Package leaflet: Information for the patient

Rosuvastatin/amlodipine Krka 10 mg/5 mg film-coated tablets
Rosuvastatin/amlodipine Krka 10 mg/10 mg film-coated tablets
Rosuvastatin/amlodipine Krka 15 mg/5 mg film-coated tablets
Rosuvastatin/amlodipine Krka 15 mg/10 mg film-coated tablets
Rosuvastatin/amlodipine Krka 20 mg/5 mg film-coated tablets
Rosuvastatin/amlodipine Krka 20 mg/10 mg film-coated tablets

Rosuvastatin/amlodipine Krka

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/amlodipine Krka is and what it is used for

Rosuvastatin/amlodipine Krka contains two active substances – rosuvastatin and amlodipine.

Rosuvastatin/amlodipine Krka is indicated in adults for treatment of increased blood pressure and concomitant high cholesterol level when changing diet and taking more exercise were not enough to correct cholesterol levels and/or for prevention of cardiovascular events if you have other factors that increase your risk of having a heart attack, stroke or related health problems.

Rosuvastatin/amlodipine Krka is indicated in patients who are already taking rosuvastatin and amlodipine at these doses. Instead of taking rosuvastatin and amlodipine as separate tablets you will receive one tablet of Rosuvastatin/amlodipine Krka which contains both ingredients in the same strength.

You should continue with your cholesterol-lowering diet and exercise while you are taking Rosuvastatin/amlodipine Krka.

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

Do not take Rosuvastatin/amlodipine Krka:
- if you are allergic to rosuvastatin, amlodipine, to any other calcium antagonists 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/amlodipine Krka stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin/amlodipine 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 called ciclosporin (used, for example, after organ transplants).
- If you have severe low blood pressure (severe hypotension).
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after an acute heart attack.

Warnings and precautions
Talk to your doctor or pharmacist before taking Rosuvastatin/amlodipine 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/amlodipine 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/amlodipine Krka can lead to serious muscle problems (rhabdomyolysis).
- If you have severe respiratory failure.
- If you had a recent heart attack.
- If you suffer from heart failure.
- If you have severe increase in blood pressure (Hypertensive crisis).
- If you are elderly.
- 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/amlodipine Krka to suit you.

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/amlodipine 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.

Children and adolescents
Rosuvastatin/amlodipine Krka should not be used in children and adolescents.

Other medicines and Rosuvastatin/amlodipine Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Rosuvastatin/amlodipine Krka may affect or be affected by other medicines, such as:
- ciclosporin (used for example, after organ transplants),
- warfarin or clopidogrel (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),
- an oral contraceptive (the pill),
- hormone replacement therapy,
- ritonavir with lopinavir and/or atazanavir, indinavir, nelfinavir (used to fight the HIV infection – please see Warnings and precautions).
- ketoconazole, itraconazole (anti-fungal medicines)
- rifampicin, erythromycin, clarithromycin (for infections caused by bacteria)
- Hypericum perforatum (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ)
- simvastatin (used to lower levels of cholesterol)

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/amlodipine Krka. Taking Rosuvastatin/amlodipine Krka with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Rosuvastatin/amlodipine Krka may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Rosuvastatin/amlodipine Krka with food and drink
You can take Rosuvastatin/amlodipine Krka with or without food.

Grapefruit juice and grapefruit should not be consumed by people who are taking Rosuvastatin/amlodipine Krka. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Rosuvastatin/amlodipine Krka.

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

Driving and using machines
Rosuvastatin/amlodipine Krka may affect your ability to drive or use machines. Some people feel dizzy during treatment with Rosuvastatin/amlodipine Krka. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Rosuvastatin/amlodipine Krka contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Rosuvastatin/amlodipine 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.

The recommended dose is one tablet per day.

Your medicine can be used before or after food and drinks. You should take your medicine at the same time each day with a drink of water. Do not take Rosuvastatin/amlodipine Krka with grapefruit juice.

Use in children and adolescents
Rosuvastatin/amlodipine 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.
Your doctor may decide to increase your dose so that you are taking the amount of Rosuvastatin/amlodipine Krka that is right for you.

If you take more Rosuvastatin/amlodipine Krka than you should
Contact your doctor or nearest hospital for advice. Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking Rosuvastatin/amlodipine Krka.

If you forget to take Rosuvastatin/amlodipine Krka
Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Rosuvastatin/amlodipine Krka
Your doctor will advise you how long to take your medicine. Your cholesterol levels might increase again if you stop taking Rosuvastatin/amlodipine Krka. Your condition may return if you stop using your medicine before you are advised.

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.

Visit your doctor **immediately** if you experience any of the following very rare, severe side effects after taking this medicine.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing and/or swallowing
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

Also, stop taking Rosuvastatin/amlodipine 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.

The following **common side-effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

ROSUVASTATIN

Common: may affect up to 1 in 10 people
- Headache
- Stomach pain
- Constipation
- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness
- A minor increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin/amlodipine Krka tablets.
- 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: 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/amlodipine Krka tablets (only doses 5–20 mg).

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/amlodipine Krka** and seek medical help immediately
- Muscle damage in adults – as a precaution, **stop taking Rosuvastatin/amlodipine 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).

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)
- Joint pain
- Memory loss
- Gynecomastia (breast enlargement in men)

Not known: cannot be estimated from the available data
- Diarrhoea (loose stools)
- Stevens-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals)
- 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.

AMLODIPINE

Very common: may affect more than 1 in 10 people
- Oedema (fluid retention)

Common: may affect up to 1 in 10 people
- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Altered bowel habits, diarrhoea, constipation, indigestion
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Ankle swelling

Other side-effects that have been reported include the following list. If any of these get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon: may affect up to 1 in 100 people
- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs; loss of pain sensation
- Ringing in the ears
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Cough
- Dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discolouration
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Inability to obtain an erection; discomfort or enlargement of the breasts in men
- Pain, feeling unwell
- Joint or muscle pain, back pain
- Weight increase or decrease

Rare: may affect up to 1 in 1,000 people
- Confusion

Very rare: may affect up to 1 in 10,000 people
- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

Not known: cannot be estimated from the available data
- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rosuvastatin/amlodipine 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.

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/amlodipine Krka contains
- The active substances are rosuvastatin (as rosuvastatin calcium) and amlodipine (as amlodipine besylate).
  10 mg/5 mg: Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium) and 5 mg amlodipine (as amlodipine besylate).
  10 mg/10 mg: Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium) and 10 mg amlodipine (as amlodipine besylate).
  15 mg/5 mg: Each film-coated tablet contains 15 mg rosuvastatin (as rosuvastatin calcium) and 5 mg amlodipine (as amlodipine besylate).
  15 mg/10 mg: Each film-coated tablet contains 15 mg rosuvastatin (as rosuvastatin calcium) and 10 mg amlodipine (as amlodipine besylate).
  20 mg/5 mg: Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium) and 5 mg amlodipine (as amlodipine besylate).
  20 mg/10 mg: Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium) and 10 mg amlodipine (as amlodipine besylate).
- The other ingredients are microcrystalline cellulose, anhydrous lactose, crospovidone type A, colloidal anhydrous silica and magnesium stearate in the tablet core.
  The other ingredients are poly(vinyl) alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172) in the film coating (10 mg/5 mg).
  The other ingredients are poly(vinyl) alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172), iron oxide red (E172) in the film coating (10 mg/10 mg).
  The other ingredients are poly(vinyl) alcohol, titanium dioxide (E171), macrogol 3350, talc,

iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172) in the film coating (15 mg/5 mg).
The other ingredients are poly(vinyl) alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172) in the film coating (15 mg/10 mg).
The other ingredients are poly(vinyl) alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172) in the film coating (20 mg/5 mg).
The other ingredients are poly(vinyl) alcohol, titanium dioxide (E171), macrogol 3350, talc in the film coating (20 mg/10 mg).

What Rosuvastatin/amlodipine Krka looks like and contents of the pack
Rosuvastatin/amlodipine Krka 10 mg/5 mg: yellowish brown, round, slightly biconvex, film-coated tablets with bevelled edges, engraved with mark 10-5 on one side of the tablet with a diameter of approx. 8.6mm
Rosuvastatin/amlodipine Krka 10 mg/10 mg: light pink, round, slightly biconvex, film-coated tablets with bevelled edges, engraved with mark 10-10 on one side of the tablet with a diameter of approx. 11mm
Rosuvastatin/amlodipine Krka 15 mg/5 mg: pale pinkish-brown, round, slightly biconvex, film-coated tablets with bevelled edges, engraved with mark 15-5 on one side of the tablet with a diameter of approx. 10mm
Rosuvastatin/amlodipine Krka 15 mg/10 mg: off pink, round, slightly biconvex, film-coated tablets with bevelled edges, engraved with mark 15-10 on one side of the tablet with a diameter of approx. 10mm
Rosuvastatin/amlodipine Krka 20 mg/5 mg: light yellow, round, slightly biconvex, film-coated tablets with bevelled edges, engraved with mark 20-5 on one side of the tablet with a diameter of approx. 11mm
Rosuvastatin/amlodipine Krka 20 mg/10 mg: white, round, slightly biconvex, film-coated tablets with bevelled edges, engraved with mark 20-10 on one side of the tablet with a diameter of approx. 11mm

Rosuvastatin/amlodipine Krka is available in blisters containing 10, 28, 30, 56, 60, 90, 98, 100 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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 medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	**Name of the medicinal product**
Austria, Hungary	Rosvaden
Czech Republic	Rosudapin
Portugal	Rosuvastatina + amlodipina Krka
Belgium, Ireland	Rosuvastatin/amlodipine Krka
Finland	Rosuvastatin/amlodipin Krka

This leaflet was last revised in