

**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, 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.

Keep this leaflet. You may need it again.

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 below the age of 18.

If one of the side effects worsens, or if you suffer from a side effect not mentioned here, please refer to your doctor immediately.

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 contraception.
- 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 if 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 medicines called fibrates to lower your cholesterol.

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 regularly consume large amounts of alcohol.
- You have impaired liver, kidney or thyroid function.
- You take other cholesterol-lowering medicines called fibrates. Please read this leaflet carefully, even if you have previously taken cholesterol-lowering medicines.
- You are taking medicines intended for the treatment of HIV- Human Immunodeficiency Virus (such as ritonavir with lopinavir and/or atazanavir). Please refer to the section “Drug interactions”.
- You are taking, or have taken in the last 7 days, antibiotics containing fusidic acid (a medicine for treatment of bacterial infection, orally or by injection). The combination of fusidic acid and Rosuvastatin-Medo can cause serious muscle problems (rhabdomyolysis). Please refer to the section “Drug interactions”.
- You have severe impairment of the respiratory system.
- 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 general unwell feeling or have a fever. Also, inform your doctor if you have a muscle weakness that is constant.
- 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.
- You are over the age of 70 (the 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 syndrome 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 blood tests for liver function before and during treatment with Rosuvastatin-Medo.

During treatment with this medicine, your doctor will monitor you closely if you have diabetes or you 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:

- Drugs used for thinning the blood (such as warfarin or clopidogrel)
- Ciclosporin (used following organ transplantation)
- 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 (an antibiotic – see below and also in the section “Special warnings regarding use of Rosuvastatin-Medo”)
- Contraceptive pills
- Regorafenib (for the treatment of cancer)
- Darolutamide (for the treatment of cancer)
- Hormone replacement therapy
- Medicines for the treatment of viral infections, including for the acquired immunodeficiency virus (HIV) or hepatitis C infection, alone or in combination with ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir (please see section “Special warnings regarding use of Rosuvastatin-Medo”)

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.

Driving and operating machinery:

Most patients are able to drive a vehicle and operate machinery while using Rosuvastatin-Medo-The medicine will not impair their ability to perform these actions. However, some patients may feel dizzy during treatment with Rosuvastatin-Medo. If you feel dizzy, refer to the doctor prior to 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 will start 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 level
- The level of risk you have of experiencing a heart attack or a stroke
- The level of probability that you will be more sensitive to possible side effects

The 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 suffer from moderate kidney function problems.
- You are at risk of suffering from muscle aches and pains (myopathy).

Increasing the dose and maximum daily dose

The 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, the doctor may decide to double the dose to Rosuvastatin-Medo 10 mg, then to 20 mg, and if necessary, it will be increased to 40 mg. If you started on Rosuvastatin-Medo 10 mg, your doctor may decide to double the dose to 20 mg, and then to 40 mg, if necessary.

There will be a gap of four weeks between every dose increase.

The maximum daily dose is 40 mg. It is usually for patients with very high cholesterol levels and a high risk of a heart attack or stroke, when cholesterol levels are not lowered enough with 20 mg.

Do not exceed the recommended dose.

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

The medicine can be taken at any time of day, with or without food. 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 took a higher dose, contact your doctor or go a hospital.

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 medicine with you.

If you forgot to take the medicine, skip the missed dose and take the next dose according to the usual schedule. Never take two doses together to compensate for a forgotten one.

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

If you stop taking 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 a 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 (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 may cause difficulty in swallowing.
 - Severe itching of the skin (with raised blisters).
 - Reddish non-elevated, target-like or circular patches on the trunk, sometimes 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 expected. As with other statins, a small number of patients have experienced an unpleasant muscle effect, and, rarely, this effect becomes life threatening, damages the 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 that occur in 1-10 users in 100):

- Constipation,
- Headaches,
- Feeling ill,
- Dizziness,
- Abdominal pain,
- Weakness,
- Muscle pain,
- A rise in urine protein levels; These usually return to normal without having to stop taking the medicine (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 that occur in 1-10 users in 1,000):

- Skin rash, itching, and other skin reactions.
- A rise in urine protein levels; These usually return to normal without having to stop taking the medicine (only for Rosuvastatin-Medo 5 mg, 10 mg and 20 mg).

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

- Severe allergic reaction – signs include: swelling of the face, lips, tongue and/or throat, difficulty swallowing and breathing, severe itching of the skin (with raised blisters). If you think you are having an allergic reaction, stop taking Rosuvastatin-Medo and seek medical assistance 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 continue for longer than expected.
- Severe abdominal pain (pancreatitis)
- Increase in liver enzymes in the blood
- Bleeding or an increased tendency to bruise 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 that occur in less than 1 user in 10,000):

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

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

- Diarrhea
- Edema (swelling due to an accumulation of fluid)
- Sleep disturbance, including insomnia and nightmares
- Sexual dysfunction
- Depression
- Shortness of breath
- Breathing problems including a persistent cough and/or shortness of breath or fever
- Constant muscle weakness
- Cough
- Tendon injury

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 with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects due to Drug Treatment” found on the Ministry of Health homepage 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 closed 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.

Manufactured by: 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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