

Package leaflet: Information for the patient

Simvastatin 10 mg Film-coated Tablets

Simvastatin 20 mg Film-coated Tablets

Simvastatin 40 mg Film-coated Tablets

Simvastatin 80 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 is and what it is used for
2. What you need to know before you take Simvastatin
3. How to take Simvastatin
4. Possible side effects
5. How to store Simvastatin
6. Contents of the pack and other information

1. What Simvastatin is and what it is used for

Simvastatin is used to lower levels of cholesterol and fatty substances called triglycerides in your blood. While taking this medicine you should stick to a cholesterol-lowering diet. This medicine belongs to the class of drugs called statins.

Simvastatin is used along with dieting if you have:

- a raised cholesterol level in your blood (primary hypercholesterolaemia) or high fat levels in your blood (mixed hyperlipidaemia) when exercise and weight loss have not worked.
- a hereditary illness called homozygous familial hypercholesterolaemia which causes the cholesterol levels in your blood to rise. You may get other medicines as well for this condition.
- coronary heart disease or are at high risk of suffering from coronary heart disease. You are more likely to suffer from coronary heart disease if you have diabetes, have previously had a stroke, or have other blood vessel disease.

Most people will not have any symptoms related to raised cholesterol. Your doctor or pharmacist can measure your cholesterol level by means of a simple blood test. Having too much cholesterol in your bloodstream can lead to coronary heart disease. It can clog up blood vessels leading to hardening of the arteries (atherosclerosis). Hardened arteries are less able to carry blood to the heart and around the body. This can lead to chest pain (angina) and heart attacks.

If you have high levels of cholesterol you are more likely to get heart disease if you also:

- Have high blood pressure (hypertension)
- Have diabetes (high blood sugar)
- Do little physical exercise
- Smoke
- Are overweight or eat a high fat diet

Talk to your doctor or pharmacist if you would like advice about any of these factors.

2. What you need to know before you take Simvastatin

Do not take Simvastatin if you:

- are allergic to simvastatin or any of the other ingredients of this medicine (listed in section 6)
- suffer from liver problems
- are pregnant or breast-feeding
- are taking medicines for fungal infections (such as itraconazole, ketoconazole, posaconazole or voriconazole), medicines used to treat HIV (such as indinavir, nelfinavir, ritonavir and saquinavir), medicines which contain cobicistat (that are also used to treat HIV infections), medicines used to treat hepatitis C (boceprevir, telaprevir), antibiotics (such as erythromycin, clarithromycin, telithromycin) or nefazodone which is used to treat depression. (See section 2 'Other medicines and Simvastatin')
- are taking gemfibrozil (a medicine for lowering cholesterol)
- are taking ciclosporin (a medicine often used in organ transplant patients)
- are taking danazol (a man-made hormone used to treat endometriosis)

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

If any of these apply to you, do not take this medicine and go back to your doctor to discuss your treatment.

Warnings and precautions

Talk to your doctor or pharmacist before taking Simvastatin 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).
- Have medical conditions including allergies.
- Have previously had problems with your liver. Simvastatin may not be right for you.
- Have high blood pressure or high levels of fats and sugars in your blood or if you have a body mass index of more than 30kg/m². You may be more at risk of developing diabetes. Your doctor will monitor you closely if this applies to you.
- Regularly drink large amounts of alcohol.
- 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 can lead to serious muscle problems (rhabdomyolysis).

Children and adolescents

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

Blood tests

Before you start taking simvastatin your doctor will do a blood test to see 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.

Once you start taking the medicine your doctor will want you to have regular blood tests to see how well the medicine is working.

During treatment

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.

Important - Keep healthcare professionals informed

Contact your doctor immediately if you suffer from any unexplained muscle pain, tenderness or weakness. This is because in a very small number of patients, muscle problems can be serious. This can lead to kidney damage and in very rare cases deaths have occurred.

You will be more at risk of muscle break down if you are on high doses of Simvastatin, particularly the 80-mg dose. The risk of muscle break down is also greater in certain patients.

Talk with your doctor if any of the following apply:

- you drink large amounts of alcohol
- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are a woman
- if you are of Asian origin, because a different dose may be applicable to you
- you have ever had muscle problems whilst being treated with cholesterol-lowering medicines such as statins or fibrates
- you or a close family member have a hereditary muscle problems

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.

If you have any breathing problems or a persistent cough, you should see your doctor.

If you have to go into hospital for an operation – you might need to stop taking simvastatin for a short time.

Other medicines and Simvastatin

Many medicines affect the way simvastatin works. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes over the counter medicines, herbal remedies and vitamin supplements and any of the following:

- **Ciclosporin** – used to prevent rejection in organ transplant patients
- A hormone called **danazol** which is used to treat heavy or painful periods
- Antifungal medicines such as **itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole**
- Fibrates such as **gemfibrozil, fenofibrate or bezafibrate** which are also used to treat high cholesterol
- **Niacin or nicotinic acid** or acipimox in large doses which are also used to treat high cholesterol
- Antibiotics such as **erythromycin, clarithromycin, telithromycin**
- HIV protease inhibitors such as **indinavir, nelfinavir, ritonavir, or saquinavir** (medicines for HIV infections) or medicines which contain cobicistat (that are also used to treat HIV infections)
- Hepatitis C antiviral agents such as (**boceprevir, telaprevir, elbasvir or grazoprevir**)
- **Glecaprevir/pibrentasvir** (also used to treat Hepatitis C)
- An antidepressant called **nefazodone**
- Drugs such as **amiodarone** (a medicine for an irregular heartbeat), **verapamil, diltiazem or amlodipine** (medicines used to treat blood pressure or heart problems)
- **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. Your doctor may decide that you stop taking Simvastatin for a while
- **Colchicine** (a medicine used to treat gout)
- **Ticagrelor** (antiplatelet medicine)

Taking simvastatin 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”).

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

Check with your doctor first before taking simvastatin if you are taking any of these medicines:

- A drug used to treat tuberculosis called **rifampicin**
- Medicines used to treat blood clots, such as **warfarin**, phenprocoumon or acenocoumarol, because the dose of warfarin, phenprocoumon or acenocoumarol may need to be changed

Also tell your doctor if you are taking niacin (nicotinic acid) or niacin-containing product and are Chinese.

Simvastatin with food and drink

Grapefruit juice can interfere with the way in which your body handles simvastatin. You should not drink grapefruit juice if you are taking simvastatin.

Pregnancy and breast-feeding

Do NOT take Simvastatin if you are pregnant, think you may be pregnant or trying to get pregnant. If you get pregnant whilst taking Simvastatin, **STOP** taking the medicine and see your doctor immediately.

Do not take Simvastatin 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 has no known effect on the ability to drive or operate machines. Simvastatin can cause dizziness so make sure you are not affected before you drive or use machines.

Simvastatin contains lactose (10 mg, 20 mg, 40 mg, 80 mg strengths).

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Simvastatin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your dose will be decided by your doctor and will depend on the results of the blood tests. The dose you should take will be on the label attached by your pharmacist.

Remember to keep to a low-fat diet and to take physical exercise.

People with coronary heart disease (CHD)

The recommended dose is 20 mg – 40 mg which you should take in the evening. Your doctor may increase the dose you take every 4 weeks. The maximum dose is 80 mg. Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment and your personal risk status. Keep taking Simvastatin unless your doctor tells you to stop.

People with high levels of cholesterol/blood fats (Hypercholesterolaemia/Hyperlipidaemia)

The recommended starting dose is 10 mg – 20 mg taken in the evening. Your doctor may increase the dose you take every 4 weeks. The maximum dose is 80 mg.

People with hereditary high cholesterol (homozygous familial hypercholesterolaemia)

The recommended starting dose is 40 mg taken in the evening. The 80 mg dose is only recommended for adult patients who have very high levels of cholesterol in their blood and are at a high risk of developing heart problems who have not reached their cholesterol goal on lower doses.

Use in children and adolescents (10-17 years of age)

The recommended starting dose for children 10–17 years of age is 10 mg. This dose should usually be taken in the evening. If necessary the dose may be increased to a maximum of 40 mg.

Some patients will need a lower dose particularly if they are also taking medicines such as fibrates or niacin and also if they have severe kidney problems.

Taking other cholesterol-lowering medicines at the same time as Simvastatin

Your doctor may ask you to take a medicine called colestyramine whilst you are taking simvastatin. This medicine can interfere with the way in which simvastatin works. You must take simvastatin 2 hours before or 4 hours after you have taken colestyramine.

Taking your medicine

Swallow the medicine with plenty of water. You can take it with or without food. The 20 mg and 80 mg tablets can be divided into equal doses.

If you take more Simvastatin than you should

Talk to your doctor or go to your nearest hospital casualty department straight away. Take the medicine pack with you.

If you forget to take Simvastatin

If you forget to take a dose take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking Simvastatin

Your doctor will tell you how long you need to keep taking your tablets. **Do not** suddenly stop taking this medicine without talking to your doctor first because your cholesterol may rise again.

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. Do not be concerned about this list of side effects. You may not get any of them, but it is important to know what to do if they occur.

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.

- Unexplained muscle problems such as muscle pain, tenderness, weakness, especially muscle weakness that is constant, muscle rupture or cramps. In rare cases, these muscle problems can be very serious and result in muscle breakdown and kidney damage. In some cases these problems can be life-threatening and very rarely 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

- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions)
- pain or inflammation of the joints
- inflammation of the blood vessels
- unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, flushing
- shortness of breath and feeling unwell
- lupus-like disease picture (including rash, joint disorders, and effects on blood cells)
- A serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis)
- Gynecomastia (breast enlargement in men)
- Inflammation of the liver with yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, which may lead to liver failure
- Severe pain in the belly which may be swollen and tender that may spread to your back, and feeling and being sick with fever caused by inflammation of the pancreas
- Inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever
- Severe joint pain with weakness and inability to move the arm or leg caused by problems with the tendons which attach the muscle to the bone
- 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.

Other possible side effects:

Rare (may affect up to 1 in 1,000 people)

- feeling tired and breathless with pale skin due to low red blood cell count (anaemia)
- numbness or weakness of the arms and legs
- headache, tingling sensation, dizziness
- blurred vision; impaired vision
- digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting)
- rash, itching, hair loss
- weakness
- raised levels of substances in the blood which indicate how the liver and the muscles are working, which show up in blood tests

Very rare (may affect up to 1 in 10,000 people)

- trouble sleeping
- poor memory, memory loss, confusion

Not known (frequency cannot be estimated from the available data)

- failure to get and maintain an erection (erectile dysfunction)
- depression
- feeling thirstier, needing to pass water more often, feeling tired due to an increase of sugar in the blood
- 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

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 Simvastatin

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date, which is stated on the carton/bottle/blister after EXP. The expiry date refers to the last day of that month.

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 contains

Simvastatin comes as film-coated tablets in four strengths containing either 10 mg, 20 mg, or 40 mg or 80 mg of the active ingredient simvastatin in each tablet.

Each film-coated tablet also contains ascorbic acid, butylhydroxyanisole (E320), citric acid monohydrate, lactose monohydrate (see section 2 “Simvastatin contains lactose”), magnesium stearate, cellulose microcrystalline, maize starch pregelatinised, sodium lauryl sulfate hypromellose, talc, hydroxypropyl cellulose, titanium dioxide (E171), macrogol, iron oxide red (E172) and iron oxide yellow (E172) (20 mg and 40 mg only).

What Simvastatin looks like and contents of the pack

Simvastatin 10 mg film-coated tablets: a pink to brick red, round, biconvex (surface curved outwards on both sides), bevel-edged, film-coated tablet, debossed with ‘S2’ on one side and blank on the other side.

Simvastatin 20 mg film-coated tablets: a dark tan, oval, biconvex (surface curved outwards on both sides), bevel-edged, film-coated tablet, debossed with ‘SV3’ on one side with a break line on the other side. The tablet can be divided into equal doses.

Simvastatin 40mg film-coated tablets: a pink, oval, biconvex (surface curved outwards on both sides), bevel-edged, film-coated tablet, debossed with ‘SV4’ on one side and ‘M’ on the other side.

Simvastatin 80 mg film-coated tablets: a pink to brick red, capsule-shaped, biconvex (surface curved outwards on both sides), bevel-edged, film-coated tablet, debossed with ‘SV5’ on one side with a break line on the other side. The tablet can be divided into equal doses.

Simvastatin film-coated tablets come in either plastic bottles or blister packs of 10, 20, 28, 30, 49, 50, 56, 60, 84, 90, 98, 100, 250, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Viatriis Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

Manufacturer:

Mylan Hungary Kft., Mylan utca 1, Hungary, H-2900, Komárom.

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Germany GmbH, Zweigniederlassung Bad Homburg v. d. Hoehe, Benzstrasse 1, Bad Homburg v. d. Hoehe, Hessen, 61352, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Simvastatine Viatriis 20 mg, 40 mg and 80 mg filmomhulde tabletten

Czech Republic: Simvastatin Viatriis

Germany: Simvastatin dura 10 mg, 20 mg, 40 mg Filmtabletten

Greece: Simvastatin/Mylan 10 mg, 20 mg, 40 mg

Ireland: Simvastatin 10 mg, 20 mg, 40 mg, 80 mg Film-coated Tablets

Italy: Simvastatina Mylan Generics

Luxembourg: Simvastatine Viatriis 20 mg, 40 mg, 80 mg comprimés pelliculés

Netherlands: Simvastatine Viatriis 10 mg, 20 mg, 40 mg, 80 mg Filmomhulde tabletten

Poland: Simvagen 20, 40

Portugal: Simvastatina Anova

United Kingdom (Northern Ireland): Simvastatin 10 mg, 20 mg, 40 mg, 80 mg Film-coated Tablets

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