

Package leaflet: Information for the user

Simvastatin Normon 10 mg film-coated tablets

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.

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1. What Simvastatin Normon 10 mg film-coated tablets is and what it is used for

Simvastatin Normon 10 mg film-coated tablets 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 Normon 10 mg film-coated tablets raises levels of “good” cholesterol (HDL cholesterol). Simvastatin Normon 10 mg film-coated tablets is 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 Normon 10 mg film-coated tablets is used in addition to your cholesterol lowering diet if you have:

- A raised cholesterol level in your blood (primary hypercholesterolemia) or elevated fat levels in your blood (mixed hyperlipidemia).
- A hereditary illness (homozygous familial hypercholesterolemia) 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 Normon 10 mg film-coated

tablets 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 Normon 10 mg film-coated tablets

Do not take Simvastatin Normon 10 mg film-coated tablets

- If you are allergic (hypersensitive) to simvastatin or to any of the other ingredients of this medicine (listed in section 6. Contents of the pack and other information).
- If you currently have liver problems.
- If you are pregnant or breast-feeding.
- If you are taking medicines with one or more 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).
- 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, in the last 7 days, have taken or been given a medicine called fusidic acid (used to treat bacterial infections).

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

Warnings and precautions

Talk to your doctor:

- about all your medical conditions including allergies;
- if you drink large amounts of alcohol;
- if you have ever had liver disease. Simvastatin Normon 10 mg film-coated tablets may not be right for you;
- if you are due to have an operation. You may need to stop taking Simvastatin Normon 10 mg film-coated tablets for a short time.

Your doctor should do a blood test before you start taking Simvastatin Normon 10 mg film-coated tablets and if you have any symptoms of liver problems while you take Simvastatin Normon 10 mg film-coated tablets.

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 Normon 10 mg film-coated tablets.

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 Normon 10 mg film-coated tablets, 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 necessary to diagnose and treat this problem.

Talk to your doctor or pharmacist before taking Simvastatin Normon 10 mg film-coated tablets

- if you are taking or have taken in the last 7 days a medicinal product containing fusidic acid (used to treat bacterial infection) orally or by injection. The combination of fusidic acid and Simvastatin Normon 10 mg film-coated tablets may lead to serious muscle problems (rhabdomyolysis).

Other medicines and Simvastatin Normon 10 mg film-coated tablets

It is particularly important to tell your doctor if you are taking medicines with any of the following active ingredients. Taking Simvastatin Normon 10 mg film-coated tablets with any of these drugs can increase the risk of muscle problems (some of these have already been listed in the above section “Do not take Simvastatin Normon 10 mg film-coated tablets”).

- 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, telithromycin or fusidic acid (used to treat bacterial infections). Do not take fusidic acid while you are taking this medicine. See section 4 of this leaflet,
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (used to treat AIDS),
- boceprevir or telaprevir (used to treat hepatitis C virus infection),
- nefazodone (used to treat depression),
- 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),
- colchicine (used to treat gout).

As well as the medicines listed above, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. In particular tell your doctor if you are taking medicines 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).

If you need to take fusidic acid to treat a bacterial infection, you will have to stop taking this medicine. Your doctor will tell you when it is safe to restart Simvastatin Normon 10 mg film-coated tablets. Taking Simvastatin Normon 10 mg film-coated tablets with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See section 4 for more information on rhabdomyolysis.

If you are Chinese, also tell your doctor if you are taking niacin (nicotinic acid) or any product containing niacin.

You should also tell any doctor who is prescribing a new medicine for you that you are taking Simvastatin Normon 10 mg film-coated tablets.

Simvastatin Normon 10 mg film-coated tablets with food and drink

Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including Simvastatin Normon 10 mg film-coated tablets. Consuming grapefruit juice should be avoided.

Pregnancy and breast-feeding

Do not take Simvastatin Normon 10 mg film-coated tablets if you are pregnant, think you may be pregnant or are planning to have a baby. If you get pregnant while taking Simvastatin Normon 10 mg film-coated tablets, stop taking it immediately and contact your doctor. Do not take Simvastatin Normon 10 mg film-coated tablets 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 medication.

Use in children and adolescents

Safety and effectiveness of treatment with Simvastatin Normon 10 mg film-coated tablets 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. How to take Simvastatin Normon 10 mg film-coated tablets). Simvastatin Normon 10 mg film-coated tablets has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Driving and using machines

Simvastatin Normon 10 mg film-coated tablets 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 Normon 10 mg film-coated tablets.

Simvastatin Normon 10 mg film-coated tablets contains lactose

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

3. How to take Simvastatin Normon 10 mg film-coated tablets

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 has told you.
Check with your doctor or pharmacist if you are not sure.

You should stay on a cholesterol-lowering diet before taking Simvastatin Normon 10 mg film-coated tablets.

Posology:

The recommended dose is 1 Simvastatin Normon 10 mg film-coated tablets 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

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

Method and duration of administration:

Take Simvastatin Normon 10 mg film-coated tablets in the evening. You can take it with or without food. Keep taking Simvastatin Normon 10 mg film-coated tablets unless your doctor tells you to stop.

If your doctor has prescribed Simvastatin Normon 10 mg film-coated tablets with another medicine for lowering cholesterol containing any bile acid sequestrant, you should take Simvastatin Normon 10 mg film-coated tablets at least 2 hours before or at least 4 hours after taking the bile acid sequestrant.

If you take more Simvastatin Normon 10 mg film-coated tablets than you should

Please contact your doctor or pharmacist.

In case of overdose or accidental intake, contact your doctor or pharmacist at once, or go to the nearest hospital, indicating the medicine and the amount taken.

If you forget to take Simvastatin Normon 10 mg film-coated tablets

Do not take a double dose to make up for a forgotten dose. Just take your normal amount of Simvastatin Normon 10 mg film-coated tablets at the usual time the next day.

If you stop taking Simvastatin Normon 10 mg film-coated tablets

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, this medicine 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 1000 patients)
- Very rare (may affect up to 1 in 10 000 patients)
- 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; muscle rupture (which may affect up to 1 in 10 000 people) 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,
 - skin 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 (dyspnea) 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-colored urine or pale-colored stool, feeling tired or weak, loss of appetite; liver failure (very rare).
- Inflammation of the pancreas often with severe abdominal pain.
- Blurred vision and impaired vision.

The following very rare serious side effects were reported:

- A severe allergic reaction that causes breathing difficulties or dizziness (anaphylactic reaction).
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions).
- Gynecomastia (breast enlargement in men).

The following side effects have also been reported rarely:

- Low red blood cell count (anemia).
- Numbness or weakness of the arms and legs.
- Headache, tingling sensation, dizziness.
- Digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhea, nausea, vomiting).
- Rash, itching, hair loss.
- Weakness.
- Trouble sleeping (very rare).
- Poor memory (very rare), memory loss, confusion.

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.
- Muscle weakness that is constant.

Additional possible side effects reported with some statins:

- Sleep disturbances, including nightmares.
- Sexual dysfunction.
- 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.

Complementary tests

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

Reporting of side effects

Do not worry about these side effects. You may not get any of them. If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Simvastatin Normon 10 mg film-coated tablets

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 container. The expiry date refers to the last day of that month.

Do not store above 30 °C. Store in the original packaging. Protect from moisture.

Do not throw away any medicines via wastewater or household waste. If you are not sure, ask your pharmacist how to throw away medicines and packs you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Simvastatin Normon 10 mg film-coated tablets contains

The active substance is simvastatin (I.N.N.). Each tablet contains 10 mg of simvastatin. The other ingredients (excipients) are: maize starch, microcrystalline cellulose, lactose monohydrate, butylhydroxyanisole (E320), magnesium stearate, ascorbic acid, anhydrous citric acid, hypromellose, titanium dioxide (E-171), yellow iron oxide (E-172), red iron oxide (E-172), talc and macrogol 6000.

What Simvastatin Normon 10 mg film-coated tablets looks like and contents of the pack

Simvastatin Normon 10 mg film-coated tablets are pinkish, round, biconvex and scored tablets. Each pack contains 28 tablets.

Marketing Authorization Holder and Manufacturer

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This leaflet was last revised in: February 2020.