

This medicine is to be supplied by physician's prescription only

Rosuvastatin Sandoz® 10 mg

Rosuvastatin Sandoz® 20 mg

Rosuvastatin Sandoz® 40 mg

Film-coated tablets

Active substance and its amount:

Each tablet of Rosuvastatin Sandoz 10 mg contains 10 mg of rosuvastatin (as calcium). Each tablet of Rosuvastatin Sandoz 20 mg contains 20 mg of rosuvastatin (as calcium). Each tablet of Rosuvastatin Sandoz 40 mg contains 40 mg of rosuvastatin (as calcium). For a list of inactive ingredients please refer to "Important information about some of the ingredients in this medicine" as well as section 6 "FURTHER INFORMATION".

Read the entire leaflet carefully before using this medicine.

This leaflet contains a summary of the information about this medicine. If you have further questions, refer to the physician 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 medical condition is similar.

1. WHAT IS ROSUVASTATIN SANDOZ USED FOR?

Rosuvastatin Sandoz is used for the treatment of primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise weight reduction) is inadequate.

Rosuvastatin Sandoz is used for the treatment of homozygous familial hypercholesterolaemia as 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 Sandoz belongs to a group of medicines called statins, and is intended to reduce fats 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 Sandoz works by helping the body block the production of "bad cholesterol" and clearing it from the body.

2. BEFORE YOU TAKE ROSUVASTATIN SANDOZ

❑ Do not take Rosuvastatin Sandoz if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see section 6).
- You are pregnant or breastfeeding. If you become pregnant while using Rosuvastatin Sandoz, stop taking Rosuvastatin Sandoz immediately and inform your doctor. Avoid becoming pregnant by using suitable contraceptives.
- You have a liver disease.
- You have severe kidney problems.
- You have myopathy: persistent or unexplained muscle aches or pains.
- You are taking ciclosporin (used for instance following organ transplantation). Please refer to your doctor.

Do not use the 40 mg tablets (the highest dosage) if:

- You have moderate problems with kidney function (if you are not sure, contact your doctor).
- You have an underactive thyroid (hypothyroidism).
- You have unexplained muscle aches or pains; you have a family or personal history of muscle problems, or if you have had muscle problems in the past while taking other cholesterol-lowering medicines.
- You consume large amounts of alcohol.
- You are of Asian origin (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese).
- You take cholesterol-lowering medicines known as fibrates (such as gemfibrozil or fenofibrate).
- You are under 18 years old.

Refer to the doctor if any of these apply to you.

⚠ Special warnings regarding use of Rosuvastatin Sandoz

Before treatment with Rosuvastatin Sandoz, tell the doctor if:

- You have or have ever had any of the conditions described above ('BEFORE YOU TAKE ROSUVASTATIN SANDOZ').
- You consume large amounts of alcohol.
- You have impaired liver, kidney, or thyroid function.
- You are taking cholesterol-lowering medicines known as fibrates.
- You are taking medicines to treat HIV (such as ritonavir with lopinavir and/or atazanavir). See also the section 'Other medicines and Rosuvastatin Sandoz'.
- You are taking or have taken in the past week an antibiotic containing fusidic acid (in tablets or by injection, to treat a bacterial infection). The combination of fusidic acid and Rosuvastatin Sandoz can lead to a serious muscle problem (rhabdomyolysis). See also 'Other medicines and Rosuvastatin Sandoz'.
- You have severe impairment of the respiratory system.
- You have unexplained or persistent muscle pain, or if you or a family member have had muscle problems, muscle pain, or muscle weakness, or if you have a history of muscle problems when taking cholesterol-lowering agents. Inform the attending doctor if you experience muscle pain or muscle weakness, especially if these are accompanied by a generally unwell feeling or fever while taking this medicine, or if they persist after stopping treatment with Rosuvastatin Sandoz.
- You are of Asian origin (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese). Your doctor will choose the right start dose of Rosuvastatin Sandoz to suit you.
- You are over 70 years of age (your doctor will choose the right start dose of Rosuvastatin Sandoz to suit you).
- You are sensitive to any food or medicine.

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

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

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

During treatment with 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 your blood, are overweight, and have high blood pressure.

This medicine contains lactose which may cause an allergic reaction in people who are sensitive to this ingredient.

⚠ Children and adolescents:

This medicine is not intended for children and adolescents under the age of 18.

⚠ Other medicines and Rosuvastatin Sandoz

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

- Anticoagulants (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.
- Antacids.
- Erythromycin (an antibiotic), fusidic acid (an antibiotic – please see below and in the section 'SPECIAL WARNINGS REGARDING USE OF ROSUVASTATIN SANDOZ').
- Contraceptive pills.
- Regorafenib (used to treat cancer)
- Hormone replacement therapy.
- Medicines used to treat viral infections, including HIV or hepatitis C viral infection, alone or in combination (please see the section 'SPECIAL WARNINGS REGARDING USE OF ROSUVASTATIN SANDOZ'): ritonavir, lopinavir, atazanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir

Rosuvastatin Sandoz could change the effects of these medicines or these medicines could change the effect of Rosuvastatin Sandoz.

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using Rosuvastatin Sandoz. Your doctor will tell you when you can restart Rosuvastatin Sandoz. Taking Rosuvastatin Sandoz with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See also in the section 'SPECIAL WARNINGS REGARDING USE OF ROSUVASTATIN SANDOZ'.

⚠ Taking Rosuvastatin Sandoz with food

You can take the medicine with or without food.

⚠ Pregnancy and breastfeeding

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

If you become pregnant while using Rosuvastatin Sandoz, stop taking Rosuvastatin Sandoz 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 car and operate machinery while using Rosuvastatin Sandoz - the medicine does not impair their ability to perform these actions. However, some patients may feel dizzy during treatment with Rosuvastatin Sandoz. If you feel dizzy, you must refer to the doctor before operating machinery or driving a car.

⚠ Important information about some of the ingredients in this medicine

The tablets contain lactose, which is a type of sugar. If your doctor has told you that you are unable to digest certain sugars, consult your doctor before taking this medicine.

Each 10 mg tablet contains 52.92 mg lactose

Each 20 mg tablet contains 105.84 mg lactose

Each 40 mg tablet contains 211.68 mg lactose

3. HOW DO YOU USE ROSUVASTATIN SANDOZ?

Always use according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure about the dosage and duration of treatment.

The dosage and manner of treatment will be determined by the doctor only.

The recommended dosage is usually:

Treatment should start with another product containing the active ingredient rosuvastatin with a strength of 5 mg, or one tablet of Rosuvastatin Sandoz 10 mg once a day, even if you have previously taken other statins.

The choice of your starting dose will depend on:

- your cholesterol level.
- your risk of having a heart attack or stroke.
- your likelihood of being more sensitive to possible side effects.

Your doctor may decide to give you the lowest dose of another product that contains the active ingredient rosuvastatin with a strength of 5 mg if:

- You are of Asian origin (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese).
- You are over 70 years of age.

- You have moderately impaired kidney function.
- You are at risk of having muscle pain (myopathy).

- Increasing the dose and maximum daily dose:

Your doctor may decide to increase your dose so that it is right for you. If you started with a 5 mg dose of another product that contains the active ingredient rosuvastatin, your doctor may decide to double this to 10 mg of Rosuvastatin Sandoz, then 20 mg and then increase to 40 mg if necessary. If you started treatment on 10 mg of Rosuvastatin Sandoz, your doctor may decide to double this to 20 mg and then increase to 40 mg if necessary. There will be a gap of 4 weeks between every dose adjustment.

- The maximum daily dose is 40 mg and is usually given to patients with very high levels of cholesterol and a high risk of heart attack or stroke whose cholesterol levels are not lowered enough with a 20 mg dose.

- **Do not exceed the recommended dose.**

- This medicine is usually not intended for children under 18 years old.
- Take this medicine at scheduled times as determined by the attending doctor.
- Swallow the tablets whole with water.
- There is no information regarding breaking and crushing the tablets.
- You can take the medicine at any time of day, with or without food. It is advisable to take your medicine at the same time every day.

- **If you take an overdose or if a child has accidentally swallowed the medicine, refer to a doctor immediately or proceed to a hospital emergency room, and bring the package of the medicine with you.**

- **If you forget to take the medicine** at the scheduled time, skip the forgotten dose and take the next dose according to the usual schedule.

- Do not take two doses together to compensate for a missed one.
- Be sure to maintain a low-cholesterol diet during treatment with this medicine.
- If you take an antacid of the aluminum or magnesium salt type, you must take Rosuvastatin Sandoz at least two hours before taking the aluminum/magnesium salt antacid.
- Regularly check cholesterol levels to confirm that your cholesterol has reached and is maintained at the desired level.

How can you contribute to the success of the treatment?

You must complete the course of treatment recommended by the doctor.

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

Your cholesterol levels might increase again if you stop taking this medicine.

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 any further questions regarding the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, Rosuvastatin Sandoz can cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

These effects usually pass within a short time following the period of adaptation to the medicine.

Effects that require special attention, stop treatment with Rosuvastatin Sandoz and contact to the doctor immediately if:

- **You experience the following hypersensitive reaction (allergy):**

- Severe allergic reaction - including signs of swelling of the face, lips, tongue and/or throat, difficulty swallowing or breathing (rare).
- Difficulty breathing with or without swelling of the face, lips, tongue and/or throat (rare).
- Severe itching of the skin with raised blisters (rare).

- You have unexplained muscle aches and pains, or prolonged muscle pains, weakness especially with fever or with spasms. As with other statins, a small number of patients have experienced an unpleasant muscle effect and, rarely, this effect can become life threatening, damaging muscles - a condition known as rhabdomyolysis.

- You have a tear in a muscle.
- You have lupus-like disease syndrome (including rash, joint disorders and an effect on blood cells).

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

Constipation; headaches; nausea; dizziness; abdominal pain; weakness; muscle pain; an increase in urine protein levels - these usually return to normal without need to discontinue use of the medication (only for Rosuvastatin Sandoz 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 (occur in 1-10 out of 1,000 users):

Skin rash, itching, hives, and other skin reactions; an increase in urine protein levels - these usually return to normal without need to discontinue use of the medication (for Rosuvastatin Sandoz 10 mg and 20 mg).

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

Severe allergic reaction whose signs include: swelling of the face, lips, tongue

and/or throat, difficulty in swallowing and breathing, severe itching of the skin (with raised blisters). If you think you are having an allergic reaction, stop taking Rosuvastatin Sandoz and seek medical help immediately; muscle damage in adults – as a precaution, stop taking Rosuvastatin Sandoz and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than usual; severe stomach pain (inflamed pancreas); 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 an effect on blood cells).

Very rare side effects (occur in less than one out of 10,000 users):

Jaundice (yellowing of the skin and whites of eyes); hepatitis (inflammation of the liver). The signs are tiredness or weakness, loss of appetite, pain in upper abdomen, dark urine; traces of blood in the urine; joint pain; damage to the nerves of your legs and arms (such as numbness or tingling sensation); memory loss; breast enlargement in men (gynaecomastia).

Side effects of unknown frequency (the frequency of these effects has not been established yet):

Diarrhea; Stevens-Johnson syndrome (emergence of blistering on the skin, mouth, eyes, and genitals); edema (swelling as a result of fluid buildup); sleep disturbances, including insomnia and nightmares; problems with sexual function; depression; shortness of breath; breathing problems including a persistent cough and/or difficulty breathing or fever; constant muscle weakness; cough; tendon injury.

Report to the doctor or pharmacist if you think you have any of these problems or any other problem while taking Rosuvastatin Sandoz.

If a side effect appears, 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 (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD ROSUVASTATIN SANDOZ BE STORED?

- **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) appearing on the carton or the blister. The expiry date refers to the last day of that month. In case of doubt, consult the pharmacist who dispensed the medicine to you.

Storage conditions

- Store at a temperature that does not exceed 25°C.
- Store in the original package in order to protect from moisture.
- Do not store different medications in the same package.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: anhydrous lactose, silicified microcrystalline cellulose, maize starch dried, hypromellose (2910), sodium stearyl fumarate, talc, titanium dioxide (E171), silica colloidal anhydrous, ferric oxide yellow (E172), mannitol, macrogol 6000, ferric oxide red (E172).
- What does the medicine look like and what are the contents of the package:
Rosuvastatin Sandoz 10 mg tablets: Brown, round, film-coated tablets with "RSV 10" debossed on one side.
Rosuvastatin Sandoz 20 mg tablets: Brown, round, film-coated tablets with "RSV 20" debossed on one side.
Rosuvastatin Sandoz 40 mg tablets: Brown, round, film-coated tablets with "RSV 40" debossed on one side.

Each package of the product contains 28 or 30 tablets in blisters.

Registration holder:

Novartis Israel Ltd., POB 7126, Tel Aviv, Israel.

Manufacturer:

Lek Pharmaceuticals d.d., Ljubljana, Slovenia.

This leaflet was checked and approved by the Ministry of Health in June 2019 and revised in December 2019 in accordance with Ministry of Health guidelines.

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

Rosuvastatin Sandoz® 10 mg: 162-39-35574-00/01

Rosuvastatin Sandoz® 20 mg: 162-40-35575-00/01

Rosuvastatin Sandoz® 40 mg: 162-41-35576-00/01