Package leaflet: Information for the patient

Rosuvastatin/Ezetimibe KRKA 10 mg/10 mg film-coated tablets
Rosuvastatin/Ezetimibe KRKA 20 mg/10 mg film-coated tablets
Rosuvastatin/Ezetimibe KRKA 40 mg/10 mg film-coated tablets

rosuvastatin/ezetimibe

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/Ezetimibe KRKA is and what it is used for
2. What you need to know before you take Rosuvastatin/Ezetimibe KRKA
3. How to take Rosuvastatin/Ezetimibe KRKA
4. Possible side effects
5. How to store Rosuvastatin/Ezetimibe KRKA
6. Contents of the pack and other information

1. What Rosuvastatin/Ezetimibe KRKA is and what it is used for

Rosuvastatin/Ezetimibe KRKA contains two different active substances. One of the active substances is rosuvastatin, which belongs to the group of so called statins, the other active substance is ezetimibe.

Rosuvastatin/Ezetimibe KRKA lowers levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Rosuvastatin/Ezetimibe KRKA raises levels of “good” cholesterol (HDL cholesterol). HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Rosuvastatin/Ezetimibe KRKA works to reduce your cholesterol in two ways: it reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

Rosuvastatin/Ezetimibe KRKA is used for patients who cannot control their cholesterol levels by cholesterol lowering diet alone. You should stay on your cholesterol lowering diet while taking this medicine.

Your doctor may prescribe Rosuvastatin/Ezetimibe KRKA if you are already taking both rosuvastatin and ezetimibe at the same dose level.

If you have heart disease, Rosuvastatin/Ezetimibe KRKA reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Rosuvastatin/Ezetimibe KRKA does not help you lose weight.

You need to **keep taking Rosuvastatin/Ezetimibe 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/Ezetimibe KRKA

Do not take Rosuvastatin/Ezetimibe KRKA
- If you are allergic to rosuvastatin/ezetimibe 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/Ezetimibe KRKA **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking Rosuvastatin/Ezetimibe 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/Ezetimibe KRKA 40 mg/10 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 contact your doctor**.

Warnings and precautions
Talk to your doctor or pharmacist before taking Rosuvastatin/Ezetimibe 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 Other medicines and Rosuvastatin/Ezetimibe KRKA.
- 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/Ezetimibe 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/Ezetimibe 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/Ezetimibe 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 related medicines.
- 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).

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.

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/Ezetimibe KRKA**.

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/Ezetimibe KRKA and seek medical attention immediately if you notice any of the symptoms described in section 4.

Children and adolescents
The use of Rosuvastatin/Ezetimibe KRKA is not recommended in children and adolescents under the age of 18 years.

Other medicines and Rosuvastatin/Ezetimibe KRKA
Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines.
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 such as phenprocoumon, acenocoumarol or fluindione),
- 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),
- an oral contraceptive (the pill),
- hormone replacement therapy,
- regorafenib (used to treat cancer),
- darolutamide (used to treat cancer),
- capmatinib (used to treat cancer),
- fostamatinib (used to treat low platelet counts),
- febuxostat (used to treat and prevent high blood levels of uric acid),
- teriflunomide (used to treat multiple sclerosis),
- leflunomide (used to treat rheumatoid arthritis),
- 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,
- roxadustat (used to treat anaemia in patients with chronic kidney disease),
- tafamidis (used to treat a disease called transthyretin amyloidosis),
- colestyramine (a medicine for lowering cholesterol), because it affects the way ezetimibe works,
- momelotinib (used to treat myelofibrosis in adults with anemia),
- 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/Ezetimibe KRKA. Taking Rosuvastatin/Ezetimibe KRKA with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information

regarding rhabdomyolysis in section 4.

The effects of these medicines could be changed by Rosuvastatin/Ezetimibe KRKA or they could change the effects of Rosuvastatin/Ezetimibe KRKA.

Rosuvastatin/Ezetimibe KRKA with food and drink
You can take Rosuvastatin/Ezetimibe KRKA with or without food.

Pregnancy and breast-feeding
Do not take Rosuvastatin/Ezetimibe KRKA if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin/Ezetimibe KRKA **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin/Ezetimibe 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/Ezetimibe KRKA – it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin/Ezetimibe KRKA. If you feel dizzy, consult your doctor before attempting to drive or use machines.

Rosuvastatin/Ezetimibe KRKA contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per dose that is to say essentially 'sodium-free'.

3. How to take Rosuvastatin/Ezetimibe 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.

- Before starting Rosuvastatin/Ezetimibe KRKA, you should be on a diet to lower your cholesterol and treated with rosuvastatin and ezetimibe at the same dose level. This medicine is not suitable to start a treament.
- You should keep on this cholesterol lowering diet whilst taking Rosuvastatin/Ezetimibe KRKA.

The recommended dose is one Rosuvastatin/Ezetimibe KRKA tablet by mouth once a day. You can take it at any time of the day, with or without food. Swallow each tablet whole with a drink of water. Take your medicine at the same time every day.

Use in children and adolescents
Rosuvastatin/Ezetimibe KRKA should not be used in children and adolescents.

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.

If you take more Rosuvastatin/Ezetimibe 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/Ezetimibe KRKA.

If you forget to take Rosuvastatin/Ezetimibe KRKA
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/Ezetimibe KRKA
Talk to your doctor if you want to stop taking Rosuvastatin/Ezetimibe KRKA. Your cholesterol levels might increase again if you stop taking Rosuvastatin/Ezetimibe 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/Ezetimibe KRKA 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).

Or if you have any of the following:
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).
- Muscle rupture.
- 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).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Also, stop taking Rosuvastatin/Ezetimibe KRKA and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect. 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*.

Common: 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/Ezetimibe KRKA tablets (only doses with 40 mg of rosuvastatin).
- 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.
- Elevations in some laboratory blood tests of liver function (transaminases)
- Muscle tenderness or weakness
- Diarrhoea
- Flatulence
- Feeling tired

Uncommon: 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/Ezetimibe KRKA tablets (only doses with 5–20 mg of rosuvastatin).
- Tingling sensation
- Dry mouth
- Hives
- Back pain
- Muscle weakness, pain in arms and legs
- Swelling, especially in the hands and feet
- Elevations in some laboratory blood tests of muscle (CK) function
- Cough
- Indigestion
- Heartburn
- Joint pain
- Muscle spasms
- Neck pain
- Decreased appetite
- Pain
- Chest pain
- Hot flush
- High blood pressure

Rare: 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/Ezetimibe KRKA** and seek medical help immediately.
- Muscle damage in adults – as a precaution, **stop taking Rosuvastatin/Ezetimibe 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).
- Reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopaenia).

Very rare: 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)
- Memory loss
- Breast enlargement in men (gynaecomastia)

Not known: frequency cannot be estimated from the available data
- 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
- Liver problems
- Raised red rash, sometimes with target-shaped lesions (erythema multiforme)
- Muscle breakdown
- Gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting)

- 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/Ezetimibe 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 blister and carton after EXP. The expiry date refers to the last day of that month.

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

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/Ezetimibe KRKA contains
- The active substances are rosuvastatin and ezetimibe.
  10 mg/10 mg: Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium) and 10 mg ezetimibe.
  20 mg/10 mg: Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium) and 10 mg ezetimibe.
  40 mg/10 mg: Each film-coated tablet contains 40 mg rosuvastatin (as rosuvastatin calcium) and 10 mg ezetimibe.
- The other ingredients in the tablet core are: microcrystalline cellulose (E460), lactose, mannitol (E421), crospovidone type A, croscarmellose sodium, magnesium stearate (E470b), povidone K30, sodium laurilsulfate (E487) and colloidal anhydrous silica (E551).
  The other ingredients in the film-coating are: lactose monohydrate, hypromellose (E464), titanium dioxide (E171), triacetin, yellow iron oxide (E172) – for 10 mg/10 mg only, red iron oxide (E172) – for 20 mg/10 mg and 40 mg/10 mg and black iron oxide (E172) – for 40 mg/10 mg.
  See section 2 "Rosuvastatin/Ezetimibe KRKA contains lactose and sodium".

What Rosuvastatin/Ezetimibe KRKA looks like and contents of the pack
10 mg/10 mg: Pale brownish-yellow to pale brown-yellow round, slightly biconvex film-coated tablet (tablet), engraved with mark R2 on one side of the tablet. Tablet diameter: approximately 10 mm.

20 mg/10 mg: Pale pink, round, slightly biconvex film-coated tablet (tablet), engraved with mark R4 on one side of the tablet. Tablet diameter: approximately 10 mm.
40 mg/10 mg: Pale greyish-violet to pale grey-violet, round, slightly biconvex film-coated tablet (tablet), engraved with mark R5 on one side of the tablet. Tablet diameter: approximately 10 mm.

Rosuvastatin/Ezetimibe KRKA is available in blisters containing 10, 30, 40, 90 and 100 film-coated tablets, in a box.
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 under the following names:

Czech Republic, Ireland	Rosuvastatin/Ezetimibe KRKA
Denmark, Cyprus	Rosazimib
Austria	Rosuvastatin/Ezetimib HCS
Greece	CO-ROSUVADOR

This leaflet was last revised in 01/2026