

Package leaflet: Information for the user

Rosuvastatin Krka 5 mg film-coated tablets
Rosuvastatin Krka 10 mg film-coated tablets
Rosuvastatin Krka 20 mg film-coated tablets
Rosuvastatin Krka 40 mg film-coated tablets
rosuvastatin

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

1. What Rosuvastatin Krka is and what it is used for
2. What you need to know before you take Rosuvastatin Krka
3. How to take Rosuvastatin Krka
4. Possible side effects
5. How to store Rosuvastatin Krka
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1. What Rosuvastatin Krka is and what it is used for

Rosuvastatin Krka belongs to a group of medicines called statins.

You have been prescribed Rosuvastatin Krka because:

- You have a **high cholesterol level**. This means you are **at risk of a heart attack or stroke**. Rosuvastatin Krka 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 Krka.

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 Krka?

Rosuvastatin Krka 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 Krka can reduce the 'bad' cholesterol and increase the 'good' cholesterol.
- It works by helping to block your body's production of 'bad' cholesterol. It also improves your body's ability to remove it from your blood.

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. By lowering your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to **keep taking Rosuvastatin Krka**, even if it has got your cholesterol to the right level, because **it prevents your cholesterol levels from creeping up again** and causing build up of fatty deposits. However, you should stop if your doctor tells you to do so, or you have become pregnant.

2. What you need to know before you take Rosuvastatin Krka

Do not take Rosuvastatin Krka

- If you are allergic to rosuvastatin or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin Krka **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking Rosuvastatin Krka by using suitable contraception.
- If you have liver disease.
- If you have severe kidney problems.
- If you have repeated or unexplained muscle aches or pains.
- If you take a drug combination of sofosbuvir/velpatasvir/voxilaprevir (used for viral infection of the liver called hepatitis C).
- If you take a drug called ciclosporin (used, for example, after organ transplants).

If any of the above applies to you (or you are in doubt), **please go back and see your doctor**.

In addition, do not take Rosuvastatin Krka 40 mg (the highest dose):

- If you have moderate kidney problems (if in doubt, please ask your doctor).
- If your thyroid gland is not working properly.
- If you have had any repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- If you regularly drink large amounts of alcohol.
- If you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- If you take other medicines called fibrates to lower your cholesterol.

If any of the above applies to you (or you are in doubt), **please go back and see your doctor**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rosuvastatin Krka:

- If you have problems with your kidneys.
- If you have problems with your liver.
- If you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever. Also, tell your doctor or pharmacist if you have a muscle weakness that is constant.
- If you regularly drink large amounts of alcohol.

- If your thyroid gland is not working properly.
- If you take other medicines called fibrates to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- If you take medicines used to fight the HIV infection e.g. ritonavir with lopinavir and/or atazanavir, please see Taking other medicines.
- If you are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Rosuvastatin Krka can lead to serious muscle problems (rhabdomyolysis).
- If you are over 70 (as your doctor needs to choose the right start dose of Rosuvastatin Krka to suit you).
- If you have severe respiratory failure.
- If you are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of Rosuvastatin Krka to suit you.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking rosuvastatin or other statins.
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).

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

- **Do not take Rosuvastatin Krka 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of Rosuvastatin Krka.**

In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will usually carry out this blood test (liver function test) before and during treatment with **Rosuvastatin Krka**.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to 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.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with rosuvastatin treatment. Stop using Rosuvastatin Krka and seek medical attention immediately if you notice any of the symptoms described in section 4.

Children and adolescents

- If the patient is under 6 years old: Rosuvastatin Krka should not be given to children younger than 6 years.
- If the patient is below 18 years of age: The Rosuvastatin Krka 30 mg and 40 mg tablets are not suitable for use in children and adolescents below 18 years of age.

Other medicines and Rosuvastatin Krka

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including any you bought without a prescription.

Tell your doctor if you are taking any of the following:

- ciclosporin (used for example, after organ transplants),
- warfarin, clopidogrel or ticagrelor (or any other drug used for thinning the blood),
- fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe),
- indigestion remedies (used to neutralise acid in your stomach),
- erythromycin (an antibiotic), fusidic acid (an antibiotic – please see below and Warnings and precautions),
- an oral contraceptive (the pill),
- regorafenib (used to treat cancer),

- darolutamide (used to treat cancer),
- hormone replacement therapy,
- any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Warnings and precautions): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

The effects of these medicines could be changed by Rosuvastatin Krka or they could change the effects of Rosuvastatin Krka.

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Rosuvastatin Krka. Taking Rosuvastatin Krka with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Rosuvastatin Krka with food and drink

You can take Rosuvastatin Krka with or without food.

Pregnancy and breast-feeding

Do not take Rosuvastatin Krka if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin Krka **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin Krka by using suitable contraception.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Most people can drive a car and operate machinery while using Rosuvastatin Krka – it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin Krka. If you feel dizzy, consult your doctor before attempting to drive or use machines.

Rosuvastatin Krka contains lactose (a type of sugar)

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Rosuvastatin Krka

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Usual doses in adults

If you are taking Rosuvastatin Krka for high cholesterol:

Starting dose

Your treatment with Rosuvastatin Krka must start with the **5 mg or the 10 mg dose**, even if you have taken a higher dose of a different statin before. The choice of your start dose 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.

Not all Rosuvastatin Krka tablet strengths may be available.

Please check with your doctor or pharmacist which start dose of Rosuvastatin Krka 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

In order to reach adequate cholesterol levels, your doctor may decide to gradually increase your dose up to a maximum dose of a 40 mg tablet once daily. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of Rosuvastatin Krka 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 Krka 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 Krka for you. The maximum daily dose of Rosuvastatin Krka 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 Krka 40 mg tablet should not be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take Rosuvastatin Krka once daily. You can take it at any time of the day.

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 Krka that is right for you.

If you take more Rosuvastatin Krka 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 Krka.

If you forget to take Rosuvastatin Krka

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

If you stop taking Rosuvastatin Krka

Talk to your doctor if you want to stop taking Rosuvastatin Krka. Your cholesterol levels might increase again if you stop taking Rosuvastatin Krka.

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 Krka and seek medical help immediately if you have any of the following side effects:

- 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 Krka 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 between 1 in 10 and 1 in 100 patients):

- 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 Krka 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 between 1 in 100 and 1 in 1,000 patients):

- 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 Krka tablets (only doses 5 mg, 10 mg and 20 mg).

Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- 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 Krka** and seek medical help immediately.
- Muscle damage in adults – as a precaution, **stop taking Rosuvastatin Krka 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 less than 1 in 10,000 patients):

- 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
- Gynecomastia (breast enlargement in men)

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rosuvastatin Krka

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 light.

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 Krka contains

- The active substance is rosuvastatin.
Each film-coated tablet contains 5 mg rosuvastatin (as rosuvastatin calcium).
Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium).
Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium).
Each film-coated tablet contains 40 mg rosuvastatin (as rosuvastatin calcium).
- The other ingredients are lactose, microcrystalline cellulose, crospovidone, magnesium stearate and colloidal anhydrous silica in the tablet core and lactose monohydrate, titanium dioxide

(E171), macrogol 6000 and basic butylated methacrylate copolymer in the film coating.

What Rosuvastatin Krka looks like and contents of the pack

Rosuvastatin Krka 5 mg film-coated tablets are white, round (diameter 7 mm), slightly biconvex, film-coated tablets with bevelled edges and with engraved number 5 on one side.

Rosuvastatin Krka 10 mg film-coated tablets are white, round (diameter 7.5 mm), slightly biconvex, film-coated tablets with bevelled edges and with engraved number 10 on one side.

Rosuvastatin Krka 20 mg film-coated tablets are white, round (diameter 10 mm), film-coated tablets with bevelled edges.

Rosuvastatin Krka 40 mg film-coated tablets are white, biconvex, capsule-shaped film-coated tablets (dimensions 16 mm x 8.5 mm).

Boxes of 10, 14, 20, 28, 30, 56, 60, 84, 90, 98 and 100 film-coated tablets in blisters are available. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area (EEA) under the following names:

Name of the Member State	Name of the medicine
Bulgaria	Розувастатин Крка
Denmark, Finland, Ireland, Slovenia, Poland, Lithuania, Iceland	Rosuvastatin Krka
Romania	Rosuvastatină Krka
Czech Republic, Slovak Republic, Latvia, Estonia	Rosuvastatin TAD

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