Package leaflet: Information for the patient

Simvastatin Krka 10 mg film-coated tablets
Simvastatin Krka 20 mg film-coated tablets
Simvastatin Krka 40 mg film-coated tablets
simvastatin

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 Simvastatin Krka is and what it is used for

Simvastatin Krka contains the active substance simvastatin. Simvastatin Krka is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol) and fatty substances called triglycerides in the blood. In addition, Simvastatin Krka raises levels of "good" cholesterol (HDL cholesterol). Simvastatin Krka is a member of the class of medicines called statins.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called "bad" cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

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.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

You should stay on a cholesterol-lowering diet while taking this medicine.

Simvastatin Krka is used in addition to your cholesterol–lowering diet if you have:

- a raised cholesterol level in your blood (primary hypercholesterolaemia) or elevated fat levels in your blood (mixed hyperlipidaemia)
- a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments
- coronary heart disease (CHD) or are at high risk of CHD (because you have diabetes, history of stroke or other blood vessel disease). Simvastatin Krka may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

In most people, there are no immediate symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, keep track of your cholesterol, and discuss your goals with your doctor.

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

Do not take Simvastatin Krka:
- if you are allergic to simvastatin or any of the other ingredients of this medicine (listed in section 6);
- if you currently have liver problems;
- if you are pregnant or breast-feeding;
- if you are taking medicine(s) with one or more than one of the following active ingredients:
  - itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections)
  - erythromycin, clarithromycin or telithromycin (used to treat infections)
  - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (HIV protease inhibitors are used for HIV infections)
  - boceprevir or telaprevir (used to treat hepatitis C virus infection)
  - nefazodone (used to treat depression)
  - cobicistat
  - gemfibrozil (used to lower cholesterol)
  - ciclosporin (used in organ transplant patients)
  - danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- 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 Simvastatin Krka can lead to serious muscle problems (rhabdomyolysis).

Do not take more than 40 mg Simvastatin Krka if you are taking lomitapide (used to treat a serious and rare genetic cholesterol condition)

Ask your doctor if you are not sure if your medicine is listed above.

Warnings and precautions
Tell your doctor:
- about all your medical conditions including allergies.
- if you drink large amounts of alcohol.
- if you have ever had liver disease. Simvastatin Krka may not be right for you.
- if you are due to have an operation. You may need to stop taking Simvastatin Krka tablets for a short time.
- if you are Asian, because a different dose may be applicable to you.
- 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).

Your doctor should do a blood test before you start taking Simvastatin Krka and if have any symptoms of liver problems while you take Simvastatin Krka. This is to check how well your liver is working.

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Simvastatin 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.

Tell your doctor if you have severe lung disease.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage and very rare deaths have occurred.

The risk of muscle breakdown is greater at higher doses of Simvastatin Krka, particularly the 80-mg dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- you consume large amounts of alcohol
- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are female
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called "statins" or fibrates
- you or a close family member have a hereditary muscle disorder.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

Children and adolescents
Safety and effectiveness of simvastatin have been studied in 10-17 year old boys and in girls who had started their menstrual period (menstruation) at least one year before (see section 3). Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Other medicines and Simvastatin Krka
It is particularly important to tell your doctor if you are taking any of the following active ingredients. Taking Simvastatin Krka with any of these medicines can increase the risk of muscle problems (some of these have already been listed in the above section "Do not take Simvastatin 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 Simvastatin Krka. Taking Simvastatin Krka with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4
- ciclosporin (often used in organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- medicines with an active ingredient like itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole (used to treat fungal infections)
- fibrates with an active ingredient like gemfibrozil and bezafibrate (used to lower cholesterol)
- erythromycin, clarithromycin or telithromycin (used to treat bacterial infections)
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used to treat AIDS)
- hepatitis C antiviral agents such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C virus infection)
- nefazodone (used to treat depression)
- medicines with the active ingredient cobicistat
- amiodarone (used to treat an irregular heartbeat)
- verapamil, diltiazem or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions)
- lomitapide (used to treat a serious and rare genetic cholesterol condition)

– daptomycin (a drug used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin (e.g. Simvastatin Krka). Your doctor may decide that you stop taking Simvastatin Krka for a while
– colchicine (used to treat gout)
– ticagrelor (antiplatelet medicine)
– ribociclib (used to treat breast cancer)
– palbociclib (used to treat breast cancer).

As well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular, tell your doctor if you are taking medicine(s) with any of the following active ingredients:
- medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)
- fenofibrate (also used to lower cholesterol)
- niacin (also used to lower cholesterol)
- rifampicin (used to treat tuberculosis).

You should also tell any doctor who is prescribing a new medicine for you that you are taking Simvastatin Krka.

Simvastatin Krka with food and drink
Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including Simvastatin Krka. Consuming grapefruit juice should be avoided.

Pregnancy, breast-feeding and fertility
Do not take Simvastatin Krka if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Simvastatin Krka, stop taking it immediately and contact your doctor. Do not take Simvastatin Krka if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

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

Driving and using machines
Simvastatin Krka is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people get dizzy after taking Simvastatin Krka.

Simvastatin 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 Simvastatin Krka

Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment and your personal risk status.

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

You should stay on a cholesterol-lowering diet while taking Simvastatin Krka.

Dosage:
The recommended dose is 1 Simvastatin Krka 10 mg, 20 mg or 40 mg tablet by mouth once a day.

Adults:
The usual starting dose is 10, 20 or in some cases, 40 mg a day. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day. **Do not take more than 80 mg a day.**

Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have certain kidney conditions.

The 80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

Children and adolescents:
For children (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.

Method and duration of administration:
Take Simvastatin Krka in the evening. You can take it with or without food. Keep taking Simvastatin Krka unless your doctor tells you to stop.

If your doctor has prescribed Simvastatin Krka along with another medicine for lowering cholesterol containing any bile acid sequestrant, you should take Simvastatin Krka at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more Simvastatin Krka than you should
- please contact your doctor or pharmacist.

If you forget to take Simvastatin Krka
- do not take a double dose to make up for a forgotten tablet. Just take your normal amount of Simvastatin Krka at the usual time the next day.

If you stop taking Simvastatin Krka
- talk to your doctor or pharmacist because your cholesterol may rise again.

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

4. Possible side effects

Like all medicines, Simvastatin Krka can cause side effects, although not everybody gets them.

The following terms are used to describe how often side effects have been reported:
- Rare (may affect up to 1 in 1,000 people)
- Very rare (may affect up to 1 in 10,000 people)
- Not known (frequency cannot be estimated from the available data)

The following rare serious side effects were reported.
If any of these serious side effects happen, stop taking the medicine and tell your doctor immediately or go to the emergency room at your nearest hospital.
- muscle pain, tenderness, weakness or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- hypersensitivity (allergic) reactions including:
  - swelling of the face, tongue and throat which may cause difficulty in breathing (angioedema)
  - severe muscle pain usually in the shoulders and hips
  - rash with weakness of limbs and neck muscles
  - pain or inflammation of the joints (polymyalgia rheumatica)
  - inflammation of the blood vessels (vasculitis)

  - unusual bruising, skin eruptions and swelling (dermatomyositis), hives, skin sensitivity to the sun, fever, flushing
  - shortness of breath (dyspnoea) and feeling unwell
  - lupus-like disease picture (including rash, joint disorders, and effects on blood cells)
- inflammation of the liver with the following symptoms: yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, feeling tired or weak, loss of appetite, liver failure (very rare)
- inflammation of the pancreas often with severe abdominal pain.

The following side effects have also been reported rarely:
- low red blood cell count (anaemia)
- numbness or weakness of the arms and legs
- headache, tingling sensation, dizziness
- blurred vision and impaired vision
- digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting)
- rash, itching, hair loss
- weakness
- trouble sleeping (very rare)
- poor memory (very rare), memory loss, confusion.

The following very rare serious side effect was reported:
- a serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis)
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions)
- muscle rupture
- gynecomastia (breast enlargement in men)

The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):
- erectile dysfunction
- depression
- inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever
- tendon problems, sometimes complicated by rupture of the tendon
- 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.

Additional possible side effects reported with some statins:
- sleep disturbances, including nightmares
- sexual difficulties
- 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
- muscle pain, tenderness, or weakness that is constant that may not go away after stopping Simvastatin Krka (frequency not known)

Laboratory Values
Elevations in some laboratory blood tests of liver function and a muscle enzyme (creatine kinase) have been observed.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Simvastatin 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. The expiry date refers to the last day of that month.

Do not store above 30°C. 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 Simvastatin Krka contains
The active substance is simvastatin.
Simvastatin Krka 10 mg film-coated tablets
Each film-coated tablet contains 10 mg simvastatin.
Simvastatin Krka 20 mg film-coated tablets
Each film-coated tablet contains 20 mg simvastatin.
Simvastatin Krka 40 mg film-coated tablets
Each film-coated tablet contains 40 mg simvastatin.

The other ingredients are pregelatinised starch, lactose monohydrate, microcrystalline cellulose, butylhydroxyanisole (E320), ascorbic acid, maize starch, citric acid, magnesium stearate in the tablet core, and hypromellose, talc, propylene glycol, titanium dioxide in the film-coating.
See section 2 "Simvastatin Krka contains lactose".

What Simvastatin Krka looks like and contents of the pack

Simvastatin Krka 10 mg film-coated tablets are oval, white, marked 10 on one side, with a breakline on the reverse. Tablet dimension: approximately 9 x 4 mm. The tablet can be divided into equal doses.
Simvastatin Krka 20 mg film-coated tablets are oval, white, marked 20 on one side, with a breakline on the reverse. Tablet dimension: approximately 11 x 5 mm. The tablet can be divided into equal doses.
Simvastatin Krka 40 mg film-coated tablets are round, white, plain on one side with a breakline on the reverse. Tablet dimension: approximately 11 mm. The tablet can be divided into equal doses.

Simvastatin Krka film-coated tablets are available in boxes of 10, 20, 28, 30, 40, 50, 56, 60, 84, 98, 100, 100x1, 110 and 120 film-coated tablets in (PVC/PE/PVDC/Alu) 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.

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

Ireland	Simvastatin Krka

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