

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

This medicine is dispensed with a doctor's prescription only

Rosuvastatin-Medo 5 mg

Film-coated tablets

Rosuvastatin-Medo 20 mg

Film-coated tablets

Rosuvastatin-Medo 10 mg

Film-coated tablets

Rosuvastatin-Medo 40 mg

Film-coated tablets

Composition:

Each tablet contains:

Rosuvastatin 5 mg
(as rosuvastatin calcium)

Rosuvastatin 10 mg
(as rosuvastatin calcium)

Rosuvastatin 20 mg
(as rosuvastatin calcium)

Rosuvastatin 40 mg
(as rosuvastatin calcium)

For inactive ingredients and allergens in the medicine, please see Section 2 - "Important information about some of the ingredients in this medicine" and Section 6 - "Additional 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 illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

Rosuvastatin-Medo is not intended for children and adolescents under the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rosuvastatin-Medo is indicated for treatment of adults with:

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

Therapeutic group

HMG-CoA reductase enzyme inhibitor

Rosuvastatin-Medo belongs to a class of medicines called statins, which works by reducing fat levels in the blood, the most common of which is called cholesterol.

There are several types of cholesterol in the blood: "bad cholesterol" and "good cholesterol".

Rosuvastatin-Medo works by helping the body block the production of "bad cholesterol" and clearing it from the body and helping to increase the "good cholesterol" levels.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- **You are sensitive to the active ingredient** or to any of the other ingredients that the medicine contains (see Section 6 - “Additional information”).
 - **You are pregnant** or breastfeeding. If you become pregnant while using Rosuvastatin-Medo, **stop taking Rosuvastatin-Medo immediately and inform your doctor**. Avoid becoming pregnant by using suitable contraceptives.
 - **You have a liver disease.**
 - **You have severe kidney problems.**
 - **You have repeated 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 ciclosporin** (ciclosporin is used for instance following organ transplantation).
 - You are under the age of 18.
- If any of the above applies to you (or you are in doubt), please refer to your doctor.

In addition, do not use the 40 mg tablets (the highest dosage) if:

- **You have moderate problems with kidney function** (if in doubt, please ask your doctor).
- **Your thyroid gland is not working properly.**
- **You have repeated or unexplained muscle aches or pains**; if you have a family or personal history of muscle problems, or have had muscle problems in the past 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 take other cholesterol-lowering medicines known as fibrates.**

If any of the above applies to you (or you are in doubt), **please refer to your doctor.**

Special warnings regarding the use of Rosuvastatin-Medo

Before treatment with Rosuvastatin-Medo, tell the doctor if:

- **You have impaired liver, kidney or thyroid function.**
- **You have repeated or unexplained muscle aches or pains**, or if you or a family member have had muscle problems in the past, 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 pains, especially if these are accompanied by a general unwell feeling or fever. Also, tell your doctor if you have a muscle weakness that is constant.
- **You suffer or have suffered in the past from myasthenia gravis** (a disease causing general muscle weakness including in some cases muscles used when breathing), or Ocular myasthenia (a disease causing eye muscle weakness), since statins can sometimes aggravate the disease or cause it to occur (see section 4).
- **You regularly consume large amounts of alcohol.**
- **You take other cholesterol-lowering medicines known as fibrates.** Please read this leaflet carefully, even if you have taken other medicines for lowering cholesterol before.
- **You are taking medicines to treat 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 antibiotics containing fusidic acid** (a medicine for bacterial infection, orally or by injection). The combination of fusidic acid and Rosuvastatin-Medo can lead to serious muscle problems (rhabdomyolysis). Please refer to section “Drug interactions”.
- **You are over the age of 70** (your doctor needs to choose the right starting dose of Rosuvastatin-Medo that is suitable for you).

- **You have severe impairment of the respiratory system.**
- **If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rosuvastatin-Medo or other related medicines.**
- **You are of Asian origin** (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese). Your doctor will choose a starting dose of Rosuvastatin-Medo that is suitable for you.

If any of the above applies to you (or if you are not sure):

Do not take Rosuvastatin-Medo 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of Rosuvastatin-Medo.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Rosuvastatin-Medo treatment. Stop using Rosuvastatin-Medo and seek medical attention immediately if you notice any of the symptoms described in section 4.

In a small number of patients, statins may affect the liver; This is identified by a simple blood test that checks for a rise in liver enzyme levels. Your doctor will therefore ask you to carry out liver- function blood tests before and during treatment with Rosuvastatin-Medo.

During treatment with this medicine, your doctor will monitor you closely to see 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 your blood or if you are overweight, and have high blood pressure.

Children and adolescents:

Rosuvastatin-Medo is not intended for children and adolescents under the age of 18.

Drug interactions:

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

- Ciclosporin (used following organ transplantation)
- Warfarin, clopidogrel or **ticagrelor** (or any other drug used for thinning the blood)
- Fibrates (such as gemfibrozil or fenofibrate) or any other cholesterol-lowering medicine (such as ezetimibe)
- Indigestion remedies (used to neutralize acid in your stomach)
- Erythromycin (an antibiotic), fusidic acid (antibiotics – see below and also in section "Special warnings regarding use of Rosuvastatin-Medo")
- Contraceptive pills
- Regorafenib (used to treat cancer)
- Darolutamide (used to treat cancer)
- capmatinib (used to treat cancer)
- Hormone replacement therapy
- fostamatinib (used to treat low platelet counts)
- febuxostat (used to treat and prevent high blood levels of uric acid)
- teriflunomide (used to treat multiple sclerosis)
- Medicines used to treat viral infections, including HIV or hepatitis C infection, alone or in combination with (please see section "Special warnings regarding use of Rosuvastatin Medo"): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

The effect of these medicines could be changed by concomitant use with Rosuvastatin-Medo or they could change the effect of Rosuvastatin-Medo.

- **Fusidic acid (antibiotic) - If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using Rosuvastatin-Medo. Your doctor will tell you when it is safe to restart taking Rosuvastatin-Medo. Taking Rosuvastatin-Medo with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). Please see additional information regarding rhabdomyolysis in Section 4.**

Use of the medicine and food:

Rosuvastatin-Medo can be taken regardless to food.

Pregnancy and breastfeeding:

Do not take Rosuvastatin-Medo if you are pregnant or breastfeeding.

If you become pregnant while using Rosuvastatin-Medo, **stop taking Rosuvastatin-Medo immediately** and inform your doctor. Avoid becoming pregnant during treatment with this medicine by using suitable contraceptives.

Consult your doctor or pharmacist before taking any medicine.

Driving and operating machinery:

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

Important information about some of the ingredients of this medicine:

The medicine contains lactose. If your doctor has told you that you have an intolerance to some sugars (lactose or milk sugar), consult your doctor before taking this medicine. Please see Section 6 - "Additional information".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and manner of treatment. The dosage and manner of treatment will be determined by the doctor only. **The recommended dosage is usually:**

Treatment with Rosuvastatin-Medo starts with one 5 mg or 10 mg tablet once a day, even if you have previously taken other statins in higher dosages. The choice of your starting dose will depend upon:

- Your cholesterol levels.
- The level of risk you have of experiencing a heart attack or a stroke.
- Whether you have a factor that may make you more sensitive to possible side effects. Please consult your doctor or pharmacist about the dosage that is most suitable for you.

Your doctor may decide to give you the lowest dose, 5 mg, if:

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

Increasing the dose and maximum daily dose

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-Medo 5 mg dose, your doctor may decide to double this to Rosuvastatin-Medo 10 mg, then 20 mg and then 40 mg if necessary. If you started on Rosuvastatin-Medo 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 dose is 40 mg. It is usually given to patients with very high cholesterol levels and a high risk of a heart attack or stroke whose cholesterol levels are not lowered enough with 20 mg.

Do not exceed the recommended dose.

If you take an antacid of the aluminum or magnesium salt type, you must take Rosuvastatin-Medo at least two hours before taking the aluminium/magnesium salt antacid. Regularly check cholesterol levels to confirm that your cholesterol has reached and is maintained at the desired level.

It is possible that the doctor will decide to increase the dose of the medicine so that you take the amount of Rosuvastatin-Medo that suits you.

You can take the medicine at any time of day, with or without food. In order to remember to take the medicine, it is recommended to take the medicine at the same time every day. Swallow the tablets whole with water.

There is no data regarding crushing, splitting or grinding up the tablet.

If you accidentally take a higher dose, contact your doctor or go to a hospital emergency room.

If you take 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. Never take two doses together to compensate for a missed one.

Adhere to treatment as recommended by your doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor.

If you stop treatment with the medicine your cholesterol levels might increase again.

Do not take medicines in the dark! Check the label and the dose each time you take the 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, the use of Rosuvastatin-Medo 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-Medo and refer to the doctor immediately if:

- You experience any of the following hypersensitivity reactions (allergy):
 - difficulty breathing with or without swelling of the face, lips, tongue and/or throat.
 - Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
 - Severe itching of the skin (with raised blisters).
 - Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
 - Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- **You have unusual muscle aches or pains**, which go on for longer than you might expect. As with other statins, a small number of patients have experienced an unpleasant

muscle effect, and ,rarely, this effect becomes life threatening, damaging muscles- a condition known as rhabdomyolysis.

- **You experience a muscle rupture.**
- **You have lupus-like disease syndrome** (including rash, joint disorders and effects on blood cells).

Common side effects (effects occurring in 1-10 of 100 users):

- Headaches,
- Abdominal pain,
- Constipation,
- Feeling ill,
- Muscle pain,
- Weakness,
- Dizziness,
- A rise in urine protein levels; These usually return to normal without the need to discontinue use of the medication (only for Rosuvastatin-Medo 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 occurring in 1-10 of 1,000 users):

- Skin rash,
- Itching or other skin reactions.
- A rise in urine protein levels; These usually return to normal without the need to discontinue use of the medication (only for Rosuvastatin-Medo 5 mg, 10 mg and 20 mg).

Rare side effects (effects occurring in 1-10 of 10,000 users):

- Severe allergic reaction – signs include: swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, severe itching of the skin (with raised lumps). **If you think you are having an allergic reaction, stop taking Rosuvastatin-Medo and seek medical help immediately.**
- Muscle damage in adults – **as a precaution, stop taking Rosuvastatin-Medo and talk to your doctor immediately if you have any unusual aches or pains in your muscles** which go on for longer than expected.
- Severe abdominal pain (pancreatitis)
- Increase in liver enzymes in the blood
- Bleeding or bruising more easily than normal due to low levels of blood platelets
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)

Very rare side effects (effects occurring in less than 1 of 10,000 users):

- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Traces of blood in the urine
- Damage to the nerves of your arms and legs (such as numbness or a tingling sensation)
- Joint pain
- Memory loss
- Breast enlargement in men (gynecomastia)

Other side effects (effects the incidence of which has not yet been determined):

- Diarrhea
- Cough
- Shortness of breath

- Edema (swelling as a result of fluid buildup)
- Sleep disturbances, including insomnia and nightmares
- Problems with sexual function
- Depression
- Breathing problems including a persistent cough and/or shortness of breath or fever
- Tendon injury
- Constant muscle weakness
- Myasthenia gravis (a disease causing general muscle weakness and including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).
Consult your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, 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 this leaflet, you must consult the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the "Report on side effects due to medication therapy" link on the Ministry of Health home page (www.health.gov.il) which 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 below 25°C.
- Store in the original package in order to protect from light.
- 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. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
- Do not store different medicines in the same package.

6. ADDITIONAL INFORMATION

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

Lactose monohydrate, cellulose microcrystalline PH-101, cellulose microcrystalline PH-102, crospovidone type A, magnesium stearate, silica colloidal anhydrous, hypromellose, titanium dioxide, triacetin,

Iron oxide yellow - 5 mg tablets

Iron oxide red - 10, 20 and 40 mg tablets

Each Rosuvastatin-Medo 5 mg tablet also contains 101.86 mg of lactose monohydrate.

Each Rosuvastatin-Medo 10 mg tablet also contains 96.79 mg of lactose monohydrate.

Each Rosuvastatin-Medo 20 mg tablet also contains 193.57 mg of lactose monohydrate.

Each Rosuvastatin-Medo 40 mg tablet also contains 174.98 mg of lactose monohydrate.

What does the medicine look like and what are the contents of the package:

Rosuvastatin-Medo 5 mg tablets: Yellow, round, biconvex film-coated tablets imprinted with "ROS" over "5" on one side and nothing on the reverse, with a diameter of 7 mm.

Rosuvastatin-Medo 10 mg tablets: Pink, round, biconvex film-coated tablets imprinted with "ROS" over "10" on one side and nothing on the reverse, with a diameter of 7 mm.

Rosuvastatin-Medo 20 mg tablets: Pink, round, biconvex film-coated tablets imprinted with "ROS" over "20" on one side and nothing on the reverse, with a diameter of 9 mm.

Rosuvastatin-Medo 40 mg tablets: Pink, oval, biconvex film-coated tablets imprinted with "ROS" on one side and "40" on the reverse, with dimensions of 6.8x11.4 mm.

The package contains 30 tablets in a blister pack.

Manufacturer: Medochemie Ltd. – Factory AZ, Limmasol, Cyprus

Registration holder and importer: A.L. Medi-Market Ltd., 3 Hakatif St., Emek Hefer Industrial Park, 3877701

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

Rosuvastatin-Medo 5 mg: 166-68-35816-00

Rosuvastatin-Medo 10 mg: 166-69-35817-00

Rosuvastatin-Medo 20 mg: 166-70-35818-00

Rosuvastatin-Medo 40 mg: 166-71-35819-00

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