has therefore chosen to prescribe this antibiotic for you because it is suitable for you and for the disease you have. Bacteria are able to survive or to reproduce despite the effect of antibiotics. This is known as resistance, and it makes some antibiotic treatments ineffective. Resistance increases with excessive or inappropriate use of antibiotics. You may promote the growth of resistant bacteria and therefore slow down your recovery, or even make this medicine ineffective, if you do not comply with:</p> <ul style="list-style-type: none">the prescribed dose, the dosing times, the duration of treatment.
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Therefore, to maintain the efficacy of this medicine:

- Only use an antibiotic when your doctor has prescribed it for you.**
- Strictly comply with your prescription.**
- Do not reuse an antibiotic without a prescription, even if you think you have a similar disease.**
- Never give your antibiotic to someone else, as it may not be appropriate for their disease.**
- Once you have finished your treatment, take all opened boxes of the medicine to your pharmacist to be disposed of properly.**

<p>THIS MEDICAMENT</p> <p>Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.</p> <p>Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.</p> <ul style="list-style-type: none">The doctor and the pharmacist are the experts in medicines, their benefits and risks. Do not by yourself interrupt the period of treatment prescribed. Do not repeat the same prescription without consulting your doctor. Keep all medicaments out of reach of children.
<p>Council of Arab Health Ministers, Union of Arab Pharmacists.</p>

<p>ان هذا الدواء</p> <p>مستحضر يؤثر على صحتك واستهلاكه خلافا للتعليمات يعرضك للخطر .</p> <p>اتبع بدقة وصفة الطبيب وطريقة الاستعمال المنصوص عليها وتعليمات الصيدلي الذي صرفها لك .</p> <ul style="list-style-type: none">الطبيب والصيدلي هما المختبران في الدواء وفي نفعه وضروره. لا تقطع مدة العلاج المحددة لك من تلقاء نفسك. لا تكرر صرف الدواء بدون استشارة الطبيب. لا تترك الاولية في متناول الاطفال.
<p>مجلس وزراء الصحة العرب والتحاد الصيدلانة العرب</p>