

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

The medicine is dispensed with a doctor's prescription only

ROSUVASTATIN INOVAMED 5 mg

Film-coated Tablets

Composition:

Each tablet contains: rosuvastatin 5 mg (as calcium)

ROSUVASTATIN INOVAMED 10 mg

Film-coated Tablets

Composition:

Each tablet contains: rosuvastatin 10 mg (as calcium)

ROSUVASTATIN INOVAMED 20 mg

Film-coated Tablets

Composition:

Each tablet contains: rosuvastatin 20 mg (as calcium)

ROSUVASTATIN INOVAMED 40 mg

Film-coated Tablets

Composition:

Each tablet contains: rosuvastatin 40 mg (as calcium)

For the list of inactive and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the 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. This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

Rosuvastatin Inovamed is not intended for children and adolescents under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rosuvastatin Inovamed is intended for the treatment of adults with:

- Primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia) (conditions in which there is a high level of cholesterol in the blood) or mixed dyslipidemia type IIb (disorder in the level of various blood lipids). The medicine is given as an adjunct to diet in conditions when the response to diet and other non-pharmacological treatments (e.g., exercise for weight reduction) is inadequate.
- Homozygous familial hypercholesterolemia (a condition in which there is a high level of cholesterol in the blood) in combination with diet and other blood lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are not appropriate.

Therapeutic group:

HMG-CoA reductase enzyme inhibitor.

Rosuvastatin Inovamed belongs to a group of medicines called statins, and acts to lower blood fat levels, the most common of which is called cholesterol. There are several types of cholesterol in the blood, "bad cholesterol" and "good cholesterol".

Rosuvastatin Inovamed acts and helps the body to block production of "bad cholesterol" and to clear it from the body, and helps to increase the levels of "good cholesterol".

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- **you are sensitive to the active ingredient** or to any of the additional ingredients contained in the medicine (please see section 6 "Further information" and section 2 "Important information about some of the ingredients of the medicine").
 - **you are pregnant**, or breastfeeding. If you become pregnant while using Rosuvastatin Inovamed, **stop taking Rosuvastatin Inovamed immediately and inform your doctor.** Avoid becoming pregnant by using appropriate contraceptives.
 - **you have a liver disease.**
 - **you have severe kidney problems.**
 - **you are suffering from recurrent or unexplained muscle aches or pains.**
 - **you are taking a drug combination of sofosbuvir/velpatasvir/voxilaprevir** (used to treat a viral infection of the liver called hepatitis C).
 - **you are taking cyclosporin** (use of cyclosporin, for example, following organ transplantation).
 - you are under 18 years of age.
- If any of these apply to you (or if you are unsure), please refer to your doctor.
- In addition, do not use the 40 mg tablets (the highest dosage) if:**
- **you have moderate kidney function problems** (if you are uncertain, please refer to the doctor).
 - **you have thyroid function problems.**
 - **you have recurrent or unexplained muscle aches or pains**, if you have a family or personal history of muscle problems, or you suffered in the past from muscle problems while taking other cholesterol-lowering medicines.
 - **you regularly consume large amounts of alcohol.**
 - **you are of Asian origin** (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese).
 - **you are taking other cholesterol-lowering medicines called fibrates.**
- If any of these apply to you (or if you are unsure), please refer to your doctor.**

Special warnings regarding use of Rosuvastatin Inovamed:

Before treatment with Rosuvastatin Inovamed, tell the doctor if:

- **You have impaired liver, kidney or thyroid function.**
- **You have recurrent or unexplained muscle aches or pains**, or if you or a family member suffered in the past from muscle problems, or if you have a history of muscle problems when taking other cholesterol-lowering medicines. Inform the attending doctor immediately if you experience unexplained muscle aches or pain, especially if these are accompanied by a generally unwell feeling or fever. Also inform the doctor if you suffer from persistent muscle weakness.
- **If you have or have had myasthenia** (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).
- **you regularly consume large amounts of alcohol.**
- **you are taking additional cholesterol-lowering medicines called fibrates;** please carefully read this leaflet, even if you have used cholesterol-lowering medicines in the past.
- **you are taking medicines to treat the human immunodeficiency virus (HIV)** (such as ritonavir with lopinavir and/or atazanavir). **Please refer to section "Drug interactions".**
- **you are taking or have taken in the last 7 days an antibiotic containing fusidic acid** (oral or by injection, to treat bacterial infection). The combination of fusidic acid with Rosuvastatin Inovamed may cause serious muscle problems (rhabdomyolysis). Please refer to section "Drug interactions".
- **you are over the age of 70** (the doctor will select a starting dosage of Rosuvastatin Inovamed that is appropriate for you).
- **you have severe respiratory failure.**
- **you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rosuvastatin Inovamed or other related medicines.**
- **you are of Asian origin** (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese). The doctor will select a starting dosage of Rosuvastatin Inovamed that is appropriate for you.

If any of the conditions listed above apply to you (or if you are not sure):

Do not take Rosuvastatin Inovamed 40 mg (the highest dosage) and check with your doctor or pharmacist before starting to use any dosage of Rosuvastatin Inovamed.

Serious skin reactions, including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms

(DRESS) syndrome have been reported in connection with Rosuvastatin Inovamed treatment. Stop using Rosuvastatin Inovamed and seek medical assistance immediately if you notice any of the symptoms described in section 4.

In a small number of patients, statins may affect the liver, which is identified by a simple blood test that checks for an increase in liver enzyme levels. Your doctor will therefore ask you to do liver function blood tests before and during treatment with Rosuvastatin Inovamed.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You may be at risk of developing diabetes if you have high levels of sugars and fats in the blood, or if you are overweight and have high blood pressure.

Children and adolescents:

Rosuvastatin Inovamed is not intended for children and adolescents under 18 years of age.

Drug interactions:

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

- cyclosporin (used following organ transplantation)
- warfarin, clopidogrel or ticagrelor (or any other drug used for thinning the blood)
- fibrates (such as gemfibrozil, fenofibrate) or any other cholesterol-lowering medicine (such as ezetimibe)
- medicines for indigestion (used as gastric antacids)
- erythromycin (an antibiotic), fusidic acid (antibiotic – see below, as well as section "Special warnings regarding use of Rosuvastatin Inovamed")
- contraceptive pills
- regorafenib (to treat cancer)
- darolutamide (to treat cancer)
- capmatinib (to treat cancer)
- hormone replacement therapy
- fostamatinib (to treat low platelet counts)
- febuxostat (to treat and prevent high levels of uric acid in the blood)
- teriflunomide (to treat multiple sclerosis)
- medicines to treat viral infections, including acquired immunodeficiency virus (HIV) or type C hepatitis, alone or in combination with (please see section "Special warnings regarding use of Rosuvastatin Inovamed"): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, velpatasvir.

The effect of these medicines may change when used concomitantly with Rosuvastatin Inovamed or they may change the effect of Rosuvastatin Inovamed.

- **Fusidic acid (antibiotic) – if you must take oral fusidic acid to treat a bacterial infection, you will have to temporarily stop the Rosuvastatin Inovamed treatment. The doctor will tell you when you can resume taking Rosuvastatin Inovamed. Taking Rosuvastatin Inovamed with fusidic acid may, in rare cases, cause muscle weakness, tenderness or pain (rhabdomyolysis). Please see further information on rhabdomyolysis in section 4.**

Use of the medicine and food:

Rosuvastatin Inovamed can be taken without regard to food.

Pregnancy and breastfeeding:

Do not take Rosuvastatin Inovamed if you are pregnant or breastfeeding.

If you became pregnant while using Rosuvastatin Inovamed, **stop taking Rosuvastatin Inovamed immediately** and inform your doctor. Avoid becoming pregnant by using appropriate contraceptives during the course of treatment with this medicine.

Consult your doctor or pharmacist before taking any preparation.

Driving and operating machinery:

Most patients are able to drive a car and operate machinery while using Rosuvastatin Inovamed – the medicine will not impair their ability to perform these activities. However, some patients may feel dizzy during treatment with Rosuvastatin Inovamed. If you feel dizzy, you must refer to the doctor before operating machinery or driving a car.

Important information about some of the ingredients of the medicine:

The medicine contains lactose monohydrate, which is a kind of sugar. If you have been told by the doctor that you have an intolerance to lactose, or you are unable to digest certain sugars, consult the doctor before taking this medicine.

The medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

Please see section 6 "Further information".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine 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. **The recommended dosage is usually:**

Treatment with Rosuvastatin Inovamed will begin with one 5 mg or 10 mg tablet once a day, even if you have previously taken a higher dosage of other statins. The starting dosage will be determined based on:

- cholesterol level.
- level of risk that you will have a heart attack or stroke.
- whether you have a factor that may make you more sensitive to a possible side effect.

Please consult your doctor or pharmacist about the dosage most suitable for you.

The doctor may decide to give you the lowest dosage of 5 mg when:

- you are of **Asian origin** (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese).
- you are **70 years of age or older.**
- you have moderate kidney function problems.
- you are at risk of suffering from muscle aches and pains (myopathy).

Increasing the dosage and maximal daily dosage

Your doctor may decide to increase your dose, so that you are taking the amount that is right for you. If you started with Rosuvastatin Inovamed 5 mg dose, your doctor may decide to double this to Rosuvastatin Inovamed 10 mg, then 20 mg and then 40 mg if necessary. If you started on Rosuvastatin Inovamed 10 mg, your doctor may decide to double this to 20 mg and then 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dosage is 40 mg. It is usually given to patients with very high levels of cholesterol and with a high risk of a heart attack or stroke, when cholesterol levels do not adequately decline with 20 mg.

Do not exceed the recommended dose.

If you are taking aluminum or magnesium salt-type antacids, you must take Rosuvastatin Inovamed at least two hours before taking aluminum/magnesium salt-type antacids.

Check cholesterol levels regularly to ensure that your cholesterol has reached the desired level and that this level is maintained.

The doctor may decide to increase the dosage of the preparation so that you receive the amount of Rosuvastatin Inovamed that suits you.

The medicine can be taken at any time of the day, with or without food. To help you remember to take the medicine, it is recommended to take the medicine at a set time each day. Swallow the tablets whole with water.

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

If you accidentally took a higher dosage, contact the doctor or proceed to a hospital emergency room.

If you took an overdose 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.

If you forget to take the medicine, skip the forgotten dose and take the next dose according to the usual schedule. Do not take two doses together to compensate for a 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.

If you stop taking the medicine, your cholesterol levels may increase again.

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 additional questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Rosuvastatin Inovamed 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.

Effects that require special attention; stop treatment with Rosuvastatin Inovamed and refer to the doctor immediately if:

- you have one of the following hypersensitivity (allergic) reactions:
 - breathing difficulty, with or without swelling of the face, lips, tongue and/or throat.
 - swelling of the face, lips, tongue and/or throat, which can cause swallowing difficulty.
 - severe skin itching (with raised blisters).
 - reddish, non-raised, target-like or round patches on the trunk, often with centralized blisters, skin peeling, ulcers in the mouth, throat, nose, genitals and eyes. Fever and flu-like symptoms may precede these serious skin rashes (Stevens-Johnson syndrome).
 - widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- **you have unusual muscle aches and pains** that last longer than expected. As with other statins, a small number of patients have experienced an unpleasant muscle effect and, rarely, this effect becomes life-threatening, damages muscles and is known as rhabdomyolysis.
- **you experience muscle rupture.**
- **you have lupus-like disease syndrome** (including rash, joint disturbances and effect on blood cells).

Common side effects (effects that occur in 1-10 users in 100):

- headaches
- abdominal pains
- constipation
- feeling sick
- muscle pain
- weakness
- dizziness
- increase in urine protein levels – this usually return to normal without need to discontinue use of the preparation (only for Rosuvastatin Inovamed 40 mg).
- diabetes. The risk of developing diabetes is more likely if you have high levels of fats and sugar in your blood, are overweight, and have high blood pressure. You must be under medical supervision during the course of treatment.

Uncommon side effects (effects that occur in 1-10 users in 1,000):

- skin rash.
- itching or other skin reactions.
- increase in urine protein levels – this usually return to normal without need to discontinue use of the preparation (for Rosuvastatin Inovamed 5 mg, 10 mg and 20 mg only).

Rare side effects (effects that occur in 1-10 users in 10,000):

- severe allergic reaction whose signs include: swelling of the face, lips, tongue and/or throat, difficulty swallowing and breathing, severe skin itch (with raised blisters). **If you think you have an allergic reaction, stop taking Rosuvastatin Inovamed** and immediately seek medical assistance.
- Muscle damage in adults – **as a safety measure, stop taking Rosuvastatin Inovamed and talk to your doctor immediately if you experience unusual muscle aches or pains** that last longer than expected.
- severe stomachache (pancreatitis).
- increased liver enzymes in the blood.
- bleeding or bruising more easily than normal due to low blood platelet levels.
- lupus-like disease syndrome (including rash, joint disturbances and effect on blood cells).

Very rare side effects (effects that occur in less than one user in 10,000):

- jaundice (yellowing of the skin and eyes)
- hepatitis (inflammation of the liver)
- traces of blood in the urine
- nerve damage in the arms and legs (e.g., numbness or tingling sensation)
- joint pains
- memory loss
- breast enlargement in men (gynecomastia)

Side effects of unknown frequency (effects whose frequency has not been determined):

- diarrhea
- cough
- shortness of breath
- edema (swelling due to fluid accumulation)
- sleep disturbances, including insomnia and nightmares
- sexual function problems
- depression
- breathing problems, including persistent cough and/or shortness of breath or fever
- tendon injury
- constant muscle weakness
- myasthenia gravis (a disease that causes generalized muscle weakness, and in some cases, also weakness of the muscles involved in breathing).
- ocular myasthenia (a disease that causes eye muscle weakness).

Consult your doctor if you experience weakness in the arms or legs that worsens after periods of activity, double vision or eyelid drooping, difficulty swallowing or shortness of breath.

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 the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effect 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?

- Store at a temperature below 25°C.
- 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.

Please note the expiry date of the preparation! In any case of doubt, consult the pharmacist who dispensed the medicine to you.

- Do not store different medicines in the same package.

6. FURTHER INFORMATION

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

Lactose monohydrate, cellulose microcrystalline, crospovidone, magnesium stearate, hypromellose, titanium dioxide, triacetin, sodium hydrogen carbonate, iron oxide red.

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

Rosuvastatin Inovamed 5 mg: a pink, round, biconvex, film-coated tablet with beveled edges, with 'R5' imprinted on one side and plain on the other side.

Rosuvastatin Inovamed 10 mg: a pink, round, biconvex, film-coated tablet with beveled edges, with 'R10' imprinted on one side and plain on the other side.

Rosuvastatin Inovamed 20 mg: a pink, round, biconvex, film-coated tablet, with 'R20' imprinted on one side and plain on the other side.

Rosuvastatin Inovamed 40 mg: a pink, oval, biconvex, film-coated tablet with 'R40' imprinted on one side and plain on the other side.

Package type:

The medicine is supplied in carton packages that contain trays/blisters, with a total of 30 tablets.

Manufacturer:

Umedica Laboratories Pvt. Ltd., Mumbai, India.

License holder and importer:

Inovamed Pharma Ltd., P.O.B. 2349, Bnei Brak.

Revised in October 2023 according to MOH guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Rosuvastatin Inovamed 5 mg: 173-64-36556

Rosuvastatin Inovamed 10 mg: 173-65-36557

Rosuvastatin Inovamed 20 mg: 173-66-36558

Rosuvastatin Inovamed 40 mg: 173-67-36559