

Package leaflet: Information for the user

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## Rosuvastatin 20 mg

film-coated tablets

rosuvastatin

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**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

- What Rosuvastatin is and what it is used for
- What you need to know before you take Rosuvastatin
- How to take Rosuvastatin
- Possible side effects
- How to store Rosuvastatin
- Contents of the pack and other information

### 1. What Rosuvastatin is and what it is used for

Rosuvastatin belongs to a group of medicines called statins.

You have been prescribed Rosuvastatin because:

- You have a **high cholesterol level**. This means you are **at risk from a heart attack or stroke**. Rosuvastatin is used in adults, adolescents and children 6 years or older to treat high cholesterol.

You have been advised to take a statin, because changing your diet and taking more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking Rosuvastatin.

Or

- You have other factors that increase your risk of having a heart attack, stroke or related health problems.

Heart attack, stroke and other problems can be caused by a disease called atherosclerosis. Atherosclerosis is due to build up of fatty deposits in your arteries.

**Why is it important to keep taking Rosuvastatin?**

Rosuvastatin is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol.

There are different types of cholesterol found in the blood – ‘bad’ cholesterol (LDL-C) and ‘good’ cholesterol (HDL-C).

- Rosuvastatin can reduce the ‘bad’ cholesterol and increase the ‘good’ cholesterol.
- It works by helping to block your body’s production of

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→ smer branja kode/direction of reading PhC

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smer branja kode/direction of reading PhC

will depend upon:

- Your cholesterol level.
- The level of risk you have of experiencing a heart attack or stroke.
- Whether you have a factor that may make you more sensitive to possible side effects.

Please check with your doctor or pharmacist which start dose of Rosuvastatin will best suit you.

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

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

**Increasing the dose and maximum daily dose**

Your doctor may decide to increase your dose. This is so that you are taking the amount of Rosuvastatin that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then 20 mg and then 40 mg if necessary. If you started on 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 of Rosuvastatin is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

**If you are taking Rosuvastatin to reduce your risk of having a heart attack, stroke or related health problems:**

The recommended dose is 20 mg daily. However, your doctor may decide to use a lower dose if you have any of the factors mentioned above.

**Use in children and adolescents aged 6–17 years**

The dose range in children and adolescents aged 6 to 17 years is 5 to 20 mg once daily. The usual start dose is 5 mg per day and your doctor may gradually increase your dose to find the right amount of Rosuvastatin for you. The maximum daily dose of Rosuvastatin is 10 or 20 mg for children aged 6 to 17 years depending on your underlying condition being treated. Take your dose once a day. Rosuvastatin 40 mg tablet should not be used by children.

**Taking your tablets**

Swallow each tablet whole with a drink of water.

**Take Rosuvastatin once daily.** You can take it at any time of the day with or without food.

Try to take your tablet at the same time every day to help you to remember it.

**Regular cholesterol checks**

It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level. Your doctor may decide to increase your dose so that you are taking the amount of Rosuvastatin that is right for you.

**If you take more Rosuvastatin than you should**

Contact your doctor or nearest hospital for advice. If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking Rosuvastatin.

**If you forget to take Rosuvastatin**

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Rosuvastatin**

Talk to your doctor if you want to stop taking Rosuvastatin.

Your cholesterol levels might increase again if you stop taking Rosuvastatin.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

**Stop taking Rosuvastatin and seek medical help immediately** if you have any of the following allergic reactions:

- Difficulty in 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 lumps).

**Also, stop taking Rosuvastatin and talk to your doctor immediately if you have any of the following:**

- Unusual aches or pains in your muscles which go on for longer than you might expect. Muscle symptoms are more common in children and adolescents than in adults. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as *rhabdomyolysis*.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).
- Muscle rupture.

- If you notice 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).
- If you notice widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

**Common possible side effects (these may affect up to 1 in 10 people):**

- Headache
- Stomach pain
- Constipation
- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin tablets (only the 40 mg dose).
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

**Uncommon possible side effects (these may affect up to 1 in 100 people):**

- Rash, itching or other skin reactions.
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin tablets (only doses 5–20 mg).

**Rare possible side effects (these may affect up to 1 in 1 000 people):**

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

**Very rare possible side effects (these may affect up to 1 in 10 000 people):**

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

**Side effects of unknown frequency may include:**

- Diarrhoea (loose stools)
- Cough
- Shortness of breath

- Oedema (swelling)
  - Sleep disturbances, including insomnia and nightmares
  - Sexual difficulties
  - Depression
  - Breathing problems, including persistent cough and/or shortness of breath or fever
  - Tendon injury
  - Muscle weakness that is constant
  - Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing)
  - Ocular myasthenia (a disease causing eye muscle weakness)
- Talk to 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.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Rosuvastatin**

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Rosuvastatin contains**

- The active substance is rosuvastatin. Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium).
- The other ingredients are lactose, microcrystalline cellulose, crospovidone (type A), magnesium stearate and colloidal anhydrous silica in the tablet core and poly vinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, in the film coating.

**What Rosuvastatin looks like and contents of the pack**

Rosuvastatin 20 mg film-coated tablets are white or almost white, round, slightly biconvex film-coated tablets with bevelled edges, engraved with number 20 on one side of the tablet (diameter: 10 mm). Rosuvastatin is available in boxes containing 10, 14, 15, 20, 28, 30, 56, 60, 90, 98 and 100 film-coated tablets in blisters. Rosuvastatin is available in boxes containing 10 x 1, 14 x 1, 15 x 1, 20 x 1, 28 x 1, 30 x 1, 56 x 1, 60 x 1, 90 x 1, 98 x 1 and 100 x 1 film-coated tablets in perforated unit dose blisters.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**  
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

**Manufacturer**  
Krka, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia  
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

**This leaflet was last revised in March 2023.**

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