

- disorders, and effects on blood cells)
- Inflammation of the liver with yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, liver failure (very rare)
- Inflammation of the pancreas (severe abdominal pain radiating to the back, nausea and vomiting).

The following very rare serious side effect was reported:

- a serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis)

The following side effects were reported rarely (may affect up to 1 in 1,000 people).

- Low red blood cells (anaemia)
- Stomach upsets (such as sickness, constipation, abdominal pain, flatulence, nausea, indigestion, diarrhoea, vomiting)
- Headache, dizziness, tingling sensation, weakness, numbness or loss of sensation in the arms and legs
- Hair loss, rash, itchiness
- Increase in blood levels of liver enzymes
- Confusion
- Memory loss

The following side effects were reported very rarely (may affect up to 1 in 10,000 people)

- Trouble sleeping
- Poor memory

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

- 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 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.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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.

Store the tablets in the original package, in order to protect from light and moisture. Do not store above 30°C.

After first opening of the HDPE container: Store below 25°C and use within 6 months. 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 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

The active substance is: Simvastatin, 10mg, 20mg or 40mg

The other ingredients are:

Tablet core: Lactose monohydrate, microcrystalline cellulose (E460), Starch (maize) pregelatinised 1500, butylhydroxyanisole (E320), ascorbic acid (E300), Citric acid, anhydrous (E330), silica, colloidal anhydrous (E551), talc (E553b), magnesium stearate (E470b).

Film-coating: Hypromellose (E464), iron oxide, red (E172), iron oxide, yellow (E172), triethylcitrate (E1505), titanium dioxide (E171), talc (E553b), povidone K-30.

What Simvastatin looks like and contents of the pack

Simvastatin 10mg is a peach-coloured, oval, biconvex, film-coated tablet, scored on one side; The tablets can be divided into equal halves along the score line.

Simvastatin 20mg is a tan-coloured, oval, biconvex, film-coated tablet, scored on one side;

The tablets can be divided into equal halves along the score line.

Simvastatin 40mg is a brick red-coloured, oval, biconvex, film-coated tablet, scored on one side; The tablets can be divided into equal halves along the score line.

The tablets are packed in blisters in a carton box, containing 28 tablets.

Marketing Authorisation Holder

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This leaflet was last revised in March 2018

If you would like a leaflet with larger text, please contact 01271 385257.

actavis

Package leaflet: Information for the user

Simvastatin 10mg, 20mg, 40mg 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. 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 contains the active substance simvastatin and belongs to a group of medicines known as statins. These work by reducing the amount of total cholesterol, 'bad' cholesterol (LDL cholesterol), and certain fatty substances called triglycerides in your blood. In addition, Simvastatin raises levels of 'good' cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking this medicine.

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.

Simvastatin is used:

- to lower cholesterol and triglycerides in the blood when a low fat diet and other measures (such as exercise, weight loss) have failed (primary hypercholesterolaemia or mixed hyperlipidaemia).
- to lower inherited high levels of cholesterol in your blood (homozygous familial hypercholesterolemia), together with dieting and other treatments (e.g. LDL-apheresis), or when such treatments are not appropriate.
- to reduce the risk of coronary heart disease if you have hardening of the arteries (arteriosclerosis) or diabetes, even if your cholesterol levels are normal, together with dieting and other treatments.

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

Do not take Simvastatin:

- if you are allergic to Simvastatin or to any of the other ingredients of this medicine (listed in section 6).
- if you currently have liver problems or a continuous high level of certain liver enzymes (serum transaminases)
- if you are pregnant or breast-feeding
- if you are taking one or more of the following medicines at the same time:
 - ketoconazole, itraconazole, posaconazole or voriconazole (medicines for fungal infections)
 - HIV-protease inhibitors, such as indinavir, nelfinavir, ritonavir and saquinavir (medicines used for HIV infections)
 - boceprevir or telaprevir (medicines used to treat hepatitis C virus infection)
 - erythromycin, clarithromycin or telithromycin (antibiotics for infections)
 - nefazodone (an antidepressant)
 - gemfibrozil (a medicine for lowering cholesterol)
 - cyclosporin (a medicine 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)
- if you are taking or, in the last 7 days, have taken or been given a medicine called fusidic acid (used to treat bacterial infection)

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Simvastatin

- Tell your doctor about all your medical conditions including allergies.
- Tell your doctor if you drink large amounts of alcohol.
- Tell your doctor if you have ever had liver disease. Simvastatin may not be right for you.
- Tell your doctor if you are due to have an operation. You may need to stop taking Simvastatin tablets for a short time.
- Your doctor should do a blood test before you start taking Simvastatin. 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.
- 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.

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.

Contact your doctor immediately if you experience unexplained muscle pain, sensitivity to pressure or muscle 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.

You may have a greater risk of muscle breakdown at higher doses of Simvastatin, particularly the 80mg dose. The risk of muscle breakdown is also greater in certain patients.

Talk with your doctor if any of the following applies to you:

- you are more than 65 years old
- you have kidney problems
- you have thyroid problems
- you or close family members have a hereditary muscle disorder
- you are female
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called 'statins' or fibrates
- if you consume large amounts of alcohol

Consult your doctor if any of the above applies to you or has applied to you in the past.

Children and adolescents

Safety and effectiveness 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).

Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Other medicines and Simvastatin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please note that the following statements may also apply to products you took some time ago or may take at some time in the future.

It is particularly important to tell your doctor if you are taking any of the following drugs. The risk of muscle problems can be greater if Simvastatin is taken with the following medicines: (some of these have already been listed in the above section "Do not take the Simvastatin")

- Fibrates (other cholesterol-lowering medicines, such as gemfibrozil, bezafibrate)
- Ciclosporin (drug used to suppress the immune system and often used in organ transplant patients)
- Medicines like itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole (antifungals)
- Erythromycin, clarithromycin and telithromycin (antibiotics)
- Certain medicines for the treatment of HIV infections (HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir)
- Boceprevir or telaprevir (a medicine used to treat hepatitis C virus infection)
- Danazol (medicine used to treat endometriosis and breast cysts in women)
- Nefazodone (medicine for depression)
- Amiodarone, a medicine used for irregular heart beat
- Verapamil, diltiazem or amlodipine (medicine used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions).
- Fusidic acid as a tablet or infusion (a medicine used to treat bacterial infections). Do not take Fusidic acid while using this medicine. Also see section 4 of this leaflet.
- Colchicine (a medicine 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, you should also tell your doctor if you take

- medicines that prevent blood clots (anticoagulants, such as phenprocoumon, acenocoumarol and warfarin). Simvastatin may increase the effect of these medicines.

- Fenofibrate (another medicine for lowering cholesterol)
- Niacin (another medicine for lowering cholesterol)
- Rifampicin (antibiotic used to treat tuberculosis)

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

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

Simvastatin with food and drink:

Grapefruit juice contains one or more components which may increase the amount of Simvastatin in the blood. Therefore, you should not drink grapefruit juice as it could increase the risk of muscle damage.

Pregnancy and breast-feeding

Do not take Simvastatin if you are pregnant, trying to become pregnant or suspect you may be pregnant, as the safety in pregnant women has not been established.

If you become pregnant while using Simvastatin, you must stop taking the tablets immediately and contact your doctor.

No data on the excretion of Simvastatin in breast milk are available. Because many medicinal products are excreted in human milk and because of the potential for serious side effects, you must not breast-feed your infant while taking Simvastatin.

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

Driving and using machines:

Simvastatin is not expected to interfere with your ability to drive or use machines.

However, there have been rare cases of dizziness reported in patients taking Simvastatin tablets (see section 4). Do not drive vehicles or operate machines that require attention if you experience this side-effect.

Simvastatin contains lactose:

Amongst other ingredients, Simvastatin tablets contain lactose monohydrate. If your doctor has informed you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3 How to take Simvastatin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure. You should stay on a cholesterol lowering diet while taking Simvastatin.

The recommended dose range is 5mg - 80mg by mouth once a day in the evening.

The 80mg dose is only recommended in 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.

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

Take Simvastatin in the evening. You can take it with or without food. The usual starting dose is 10, 20 or, in some cases, 40mg a day. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80mg a day. Do not take more than 80mg a day. Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have certain kidney conditions. Keep taking Simvastatin unless your doctor tells you to stop.

If your doctor has prescribed a bile acid sequestrant (another medicine for lowering cholesterol such as colestyramine) along with Simvastatin you should take Simvastatin at least two hours before or four hours after taking the bile acid sequestrant.

Use in children and adolescents

For children (10 -17 years old) with a hereditary illness called familial hypercholesterolaemia, the recommended usual starting dose is 10mg a day in the evening. The maximum recommended dose is 40mg a day.

Elderly patients

The dose of Simvastatin does not need to be changed for elderly patients

Instructions for use

Simvastatin tablets should be taken with water. Take the tablets either on an empty stomach or after a meal.

Duration of treatment:

You will have to take Simvastatin over a long period of time. Your doctor will tell you how long you need to take Simvastatin. *If you have the impression that the effect of Simvastatin is too strong or too weak, talk to your doctor or pharmacist.*

If you take more Simvastatin than you should:

If you take too many tablets by mistake, contact a doctor or pharmacist immediately.

If you forget to take Simvastatin:

If you realise you have forgotten to take a dose soon after its due time, take it as soon as possible. However, if it is almost time to take the next dose, omit the forgotten dose and take the next one when it is due. Ask your doctor or pharmacist in case of doubt. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Simvastatin:

If you suddenly stop taking this medicine, your cholesterol may rise again. It is therefore important that you consult a doctor before stopping treatment, even if you suffer from physical complaints. He/she can tell you if you can stop and the best way to do so.

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. For the most part side effects have been mild and short lived.

If any of the following 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. This is because on rare occasions, muscle damage can be serious, including muscle breakdown resulting in kidney damage and very rare deaths have occurred (see section 2 "Warnings and precautions").
- 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 (dyspnea) and feeling unwell
 - lupus-like disease picture (including rash, joint