Package leaflet: Information for the patient

Simvastatin 10mg, 20mg and 40mg 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 Tablets are and what they are used for
2. What you need to know before you take Simvastatin Tablets
3. How to take Simvastatin Tablets
4. Possible side effects
5. How to store Simvastatin Tablets
6. Contents of the pack and other information

1. What Simvastatin Tablets are and what they are used for

This medicine contains simvastatin which belongs to a group of drugs known as HMG-CoA reductase inhibitors. These are used to reduce the amount of cholesterol and fatty substances called triglycerides in your blood. Cholesterol is vital to the normal functioning of the body, but if levels of cholesterol in the bloodstream get too high it can be deposited on the walls of the arteries, where it builds up eventually leading to the blocking of the blood vessel. Only a small amount of cholesterol comes from our diet. Nearly all of the cholesterol in our bodies is made by our own livers and is produced mostly at night.

If you have had a blood test which shows that you have too much fat (including cholesterol) in your blood, this medicine should lower these levels which will reduce the risk of developing heart disease. If you have coronary heart disease, simvastatin will lessen the risk of heart attack or of needing heart surgery.

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

DO NOT take Simvastatin Tablets if:
- you are allergic to simvastatin or any of the other ingredients of this medicine (listed in section 6)
- you are pregnant or breast-feeding
- you have liver problems
- you are taking any of the following medicines:
  - itraconazole, ketoconazole, voriconazole or posaconazole which are used to treat fungal infections
  - erythromycin, clarithromycin or telithromycin (used to treat infections)
  - nefazodone, an antidepressant
  - indinavir, nelfinavir, ritonavir or saquinavir, drugs for HIV
  - boceprevir or telaprevir used to treat hepatitis C virus infection
  - cobicistat
  - gemfibrozil (a lipid-lowering medicine)
  - ciclosporin, used in organ transplant patients
  - danazol, an hormone used to treat endometriosis

- you are taking, or have taken within the last 7 days, a medicine called fusidic acid which is used to treat bacterial infections. The combination of fusidic acid and Simvastatin can lead to serious muscle problems (rhabdomyolysis).

DO NOT take more than 40mg simvastatin 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
Talk to your doctor or pharmacist before taking Simvastatin Tablets:

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).

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 Tablets may not be right for you,
- if you are due to have an operation. You may need to stop taking Simvastatin Tablets for a short time,
- if you are Asian, because a different dose may be applicable to you

Your doctor should do a blood test before you start taking Simvastatin Tablets and if you have any symptoms of liver problems while you take Simvastatin 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 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 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 needed to diagnose and treat this.

Children and adolescents

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

Other medicines and Simvastatin Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any you can buy without a prescription. Taking Simvastatin Tablets with any of the following medicines can increase the risk of muscle problems. This is especially important if you are taking any of the medicines listed above under "DO NOT take Simvastatin Tablets if" or any of the following other medicines:

- **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 Tablets. Taking Simvastatin Tablets 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 or bezafibrate (used to lower cholesterol)
- erythromycin, clarithromycin, telithromycin, or fusidic acid (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)
- colchicine (used to treat gout)

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 medicines with any of the following active ingredients:
- medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)
- fenofibrates (also used to lower cholesterol)
- niacin (also used to lower cholesterol)
- rifampicin (used to treat tuberculosis)
- Ribociclib (used to treat breast cancer)
- Palbociclib (used to treat breast cancer)

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

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

Pregnancy and breast-feeding
DO NOT take this medicine if you are pregnant or breast feeding. DO NOT become pregnant whilst taking this medicine.

If you discover you are pregnant, STOP taking this medicine IMMEDIATELY and consult your doctor.
If you are a woman who could bear children, DO NOT take this medicine unless you are using a reliable form of contraceptive; you may wish to discuss this with your doctor.

Driving and using machines
Simvastatin 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 Tablets.

Simvastatin Tablets contains lactose
Simvastatin Tablets contain a sugar called 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 Tablets

Your doctor will decide the dose that is best 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 while taking Simvastatin.

Dosage:
The dose is 1 Simvastatin 5mg, 10mg, 20mg, 40mg, or 80mg 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 if you are taking certain other medicines (as listed above) or if you have certain kidney conditions.

The 80mg 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.

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

Method of administration:
Take Simvastatin Tablets in the evening. You can take it with or without food. Keep taking your tablets for as long as your doctor has asked you to.

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

If you take more Simvastatin Tablets than you should
If you think you have taken too many tablets, contact your doctor straight away or go to the nearest hospital casualty department.
Take with you any remaining tablets and the pack so that the medicine can be identified.

If you forget to take Simvastatin Tablets

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and continue with the regular dosing schedule. **DO NOT take a double dose to make up for a forgotten dose**.

If you stop taking Simvastatin 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 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, **muscle rupture** or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- allergic reactions. Signs of an allergic reaction include:
  - swelling of the face, tongue and throat which may cause difficulty 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
  - inflammation of the blood vessels (vasculitis), often with skin rash
  - 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)
  - rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions)
- 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 serious side effects were reported as Very Rare (may affect up to 1 in 10,000 people):

- a serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis).
- gynecomastia (breast enlargement in men)

The following side effects have also been reported as Rare (may affect up to 1 in 1,000 people):

- low red blood cell count (anaemia)
- numbness or weakness of the arms and legs,
- headache, tingling sensation, dizziness,
- 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.
- blurred vision; impaired vision
- eosinophilia,
- changes to the way your blood coagulates
- inflammation of the joints (arthritis) and joint pain (arthralgia)

The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):

- erectile dysfunction
- 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
- depression
- 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 sugar 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 Tablets (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 to ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Simvastatin 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 blister and carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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 Tablets contain:

- The active substance is simvastatin. One film-coated tablet contains 10mg, 20mg or 40mg of simvastatin.
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, pregelatinised starch, butylated hydroxyanisole (E320), ascorbic acid, citric acid, colloidal anhydrous silica, talc,

magnesium stearate, hypromellose, iron oxides (E172), triethyl citrate, titanium dioxide (E171) and povidone.

What Simvastatin Tablets look like and contents of the pack
Simvastatin Tablets 10mg are peach coloured, oval, biconvex film-coated tablets with score line.

Simvastatin Tablets 20mg are tan coloured, oval, biconvex film-coated tablets.

Simvastatin Tablets 40mg are brick red coloured, oval, biconvex film-coated tablets.

This medicine is available in pack sizes of 28 or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Crescent Pharma International Limited
260, Triq San Albert
Gzira GZR 1150
Malta

Manufacturer
SGS Pharma Magyarorszag Kft.
Derkovits Gyula Utca 53,
Budapest XIX, 1193, Hungary

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