



Simvastatin 10mg, 20mg and 40mg Film Coated Tablets

Patient Information Leaflet

Read this entire leaflet carefully before you start taking this medicine

- **Keep this leaflet.** You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **This medicine has been prescribed for you personally and you should not pass it on to others.**

In this leaflet:

1. What Simvastatin tablets are and what are they used for?
2. Before you take Simvastatin tablets.
3. How to take Simvastatin tablets.
4. Possible side effects.
5. Storing Simvastatin tablets
6. Further Information

1. WHAT SIMVASTATIN TABLETS ARE AND WHAT ARE THEY USED FOR?

The simvastatin contained in your tablets belongs to a group of medicines known as 'statins' or 'HMG-CoA reductase inhibitors'. These work by reducing the amount of "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition they raise levels of "good" cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking this medicine.

Cholesterol is vital to the normal functioning of the body but if levels of cholesterol in the bloodstream are too high it can be deposited on the walls of the arteries. There it builds up to form plaques that can eventually block the blood vessel, just like scale furring up a water pipe.

We only get a small amount of cholesterol from our diet; egg yolks and liver contain large amounts of cholesterol, but many foods like fruit, vegetables and fish are quite low in cholesterol. Nearly all of the cholesterol in our bodies is made by our own livers. The body produces most cholesterol at night, which is why it is recommended that Simvastatin tablets are taken in the evening or at night.

Your doctor may have done some blood tests which show that, even though you may be taking a low-fat diet, you still have too much fat (of which cholesterol is a type) in your blood.

You have been prescribed Simvastatin Tablets because 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 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. BEFORE YOU TAKE SIMVASTATIN TABLETS

Warning 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).

Do not take Simvastatin

- if you are allergic (hypersensitive) to simvastatin or any of the other ingredients of 'Simvastatin' tablets (see section 6: Further information)
- if you currently have liver problems
- if you are pregnant or breast-feeding
- if you are taking itraconazole or ketoconazole (medicines for fungal infections)
- erythromycin, clarithromycin, or telithromycin (antibiotics for infections)
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (medicines used for HIV infections).
- nefazodone (a medicine for depression).

Take special care with Simvastatin

Tell Your Doctor

- if you drink large amounts of alcohol
- if you have ever had liver disease. 'Simvastatin' may not be right for you.
- if you have problems with your kidneys
- if you are due to have an operation. You may need to stop taking 'Simvastatin' tablets for a short time.
- if you have severe respiratory failure

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.

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'.

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' and is greater in certain patients. Tell your doctor if any of the following applies to you:

- you consume large amounts of alcohol
- kidney problems
- thyroid problems
- you are more than 70 years old
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called "statins" or fibrates
- you or close family members have a hereditary muscle disorder.

Using other medicines

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

- ciclosporin (a medicine often used in organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis)
- fibrates like gemfibrozil and bezafibrate (medicines for lowering cholesterol)
- erythromycin, clarithromycin, telithromycin or fusidic acid (medicines for bacterial infections)
- amiodarone, (a medicine used for an irregular heart beat)
- verapamil or diltiazem (medicines for high blood pressure, chest pain associated with heart disease, or other heart conditions)
- large amounts (at least 1 gram each day) of niacin or nicotinic acid (medicines for lowering cholesterol).

Continued overleaf

- As well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any medicines, including those obtained without a prescription. In particular, tell your doctor if you are taking any of the following:
- medicines to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants).
- fenofibrate (another medicine for lowering cholesterol).

Taking Simvastatin with food and drink

Grapefruit juice contains one or more components that reduces elimination of Simvastatin from the body and thereby increases levels of Simvastatin in the body. Drinking of grapefruit juice during treatment with simvastatin should therefore be avoided.

Pregnancy and breast feeding

Do not take Simvastatin if you are pregnant, trying to become pregnant or think you may be pregnant. If you get pregnant while taking 'Simvastatin', stop taking it immediately and contact your doctor. It is not known whether Simvastatin is passed into breast milk and because of the potential for serious adverse reactions, women taking Simvastatin should not breast-feed their infants.

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

Children

Simvastatin is not recommended for use in children.

Driving and Using machines

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

Important information about some of the ingredients of Simvastatin

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

- You should take your tablets exactly as advised by your doctor or pharmacist.
- 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 80 mg a day.
- The 80mg dose is only recommended in patients with very high blood cholesterol levels and high risk of other complications related to heart disease.
- Your doctor may prescribe lower doses, particularly if you are taking certain medicines listed above or you have certain kidney conditions.
- Your doctor may need to change this dose in order to have the best effect.
- Do not take more or less than your doctor has prescribed.

Keep taking your tablets for as long as your doctor has asked you to. If you stop taking Simvastatin, your cholesterol may rise again.

If you forget to take Simvastatin tablets

If you miss a dose do not worry. Simply take your normal dose when it is next due. Do not take a double dose to make up for forgotten individual doses.

If you take more Simvastatin than you should

If you have taken more Simvastatin tablets than you should, or if someone accidentally swallows some, contact your doctor or a pharmacist, or go to your nearest hospital casualty department immediately. If possible take your tablets or the box with you to show the doctor.

4. POSSIBLE SIDE EFFECTS

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

The following rare (occurring in 1 or more of 10,000 and less than 1 of 1000 patients treated) serious side effects were reported

Stop taking Simvastatin and seek medical help immediately

If you have any of the following **allergic reactions**:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- Severe itching of the skin (with raised lumps)

Contact your doctor immediately if you experience muscle pain, tenderness or weakness.

This is because, on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage (see section headed 'Before you take Simvastatin tablets')

The following side effects were reported rarely: Stomach upsets (such as sickness, constipation, diarrhoea, flatulence, indigestion and abdominal pain), weakness, headache, dizziness, numbness or loss of sensation in the arms and legs, hair loss, rash, itchiness, liver disease (possibly presenting as yellowing of the eyes and/or skin, itchiness of the skin, dark coloured urine, pale coloured stools), muscle disease (presenting as pains and aches, tenderness, weakness or cramps), or an allergic reaction to Simvastatin tablets.

The following rare side effects have also been reported: Sleep disturbances, including insomnia and nightmares, memory loss, sexual difficulties, depression, breathing problems including persistent cough and/or shortness of breath or fever.

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.

Adverse reactions with frequency not known: 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING SIMVASTATIN TABLETS

Keep all medicines out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not take Simvastatin tablets after the expiry date (the last day of that month), which is marked on both the outer carton and on each blister strip of tablets.

If you find that you have tablets that have passed their expiry date (the last day of that month), return them to your local pharmacist (chemist) who will dispose of them properly.

6. FURTHER INFORMATION

What is this medicine

Each tablet contains 10mg, 20mg or 40mg of the active substance simvastatin.

The other ingredients are, for the core: lactose anhydrous, microcrystalline cellulose (E460), pregelatinised maize starch, butylhydroxyanisole (E320), magnesium stearate (E572), talc (E553b); and, for the film coating: titanium dioxide (E171), magnesium stearate (E572), talc (E553b), hypromellose (E464) and hydroxypropylcellulose (E463).

What this medicine looks like and contents of the pack:

Simvastatin tablets are white, biconvex film-coated tablets with 10, 20 or 40 embossed on one side and SVT on the other side. Each film-coated tablet contains 10, 20 or 40mg of simvastatin. The film-coated tablets come in packs of 28.

Marketing Authorisation Holder:

Somex Pharma, High Road, Ilford, Essex IG3 8BS. UK

Manufacturer:

Somex Pharma, High Road, Ilford, Essex IG3 8RA. UK

Leaflet last revised : 03/2023