

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

The medicine is dispensed with a doctor's prescription only

Rosuvastatin Teva New 5 mg

Film-coated tablets

Each film-coated tablet contains:
Rosuvastatin 5 mg (as rosuvastatin calcium)

Rosuvastatin Teva New 10 mg

Film-coated tablets

Each film-coated tablet contains:
Rosuvastatin 10 mg (as rosuvastatin calcium)

Rosuvastatin Teva New 20 mg

Film-coated tablets

Each film-coated tablet contains:
Rosuvastatin 20 mg (as rosuvastatin calcium)

Rosuvastatin Teva New 40 mg

Film-coated tablets

Each film-coated tablet contains:
Rosuvastatin 40 mg (as rosuvastatin calcium)

For information regarding inactive ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist. This medicine has been prescribed for treatment of 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 Teva New is not intended for children and adolescents under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rosuvastatin Teva New is intended for treatment of adults:

- For primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia) (conditions in which the blood cholesterol level is high) or type IIb mixed dyslipidemia (disorder in the levels of different blood lipids). The medicine is given as an adjunct to diet in situations in which the response to diet and to other non-pharmacological treatments (such as exercising for weight loss) is insufficient.
- For homozygous familial hypercholesterolemia (a condition in which the blood cholesterol level is high) in combination with diet and other treatments for reducing lipid levels in the blood (such as LDL apheresis) or in cases where these treatments are not appropriate.

Therapeutic class

HMG-CoA reductase enzyme inhibitor.
Rosuvastatin Teva New belongs to a group of medicines called statins, which works to reduce lipid 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 Teva New works to help the body block the production of "bad cholesterol" and eliminate 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 (allergic) to the active ingredient** or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
 - **You are pregnant or breastfeeding.** If you become pregnant while using Rosuvastatin Teva New **stop taking Rosuvastatin Teva New immediately and inform your doctor.** Avoid becoming pregnant by using suitable contraceptives.
 - **You have a liver disease.**
 - **You suffer from severe kidney problems.**
 - **You suffer from repeated or unexplained muscle soreness or pain.**
 - **You are taking a medicine combination of sofosbuvir/velpatasvir/voxilaprevir** (used for treatment of viral infection of the liver called hepatitis C).
 - **You are taking cyclosporine** (e.g. after organ transplantation).
 - You are under the age of 18.
- Please refer to your doctor if any of these applies to you (or if you are in doubt).
- In addition, do not use Rosuvastatin Teva New 40 mg tablets (the highest dosage) if:**
- **You suffer from moderate problems with kidney function** (if in doubt, refer to the doctor).
 - **You suffer from thyroid function problems**
 - **You suffer from repeated or unexplained muscle soreness or pain,** if you have a personal or family history of muscle problems or if you have suffered in the past from muscle problems while taking other medicines for lowering cholesterol.
 - **You regularly consume large amounts of alcohol.**
 - **You are of Asian descent** (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese).
 - **You are taking other medicines for lowering cholesterol called fibrates.**
- Please refer to the doctor if any of these applies to you (or if in doubt).**

Special warnings regarding the use of the medicine

Before treatment with the medicine, tell the doctor if:

- **You suffer from impaired function of the liver, kidneys or thyroid.**
- **You suffer from repeated or unexplained muscle soreness or pain** or if you or a family member has suffered in the past from muscle problems or if you have a history of muscle problems while taking other medicines for lowering cholesterol. Inform the treating doctor immediately if unexplained muscle soreness or pain occur, especially if they are accompanied by general malaise or fever. Also, inform the doctor if you suffer from constant muscle weakness.
- **You suffer or have suffered in the past from myasthenia** (a disease that leads to general muscle weakness that includes in certain cases weakness of the muscles involved in respiration) or ocular myasthenia (a disease that causes weakness of the eye muscles), since statins may sometimes worsen the disease or lead to its appearance (see section 4 - "Side effects").
- **If you have ever developed severe skin rash or peeling of the skin, blisters and/or mouth sores after taking rosuvastatin or other related medicines.**
- **You regularly consume large amounts of alcohol.**
- **You are taking other medicines for lowering cholesterol called fibrates,** please read this leaflet carefully even if you have used medicines for lowering cholesterol in the past.
- **You are taking medicines intended to treat infection of the human immunodeficiency virus (HIV)** (such as: ritonavir with lopinavir and/or atazanavir). **See below in section 2 – "Drug interactions"**
- **You are taking or have taken in the last 7 days an antibiotic that contains fusidic acid** (for treatment of bacterial infection, orally or by injection). The combination of fusidic acid and rosuvastatin may lead to serious muscle problems (rhabdomyolysis). **See below in section 2 – "Drug interactions"**
- **You are above the age of 70** (the doctor will choose a starting dosage of Rosuvastatin Teva New that is suitable for you).
- **You suffer from severe respiratory failure.**
- **You are of Asian descent** (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese). The doctor will choose a starting dosage of Rosuvastatin Teva New that is suitable for you.

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

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

Severe skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in relation to treatment with rosuvastatin. Stop using Rosuvastatin Teva New and seek immediate medical assistance if you notice any of the symptoms described in section 4 – "Side effects".

In a small number of patients, statins may affect the liver; this effect can be identified in a simple blood test that checks for an elevation of liver enzyme levels. Therefore, the doctor will usually refer you for liver function blood tests before and during treatment with the medicine.

While you are being treated 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.

Children and adolescents

Rosuvastatin Teva New 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, tell the doctor or the pharmacist.

- Cyclosporine (used after organ transplantation)
- Warfarin, clopidogrel or ticagrelor (or any other blood thinning medicine)
- Fibrates (such as gemfibrozil or fenofibrate) or any other cholesterol-reducing medicine (such as ezetimibe)
- Medicines for treatment of indigestion (used as antacids in the stomach)
- Erythromycin (an antibiotic), fusidic acid (an antibiotic – see below and above in the section "Special warnings regarding the use of the medicine")
- Contraceptive pills
- Regorafenib (for the treatment of cancer)
- Darolutamide (for the treatment of cancer)
- Capmatinib (for the treatment of cancer)
- Hormone replacement therapy
- Fostamatinib (for treatment of low platelet count)
- Febuxostat (for treatment and prevention of high uric acid levels in the blood)
- Teriflunomide (for treatment of multiple sclerosis)
- Medicines for treatment of viral infections, including an infection of the human immunodeficiency virus (HIV) or liver infection (hepatitis) type C, alone or in combination with (see section "Special warnings regarding the use of the medicine"): ritonavir, lopinavir, atazanavir, sofosbuvir, velpatasvir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

The effect of these medicines may change as a result of concomitant use with Rosuvastatin Teva New or they may change the effect of Rosuvastatin Teva New.

Fusidic acid (an antibiotic) – if you need to take fusidic acid orally to treat a bacterial infection, you will need to temporarily stop the treatment with Rosuvastatin Teva New. The doctor will tell you when you can restart taking Rosuvastatin Teva New. Taking rosuvastatin with fusidic acid may rarely cause muscle weakness, tenderness or pain (rhabdomyolysis). See further information regarding rhabdomyolysis in section 4 – "Side effects".

Use of the medicine and food

Rosuvastatin Teva New can be taken with or without food.

Pregnancy and breastfeeding

Do not take Rosuvastatin Teva New if you are pregnant or breastfeeding. If you become pregnant while using Rosuvastatin Teva New **stop taking Rosuvastatin Teva New immediately** and inform your doctor. Avoid becoming pregnant during treatment with this medicine by using suitable contraceptives.

Consult with your doctor or pharmacist before taking any medicine.

Driving and operating machinery

Most patients can drive a vehicle and operate machinery while using Rosuvastatin Teva New – the medicine will not impair their ability to perform these activities. However, some patients may feel dizzy while using the medicine. If you feel dizzy, you should refer to the doctor before operating machinery or driving a vehicle.

Important information about some of the ingredients of the medicine

The medicine contains lactose. If you have been told by the doctor that you have an intolerance to some sugars (lactose or milk sugar), consult your doctor before taking this medicine.

The medicine contains less than 1 mmol of sodium (23 mg) per tablet, and is thus considered to be "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be determined only by the doctor.

The generally accepted dosage is: treatment with Rosuvastatin Teva New will begin with **one 5 mg or 10 mg tablet** once daily, even if you have previously taken other statins at a higher dosage. The choice of the starting dosage will depend on:

- The level of cholesterol.
- Your level of risk of having a heart attack or a stroke.
- How likely you are to be more sensitive to possible side effects.

Please consult your doctor or pharmacist regarding the dosage that is most suitable for you.

The doctor may decide to give you the lowest dosage – 5 mg if:

- You are of **Asian** descent (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese).
- You are **70 years old or older.**
- You suffer from moderate problems with kidney function.
- You are at risk of suffering from muscle pain (myopathy).

Increasing the dosage and maximum daily dosage

The doctor may decide to increase the dosage that you take so that it is suitable for you. If you started with a dosage of Rosuvastatin Teva New 5 mg, the doctor may double the dosage to Rosuvastatin Teva New 10 mg, then to 20 mg, and if needed, he will increase it to 40 mg. If you started with a dosage of Rosuvastatin Teva New 10 mg, the doctor may double the dosage to 20 mg and then, if needed, he will increase it to 40 mg. There will be an interval of 4 weeks between each dose increase.

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

Do not exceed the recommended dose.

Regular cholesterol tests

Cholesterol levels should be checked regularly, in order to make sure that your cholesterol has reached the desired level and that this level is maintained. The doctor may decide to increase the dosage so that you take the amount of medicine that is suitable for you.

Method of use

The medicine may be taken at any time of the day with or without food. It is recommended to take the medicine at the same time every day in order to remember to take the medicine.

The tablets should be swallowed with water.

If you take antacids of the aluminum or magnesium salt type, take Rosuvastatin Teva New at least two hours before taking antacids of the aluminum/magnesium salt type.

The tablets of Rosuvastatin Teva New 10 mg, 20 mg and 40 mg can be halved at the score line.

Do not halve the Rosuvastatin Teva New 5 mg tablet.

No information is available regarding crushing and pulverizing the tablet.

If you accidentally took a higher dosage contact the doctor or refer to the hospital. If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

If you forgot 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.

Follow the treatment 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 every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Rosuvastatin Teva New may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Side effects that require special attention

Stop the treatment with Rosuvastatin Teva New and seek medical attention immediately if:

- You have any of the following hypersensitivity (allergy) reactions:
 - 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 swallowing difficulties.
 - Acute itching of the skin (with the appearance of raised blisters).
 - Reddish non-raised, target-like or circular spots on the body, sometimes with blisters in the center, peeling skin, ulcers in the mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
 - Extensive rash, high fever and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

In addition, stop the treatment with Rosuvastatin Teva New and refer immediately to the doctor if:

- **You have unusual muscle pain and soreness** that last longer than expected. As with other statins, a small number of patients have experienced an unpleasant effect in the muscles, and this effect can rarely become potentially life-threatening muscle damage known as rhabdomyolysis.
- **You have a muscle rupture.**
- **You have lupus-like syndrome** (including rash, joint disorders and an effect on blood cells).

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

- Headaches.
- Abdominal pain.
- Constipation.
- Malaise.
- Muscle pain.
- Weakness.
- Dizziness.

- An increase in the amount of protein in the urine – this usually returns to normal without the need to stop taking the medicine (only for Rosuvastatin Teva New 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 treatment period.

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

- Skin rash.
- Itch or other skin reactions.
- An increase in the amount of protein in the urine – this usually returns to normal without the need to stop taking the medicine (only for Rosuvastatin Teva New 5 mg, 10 mg and 20 mg).

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

- A severe allergic reaction whose 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 Teva New and seek immediate medical attention.**
- Muscle damage in adults – **as a precaution, stop taking Rosuvastatin Teva New and talk to your doctor immediately if you feel unusual muscle pain or soreness** that last longer than expected.
- Severe abdominal pain (inflammation of the pancreas – pancreatitis).
- Increased liver enzymes in the blood.
- Bleeding or increased tendency to bruising as a result of low platelet levels.
- Lupus-like syndrome (including rash, joint disorders and an effect on blood cells).

Very rare side effects (effects that occur in less than 1 user out of 10,000 users):

- Jaundice (yellowing of the skin and the eyes).
- Inflammation of the liver (hepatitis).
- Blood traces in the urine.
- Damage to the nerves in the arms and legs (such as loss of sensation or sensation of numbness).
- Joint pain.
- Memory loss.
- Breast enlargement in men (gynecomastia).

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

- Diarrhea.
- Cough.
- Shortness of breath.
- Edema (swelling due to accumulation of fluids).
- Sleep disorder, including insomnia and nightmares.
- Sexual dysfunction.
- Depression.
- Breathing problems including persistent cough and/or shortness of breath or fever.
- Tendon injury.
- Constant muscle weakness.
- Myasthenia gravis (a disease that leads to general muscle weakness that includes in certain cases weakness of the muscles involved in respiration).
- Ocular myasthenia (a disease that causes weakness of the eye muscles).

Consult your doctor if you experience weakness in the arms or legs that worsens after periods of activity, double vision or drooping 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 the leaflet, consult with the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:

<https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

Store below 25°C.

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store different medicines in the same package.
- Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

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

Lactose monohydrate, microcrystalline cellulose, crospovidone, Hydroxypropylcellulose, magnesium stearate, Sodium hydrogen carbonate, hypromellose, titanium dioxide (E171), Triacetin.

Rosuvastatin Teva New 5 mg:

Iron oxide yellow (E172)

Rosuvastatin Teva New 10 mg, 20 mg and 40 mg:

Iron oxide red (E172)

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

Rosuvastatin Teva New 5 mg: a round, biconvex, yellow film-coated tablet, one side of the tablet is debossed with "5" and the other side is plain.

Rosuvastatin Teva New 10 mg: a round, biconvex, pink film-coated tablet, with a score line on one side of the tablet and the other side is debossed with "10".

Rosuvastatin Teva New 20 mg: a round, biconvex, pink film-coated tablet, with a score line on one side of the tablet and the other side is debossed with "20".

Rosuvastatin Teva New 40 mg: an oval, biconvex, pink film-coated tablet, with a score line on one side of the tablet and the other side is debossed with "40".

The package contains 30 tablets in a blister pack.

Name and address of the license holder and manufacturer:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

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

Rosuvastatin Teva New 5 mg: 175.43.36936

Rosuvastatin Teva New 10 mg: 175.44.36937

Rosuvastatin Teva New 20 mg: 175.45.36938

Rosuvastatin Teva New 40 mg: 175.46.36939

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