

PATIENT LEAFLET: INFORMATION FOR THE USER

SIMVASTATIN 10 MG TABLETS
Simvastatin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to take Simvastatin Tablets carefully to get the best results from it.

- Keep the leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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

Simvastatin Tablets belong to a group of medicines known as ‘statins’ or ‘HMG-CoA reductase inhibitors’.

Simvastatin 10 mg Tablets can be used to help maintain a healthy heart as part of a lifestyle program for people with a moderate risk of heart attack.

The active ingredient simvastatin helps to lower cholesterol and triglycerides levels in the blood. High levels of LDL-cholesterol can cause narrowing of the coronary arteries due to plaque deposition. A subsequent blood clot in this narrowed artery can lead to heart attack. Simvastatin 10 mg Tablets should be taken regularly on a long term basis together with a healthy regime in order to gain full benefit of the treatment.

Studies have shown that these tablets can reduce LDL cholesterol by 27% after 4 weeks, and when taken on a long term basis can reduce the risk of a heart attack by about 30% over three years.

You are likely to be at moderate risk if you are a man aged 55 or over.

You are likely to be at moderate risk if you are a man aged between 45 and 54 or a woman aged 55 or over and:

- Have family history of Coronary heart Disease (CHD) in a first degree relative (parent or sibling) below 55 years for men, or 65 years for women
- You smoke or have been smoking in the last five years
- Are overweight. This means you have body mass index over 25kg/m² (your weight in kilos divided by your height in meters squared), or your waist is greater than 40 inches or 102 cm (for men), or 35 inches or 88 cm (for women).
- Are of South Asian ethnic origin.

At the same time as taking Simvastatin 10 mg Tablets, try to reduce your risk of heart attack by doing the following:

- **Stop smoking**
- **Eat a healthy diet**

- **Lose weight**
- **Exercise**

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

Do not take Simvastatin Tablets if you:

- **experience unexplained muscle pain, tenderness or weakness. Please inform your doctor immediately** because on rare occasions, there is a risk of muscle problems which may be serious, including muscle breakdown, which can result in kidney damage. Your doctor may perform a blood test to check the condition of your muscles before and after starting treatment.
- have ever been told you are allergic to simvastatin or to any other ingredients (these are listed in section 6, Further information)
- have liver problems or have been told you have abnormal liver function blood tests
- drink more than 4 units of alcohol a day for men and 3 units of alcohol a day for women
- are pregnant, are planning to become pregnant, or are breast feeding
- discover you are pregnant while taking Simvastatin 10mg tablets, in this case you should stop taking these tablets immediately and contact your doctor
- are already taking cholesterol lowering drugs
- have had muscle problems in the past after taking a cholesterol lowering medicine

Things to note regarding muscle effects

- the risk of muscle breakdown is greater at higher doses of Simvastatin
- the risk of muscle breakdown is greater in certain patients

Warning and precautions

Take special care whilst taking this medicine if you:

- have an under active thyroid gland (hypothyroidism)
- you have severe respiratory failure.
- kidney problems
- have angina or have a heart attack or stroke
- have diabetes
- have diabetes: 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.
- have disease of the arteries of your legs or neck
- have inherited very high blood cholesterol levels
- have a family history of muscle disorders
- are aged over 70 years
- 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.
- 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).

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 your skin or whites of your eyes turn yellow or your urine appears very dark in colour, this may mean that you have a liver problem. So, stop taking your tablets and see your doctor.

If you go in to hospital for elective major surgery, tell your doctor you are taking Simvastatin 10mg tablets as you will need to stop taking it a few day beforehand.

Children and Adolescents:

- Safety and effectiveness have 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.

Other medicines and Simvastatin tablets

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed, for example, herbal remedies and health food shop.

- cholesterol lowering medicines (such as bezafibrate, gemfibrozil) and high doses of niacin or nicotinic acid (more than 1000mg/day)
- oral antifungal medicines (such as itraconazole, ketoconazole)
- medicines for bacterial infections (erythromycin, telithromycin, clarithromycin and fusidic acid)
- antidepressants (e.g. nefazodone)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, saquinavir) (used to treat AIDS)
- Hepatitis C antiviral agents such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C virus infection)
- drugs used to suppress the immune system (e.g. ciclosporin)
- medicine used for the treatment of endometriosis and breast cycts in women (e.g. danazol)
- medicine for thinning the blood (e.g. warfarin)
- ticagrelor (a medicine to help prevent blood clots)

If you are taking any prescription, your pharmacist may advice you to check with your doctor before taking Simvastatin 10 mg Tablets.

If your doctor prescribes a new medicine for you while you taking this product (for example, if you develop an infection and your doctor decided to give you a course of antibiotics), you should mention that you are taking Simvastatin 10 mg Tablets. If your doctor has told you that you have high blood pressure, check with your doctor before taking Simvastatin 10mg Tablets. If you have any doubt please consult your doctor or pharmacist prior to taking Simvastatin 10 mg Tablets.

Pregnancy, breast-feeding and fertility

Pregnancy

- Do **NOT** take this medicine if you are pregnant, think you have become pregnant or intend to become pregnant whilst taking these tablets.
- Always ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

- Do not take Simvastatin Tablets if you are breast-feeding. Consult your doctor before taking the tablets if you are breast-feeding or planning to breast-feed.

Taking food or drink with Simvastatin Tablets

- Grapefruit juice contains one or more components that alter the metabolism of some medications, including Simvastatin. Therefore, consuming grapefruit juice should be avoided as it could increase your risk of muscle damage.

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Driving and using Machines

- It is unlikely that these tablets will affect your ability to drive or operate machinery. If you experience any dizziness make sure that you are fit to drive or operate machinery before attempting to do so.

Simvastatin tablets contains lactose

This medicine contains **lactose**. If you have been previously told by your doctor that you have intolerance to some sugars (such as lactose), contact your doctor before taking this medicinal product..

3. How to take Simvastatin Tablets

- Always take these tablets exactly as advised by your doctor. You should check with your doctor or pharmacist if you are not sure.
- You should check the label to see how often you should take your tablets. Check with your doctor or pharmacist if you are not sure.
- Ensure that you do not run out of your tablets.
- The number of tablets you need will depend on your condition. The tablets should be swallowed whole with a glass of water.
- The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The usual dosages are as follows:

Adults

- Take one tablet daily. The evening is the best time because it means that your medicine will be working when your body is producing the most cholesterol. Simvastatin 10mg Tablets should be taken regularly and on a long-term basis in order to gain the full benefits of treatment.
- Never take more than one tablet each day

Children

- Simvastatin Tablets are not recommended for use in children.

If you take more Simvastatin Tablets than you should

If you have taken more Simvastatin Tablets than you should, or if someone accidentally swallows some, tell your doctor immediately or contact your nearest Hospital Casualty/Accident and Emergency Department even if there are no signs of discomfort. Take your medicine in its original packaging with you in order to identify your medication easily.

If you forget to take Simvastatin Tablets

If you forget to take a dose, take it as soon as you remember.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.

4. Possible Side Effects

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

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 (see section 2)
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions)

- any allergic reaction to Simvastatin, The allergic reaction may include some of the following:
 - swelling of the face, tongue and throat (which may cause difficulty in breathing (angioedema)),
 - joint pains, joint and blood vessel inflammation
 - unusual bruising, skin eruptions, swelling, hives, skin sensitivity to the sun, a high temperature, flushing, tiredness
- heart burn, blurred vision, sleep disturbances including insomnia and nightmares, memory loss, sexual difficulties such as erectile dysfunction, depression, fever, gas.
- 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.

The following very rare serious side effect was reported:

- 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 rarely:

- Stomach upset (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
- blurred vision; impaired vision
- liver disease (possibly presenting as yellowing of the eyes and/ or skin, itchiness of the skin, dark coloured urine, pale coloured stools).

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

- Muscle weakness that is constant
- 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.

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 yellow card scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to Store Simvastatin Tablets

- Keep out of the sight and reach of children.
- Do not use Simvastatin Tablets after the expiry date which is stated on the carton (exp.). The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Simvastatin Tablets contain

- The active substance is simvastatin.
- Each tablet contains 10 mg of the active ingredient.
- The other ingredients are lactose (anhydrous), cellulose (microcrystalline), maize starch (pregelatinised), butylhydroxyanisole (E320), magnesium stearate, talc, hypromellose, hypromellose, titanium dioxide (E171).

What Simvastatin Tablets look like and contents of the pack

- Simvastatin 10mg tablets are white, oblong, biconvex film-coated tablets, scored on one side, debossed with “10” on the scored side and with “SVT” on the opposite side.
- Simvastatin Tablets come in blister packs containing 28 tablets.

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