

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

The medicine is dispensed with
a doctor's prescription only

**ROSUVASTATIN TEVA® 5 mg
Tablets**

Composition:

Each tablet contains:
Rosuvastatin (as calcium) 5 mg

**ROSUVASTATIN TEVA® 10 mg
Tablets**

Composition:

Each tablet contains:
Rosuvastatin (as calcium) 10 mg

**ROSUVASTATIN TEVA® 20 mg
Tablets**

Composition:

Each tablet contains:
Rosuvastatin (as calcium) 20 mg

**ROSUVASTATIN TEVA® 40 mg
Tablets**

Composition:

Each tablet contains:
Rosuvastatin (as calcium) 40 mg

Inactive and allergenic ingredients – see
section 6 – “Further Information”.

**Read this 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 Teva® is not intended for
children and adolescents under 18 years
of age.

**1. WHAT IS THE MEDICINE INTENDED
FOR?**

Rosuvastatin Teva® is indicated for lowering
high levels of cholesterol and triglycerides
in the blood when changes in diet and
exercise have failed to do so.

During treatment with Rosuvastatin Teva®,
continue with a cholesterol-reducing diet
and physical activity.

High levels of cholesterol in the blood may
cause risk of heart attack or stroke.

Therapeutic group

Statins which inhibit the activity of the
HMG-CoA reductase enzyme.

There are several types of cholesterol in
the blood, “bad cholesterol” and “good
cholesterol”.

Rosuvastatin Teva® acts and helps the body
block production of “bad cholesterol” and
to clear it from the body.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- You are pregnant, planning to become pregnant, or if you are of childbearing age and are not using contraceptives. If you become pregnant while using Rosuvastatin Teva®, stop treatment and consult the doctor immediately!
- You are breastfeeding.
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine.
- You are suffering from acute kidney problems.
- You are taking ciclosporin (a medicine given following transplantation). Please refer to your doctor.
- You are suffering from recurrent or unexplained muscle pain (myopathy).
- You are suffering from liver disease or from an unexplained increase in blood transaminase (enzyme) levels.
- In children and adolescents under 18 years of age.

Do not take a dosage of 40 mg per day if:

- There is a kidney or liver function impairment.
- There is a thyroid function impairment.
- You are taking ciclosporin (used after organs transplantation).
- You are suffering, or have suffered in the past, from unexplained muscle pain, if there is a history of muscle problems while taking other cholesterol-lowering medicines, or if there is a family history of muscle problems.
- You consume large amounts of alcohol.
- You are of East-Asian origin (Japanese, Chinese, Filipino, Indian, Korean, Malaysian, Vietnamese).
- You are taking other blood lipid-lowering medicines from the fibrate group (such as: fenofibrate, gemfibrozil).

**Special warnings regarding use of
Rosuvastatin Teva®**

Before treatment with Rosuvastatin Teva®,
tell the doctor if:

- You are suffering, or have suffered in the past, from any of the conditions described above (“Before Using The Medicine”).
- You consume large amounts of alcohol.
- You suffer from a impaired liver, kidney or thyroid function.
- You take cholesterol-lowering medicines known as fibrates.
- You are taking medicines to treat the human immunodeficiency virus (such as: ritonavir with lopinavir and/or atazanavir).
- You are taking antibiotics containing fusidic acid.
- You are suffering from a severe impairment of the respiratory system.
- You are suffering from high levels of sugar or of HbA1c in the blood.
- You are suffering from an unexplained or persistent muscle pain, or if you or your family member have suffered in the past from muscle problems, muscle pain or muscle weakness, or if you have a history of muscle problems while taking cholesterol-lowering preparations. Inform the attending doctor if muscle pain or weakness appears, especially if these are accompanied by a generally unwell feeling or fever, during treatment with this medicine, or if they persist after stopping treatment with Rosuvastatin Teva®.
- You are of East-Asian origin (Japanese, Chinese, Filipino, Indian, Korean, Malaysian, Vietnamese).
- You are over the age of 70.
- You are sensitive to any food or medicine.

If any of the effects listed above applies to you (or if you are uncertain):

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

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. Therefore, the doctor will ask you to perform liver function blood tests before and during treatment with Rosuvastatin Teva®.

While you are being treated with this medicine, your doctor will monitor you closely if you have diabetes or if 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, are overweight, and have high blood pressure.

If you are seriously ill or go to a hospital, please inform the medical staff that you are taking Rosuvastatin Teva®.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially if you are taking:

- Anticoagulants (such as: warfarin),
- Erythromycin (an antibiotic),
- Ciclosporin (given following organ transplantations),
- Fibrates (such as: gemfibrozil, fenofibrate) or other cholesterol-lowering medicines (such as: ezetimibe),
- Contraceptive pills,
- Hormone replacement therapy,
- Niacin and nicotinic acid,
- Protease enzyme inhibitors to treat AIDS and hepatitis C (such as: lopinavir, ritonavir, atazanavir),
- Fusidic acid (an antibiotic),
- Antacids (for indigestion) – wait for a period of at least two hours between taking this medicine and taking antacids.
- Antifungal medicines (such as: itraconazole, ketoconazole and fluconazole),
- Colchicine (a medicine to treat gout).

❗ Use of the medicine and food

The medicine can be taken once a day, at any time of the day, with or without food.

Be sure to maintain a low-cholesterol diet during the course of treatment with the medicine.

❗ Use of the medicine and alcohol consumption

Do not drink large quantities of wines or alcoholic beverages during the course of treatment with the medicine.

❗ Pregnancy and breastfeeding

Do not use the medicine if you are pregnant or breastfeeding, planning to become pregnant or if you are of childbearing age and are not using contraceptives.

If you become pregnant while using Rosuvastatin Teva®, stop treatment and consult the doctor immediately!

❗ Driving and use of machines

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

❗ Important information regarding some of the ingredients of the medicine

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

**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.

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

The usual dosage is generally:

- Treatment with Rosuvastatin Teva® will begin with one 5 mg or 10 mg tablet once a day, even if you have previously taken other statins.
- The maximum daily dosage is 40 mg and is usually given to patients with very high levels of cholesterol and who are receiving the treatment according to a specialist's advice.
- **Do not exceed the recommended dose.**
- This medicine is not intended for children under 18 years of age.
- Take this medicine at set intervals, as determined by the attending doctor.
- During the course of treatment with this medicine, be sure to maintain a low-cholesterol diet.
- If you are taking antacids of the aluminium or magnesium salt type, take Rosuvastatin Teva® at least two hours before taking aluminium/magnesium salt antacids.
- Check cholesterol levels regularly in order to ensure that your cholesterol has reached the desired level and that this level is maintained.
- Swallow the tablets whole with water.
- The medicine can be taken at any time of the day, with or without food.

Mode of administration: Do not chew, crush or halve! Swallow the tablets with water.

Tests and follow-up

During the course of treatment with this medicine, perform the following tests: blood fat levels, liver function before and during treatment with Rosuvastatin Teva®.

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

If you forget to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

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

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

4. SIDE EFFECTS

As with any medicine, use of Rosuvastatin Teva® 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 and refer to the doctor immediately if the following effects develop:

- An acute allergic reaction including swelling of the face, lips, tongue and/or throat, that may cause difficulty swallowing.
- Difficulty breathing, with or without swelling of the face, lips, tongue and/or throat.
- Unexplained muscle aches and pain, or prolonged muscle pain, weakness especially with fever or with seizures. 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.
- Acute itching of the skin accompanied by emergence of raised blisters (rare).
- Severe abdominal pain (inflammation of the pancreas).
- Increase in liver enzyme levels in the blood.
- Jaundice (yellowing of the skin and the eyes) (very rare).
- Interstitial lung disease, which may manifest as shortness of breath, a dry cough and a decline in general health (such as: tiredness, weight loss and fever). Refer to a doctor immediately! (unknown frequency).

Additional side effects

Common side effects – occur in 1-10 users in 100 patients

- Constipation, nausea, headaches, feeling ill, dizziness, abdominal pain, exhaustion, weakness.
- An increase in urine protein levels (for Rosuvastatin Teva® 40 mg only) - this usually returns to normal without need to stop treatment with the preparation.
- Diabetes. The risk of developing diabetes is more likely if you have high levels of fats and sugar in the 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 users in 1,000 patients

- Skin rash, itching, hives and other skin reactions.
- An increase in urine protein levels (for Rosuvastatin Teva® 5, 10 and 20 mg only) - this usually returns to normal without need to stop treatment with the preparation.

Very rare side effects – occur in less than one user in 10,00 patients

A tingling sensation or numbness in the hands and legs, hepatitis (inflammation of the liver, whose signs are tiredness or weakness, loss of appetite, upper abdominal pain, dark urine), traces of blood in the urine, joint pain, memory loss, breast enlargement in men (gynaecomastia).

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

Diarrhea, confusion, cough, shortness of breath, edema, sleep disturbances (including insomnia and nightmares), numbness, tingling or pain in the arms or legs (peripheral neuropathy), impaired sexual function, depression, Stevens-Johnson syndrome (emergence of blisters on the skin, mouth, eyes and genitals), tendon injury, constant muscle weakness, breathing problems including persistent cough and/or breathing difficulties or fever.

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, consult the doctor.

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:

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from 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.
- Store in a dry place, at a temperature below 25°C.

6. FURTHER INFORMATION

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

Lactose anhydrous, microcrystalline cellulose, croscarmellose, povidone, sodium stearyl fumarate, polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, iron oxide yellow.

– Present only in 5 mg tablet: FD&C yellow #6, iron oxide black.

– Present only in 10 mg, 20 mg & 40 mg tablets: iron oxide red, carmoisine aluminium lake, FD&C blue #2.

Each 5 mg tablet contains: 55 mg lactose, 0.2 mg sodium.

Each 10 mg tablet contains: 52.4 mg lactose, 0.2 mg sodium.

Each 20 mg tablet contains: 104.7 mg lactose, 0.4 mg sodium.

Each 40 mg tablet contains: 94.3 mg lactose, 0.4 mg sodium.

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

- Rosuvastatin Teva® 5 mg – each package contains 30 round, orange tablets, with the letter N imprinted on one side and the number 5 on the other side.
- Rosuvastatin Teva® 10 mg – each package contains 30 round, pink tablets, with the letter N imprinted on one side and the number 10 on the other side.
- Rosuvastatin Teva® 20 mg – each package contains 30 round, pink tablets, with the letter N imprinted on one side and the number 20 on the other side.
- Rosuvastatin Teva® 40 mg – each package contains 30 oval, pink tablets, with the letter N imprinted on one side and the number 40 on the other side.

• Manufacturer, license holder and address: Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva

• This leaflet was checked and approved by the Ministry of Health on 06.06.16

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

- Rosuvastatin Teva® 5 mg: 144.36.31959
- Rosuvastatin Teva® 10 mg: 144.37.31960
- Rosuvastatin Teva® 20 mg: 144.38.31961
- Rosuvastatin Teva® 40 mg: 144.39.33139

