

PRODUCT MONOGRAPH

PrROVAMYCINE[®] (Spiramycin Capsules)

**250 mg (750,000 I.U.)
and
500 mg (1,500,000 I.U.)**

Antibiotic

Odan Laboratories Ltd.
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www.odanlab.com

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(Spiramycin Capsules)
250 mg (750,000 I.U.) and 500 mg (1,500,000 I.U.)

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Non-medicinal Ingredients
Oral	Capsules 250 mg	gelatin, lactose, magnesium stearate, sodium croscarmellose and titanium dioxide
	Capsules 500 mg	gelatin, lactose, magnesium stearate, microcrystalline cellulose, povidone, sodium croscarmellose, talc and titanium dioxide

INDICATIONS AND CLINICAL USE

- The treatment of infections of the respiratory tract, buccal cavity, skin and soft tissues due to susceptible organisms.
- *Neisseria gonorrhoeae*: as an alternate choice of treatment for gonorrhea in patients allergic to the penicillins. Before treatment of gonorrhea, the possibility of concomitant infection due to *T. pallidum* should be excluded.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Rovamycine and other antibacterial drugs, Rovamycine should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS

Rovamycine (spiramycin) is contraindicated in patients with known hypersensitivity to the drug.

The levels of spiramycin attained in the cerebrospinal fluid are much lower than those in the blood and are too low to be clinically useful. Therefore Rovamycine must not be used in patients with meningitis.

WARNINGS AND PRECAUTIONS

Administer antibiotics, including Rovamycine (spiramycin) cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

The possibility of superinfection caused by overgrowth of nonsusceptible organisms should be kept in mind during prolonged or repeated therapy. If superinfection occurs, discontinue the drug and take appropriate measures.

Safety of this product for use during pregnancy has not been established.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing Rovamycine in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

ADVERSE REACTION

Gastrointestinal effects: nausea, vomiting, diarrhea and very rare cases of pseudo-membranous colitis.

Liver system: very rare cases of liver tests function abnormalities.

Hypersensitivity reactions: rash, urticaria, pruritus, very rarely angioedema and anaphylactic shocks. Isolated cases of vasculitis, including Henoch-Schonlein purpura.

Peripheral and central nervous system: occasional cases of transient paresthesia.

Hematology: very rare cases of acute hemolysis have been reported.

DRUG INTERACTIONS

Rovamycine has been reported to inhibit the absorption of carbidopa and decrease levodopa plasma levels. When necessary, patients should be closely monitored and the levodopa dosage levels adjusted.

DOSAGE AND ADMINISTRATION

ADULTS: 6,000,000 to 9,000,000 International Units (4 to 6 capsules of Rovamycine '500') per 24 hours, in 2 divided doses.

In severe infections, the daily dosage may be increased to 12,000,000 to

15,000,000 International Units (8 to 10 capsules of Rovamycine '500' per day).

Gonorrhoea: 12,000,000 to 13,500,000 I.U. (8 or 9 capsules) in a single dose.

CHILDREN: The usual daily dosage is based on 150,000 I.U./kg body weight in 2 or 3 divided doses; the following calculated dosages are given as a guide.

BODY WEIGHT	DOSAGE IN CAPSULES OF ROVAMYCINE "250" (750,000 I.U. SPIRAMYCIN/CAPSULE)
15 kg	3 capsules/day
20 kg	4 capsules/day
30 kg	6 capsules/day

Spiramycin is stable in gastric juices and absorption is not affected by food. In severe infections, the daily dosage may be increased by one half.

In the treatment of beta hemolytic streptococcal infections, adequate Rovamycine dosage should be administered for 10 days.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Symptoms: No case of accidental overdose has been reported. In oral doses over 4g per day, abdominal discomfort, nausea or diarrhea may occur.

Treatment: No specific treatment has been proposed. Management should be symptomatic.

ACTION AND CLINICAL PHARMACOLOGY

Rovamycine (spiramycin) is a macrolide antibiotic produced by *Streptomyces ambofaciens*.

It is active against the following Gram-positive organisms: *Staphylococcus aureus* (including penicillin-resistant strains), β -haemolytic streptococci, *Streptococcus viridans*, *Streptococcus faecalis* and *Streptococcus pneumoniae*, *Corynebacterium diphtheriae*, clostridia.

Except for *Bordetella pertussis*, *Haemophilus influenzae* (approximately 50% of strains) and *Neisseria*, gram-negative organisms are generally considered as resistant to spiramycin.

Bacterial resistance to spiramycin has been reported to develop, including cross-resistance between spiramycin and erythromycin. However, most of the erythromycin-resistant strains of *S. aureus* are still sensitive to spiramycin.

The mechanism of action of spiramycin has not been elucidated.

STORAGE AND STABILITY

Store in a dry place between 15 °C and 30 °C.

DOSAGE FORMS, COMPOSITION AND PACKAGING

ROVAMYCINE '250':

Each orange and red capsule contains: Spiramycin 750,000 I.U.

Non-medicinal ingredients: D&C Red No. 28, FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, lactose, magnesium stearate, sodium croscarmellose and titanium dioxide. Tartrazine-free. Capsules are imprinted "ODAN 250" in black ink. Bottles of 50 capsules.

ROVAMYCINE '500':

Each blue and violet capsule contains: Spiramycin 1,500,000 I.U.

Non-medicinal ingredients: D&C Red No. 28, D&C Red No. 33, FD&C Blue No. 1, FD&C Red No. 40, gelatin, lactose, magnesium stearate, microcrystalline cellulose, povidone, sodium croscarmellose, talc and titanium dioxide. Tartrazine-free. Capsules are imprinted "ODAN 500" in black ink. Bottles of 50 capsules.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance:

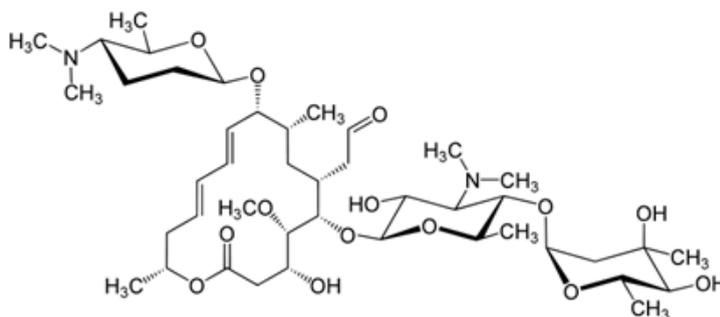
Proper Name: Spiramycin

Chemical Name: 2-[(4R,5S,6S,7R,9R,10R,11E,13E,16R)-6{[(2S,3R,4R,5S,6R)-5-{[(2S,5S,6S)-4,5-dihydroxy-4,6-dimethyloxan-2-yl]oxy}-4(dimethylamino)-3-hydroxy-6-methyloxan-2-yl]oxy}-10-{[(2R,5S,6R)-5-(dimethylamino)-6-methyloxan-2-yl]oxy}-4-hydroxy-5-methoxy-9,16-dimethyl-2-oxo-1oxacyclohexadeca-11,13-dien-7-yl]acetaldehyde

Molecular Formula: C₄₃H₇₄N₂O₁₄

Molecular Weight: 843.053 g/mol

Structural Formula:



Physicochemical Properties: White or slightly yellowish powder, slightly hygroscopic. Soluble in most organic solvents. Slightly soluble in water.

PATIENT MEDICATION INFORMATION

Pr Rovamycine®
(Spiramycin capsules)
250 mg (750,000 I.U.) & 500 mg (1,500,000 I.U.)

Read this carefully before you start taking **Rovamycine (spiramycin)** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Rovamycine**.

What is Rovamycine used for?

Rovamycine is used to treat certain types of infections that are caused by bacteria. It is most commonly used to treat infections of the:

- Lungs
- Skin
- Mouth

Rovamycine is sometimes used to treat gonorrhea for people who are allergic to penicillin.

Antibacterial drugs like Rovamycine treat only bacterial infections. They do not treat viral infections.

How does Rovamycine work?

Rovamycin is an antibiotic. It reduces infections by stopping the growth of bacteria.

What are the ingredients in Rovamycine?

Rovamycine 250:

Active Ingredients: Spiramycin 250 mg (750, 000 IU)

Inactive Ingredients: Each capsule contains the following inactive ingredients: D&C Red No. 28, FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, lactose, magnesium stearate, sodium croscarmellose and titanium dioxide.

Rovamycine 500

Active Ingredients: Spiramycin 500 mg (1,500,000 IU)

Inactive Ingredients: Each capsule contains the following inactive ingredients: colloidal silicon dioxide, D&C Red No. 28, D&C Red No. 33, FD&C Blue No. 1, FD&C Red No. 40, gelatin, lactose, magnesium stearate, microcrystalline cellulose, povidone, sodium croscarmellose, talc and titanium dioxide.

Rovamycine (spiramycin) comes in the following dosage forms:

250 mg capsules and 500 mg capsules, available in bottles of 50 capsules.

Do not use Rovamycine (spiramycin):

- If you are allergic to spiramycin or to any of the ingredients of the medication.
- If you have meningitis.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Rovamycine.

Talk about any health conditions or problems you may have, including if you:

- Have allergies to other drugs.
- Are pregnant or planning to become pregnant.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Rovamycine:

- levodopa - carbidopa

How to take Rovamycine (spiramycin):

Your doctor will decide the total amount of Rovamycine to take, for the specific infection.

- Although you may feel better early in treatment, Rovamycine should be used exactly as directed.
- Misuse or overuse of Rovamycine could lead to the growth of bacteria that will not be killed by Rovamycine (resistance). This means that Rovamycine may not work for you in the future.
- Do not share your medicine.

Usual dose:

- Adults: 2 to 3 capsules at 500 mg (for a daily total dosage of 2,000 mg to 3,000 mg) every 24 hours in 2 divided doses.
- For severe infections, the dose may be increased to 4 to 5 capsules at 500 mg twice a day (for a daily total dosage of 4,000 mg to 5,000 mg) in 2 divided doses.
- For the treatment of gonorrhea, the dose is usually 8 or 9 capsules at 500 mg in a single dose.

Children's doses are based on their body weight (150,000 I.U. /kg body weight/24 hours) and are given 2 to 3 times a day.

Overdose:

In oral doses over 4,000 mg (16,400,000 I.U.) per day, abdominal discomfort (stomach pain), nausea or diarrhea may occur.

If you think you have taken too much Rovamycine, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of Rovamycine by a few hours, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using Rovamycine?

These are not all the possible side effects you may feel when taking Rovamycine. If you experience any side effects not listed here, contact your healthcare professional.

Side effects of include:

- nausea
- vomiting
- diarrhea
- inflamed bowels
- pruritus (itchy skin)
- tingling or numbness in the skin

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
blood in the urine			✓
bloody stools			✓
chest pain			✓
fainting or dizziness			✓

irregular heartbeat			✓
signs of a severe allergic reaction (e.g., severe rash, hives, swollen face or throat, difficulty breathing)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Suspected Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

The capsules should be stored in a dry place at room temperature 15 - 30°C. Keep out of reach and sight of children.

If you want more information about Rovamycine (spiramycin):

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website <http://www.odanlab.com>, or by calling 1-800-387-9342.

This leaflet was prepared by Odan Laboratories Ltd., Montreal, Canada, H9R 2Y6

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