

PACKAGE LEAFLET: INFORMATION FOR THE USER

Simvador 10mg, 20mg, 40mg and 80mg 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.

- Simvador is used to lower levels of cholesterol and triglycerides in your blood and can help reduce your risk of developing coronary heart disease. (See Section 1 'What Simvador is and what it is used for').
- Simvador can cause serious muscle problems in a very small number of patients. If you suffer from unexplained pain, tenderness or weakness in your muscles STOP TAKING the medicine and talk to your doctor at once.
- DO NOT TAKE this medicine if you are already taking medicines for fungal infections (such as itraconazole, ketoconazole, voriconazole or posaconazole), HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir and saquinavir), medicines for Hepatitis C virus infection (such as boceprevir or telaprevir), antibiotics (such as erythromycin, clarithromycin, telithromycin), nefazodone which is used to treat depression, gemfibrozil used for lowering cholesterol, ciclosporin a medicine often used in organ transplant patients, danazol a man-made hormone used to treat endometriosis, fusidic acid (if you are taking, or in the last 7 days have taken) used to treat bacterial infections. (See Section 2 'Taking other medicines').
- If you are pregnant or trying to get pregnant or breast feeding you MUST NOT take Simvador (See Section 2 'Before you take Simvador').
- If you have high blood pressure, high levels of fats or sugars in your blood or have a body mass index of more than 30kg/m² you may be at risk of developing diabetes. Your doctor will monitor you closely if this applies. (See section 2 'Before you take Simvador' and Section 4 'Possible side effects').

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1. What Simvador is and what it is used for

Simvador is used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in your blood. In addition, Simvador raises levels of "good" cholesterol (HDL cholesterol). While taking this medicine you should stick to a cholesterol-lowering diet. This medicine belongs to the class of drugs called statins.

Simvador 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). Simvador may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

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 Simvador

Do not take Simvador if you:

- are **allergic (hypersensitive)** to simvastatin, or to any of the other ingredients (see section 6)
- suffer from liver problems
- are **pregnant** or breastfeeding
- if you are taking one or more than one of the following drugs at the same time:
 - itraconazole, ketoconazole, posaconazole, or voriconazole (medicines for fungal infections)
 - HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir and saquinavir), (HIV protease inhibitors are used for HIV infections)
 - boceprevir or telaprevir (medicines for Hepatitis C virus infection)
 - erythromycin, clarithromycin or telithromycin (antibiotics for infections)
 - nefazodone (a medicine for depression)
 - gemfibrozil (a medicine for lowering cholesterol)
 - ciclosporin (a medicine often used in organ transplant patients)
 - danazol (a man-made hormone used to treat endometriosis).
- If you are taking or, in the last 7 days, have taken or been given a medicine called fusidic acid (used to treat bacterial infections).

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 Simvador if you:

- Have any medical conditions including allergies
- Have previously had problems with your liver
- 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
- Have to go into hospital for an operation - you may need to stop taking Simvastatin
- Have severe lung disease

Blood tests

Before you start taking simvastatin your doctor will do a blood test to see how well your liver is working. Once you start taking the medicine your doctor will want you to have regular blood tests to see how well the medicine is working.

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 breakdown if you are on higher doses of simvastatin particularly the 80 mg dose. Also some other patients are more at risk. Talk to 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
- 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 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.

Other medicines and Simvador

Many medicines affect the way simvastatin works. You must **tell your doctor before you start taking any other medicines** including over the counter medicines, herbal remedies and vitamin supplements.

Do not take Simvastatin and tell your doctor if you are taking:

- **ciclosporin** (a medicine often used in organ transplant patients)
- **danazol** (a man-made hormone used to treat endometriosis)
- medicines such as **ketoconazole, itraconazole, fluconazole, posaconazole** or **voriconazole** (medicines for fungal infections)
- fibrates such as **gemfibrozil** or **bezafibrate** (medicines for lowering cholesterol)
- **erythromycin, clarithromycin, telithromycin, or fusidic acid** (medicines for bacterial infections). Do not take fusidic acid while using this medicine. Also see section 4 of the leaflet.
- HIV protease inhibitors such as **indinavir, nelfinavir, ritonavir, and saquinavir** (medicines for AIDS)
- **boceprevir or telaprevir** (medicines for hepatitis C virus infection)
- **nefazodone** (a medicine for depression)
- drugs such as **amiodarone, verapamil, diltiazem** or **amlodipine** (which are used to treat heart problems)
- **colchicine** (a medicine used to treat gout)

If you are taking any of the medicines in the list above you **must tell your doctor and not take Simvador** because these medicines can make it more likely that you will have muscle problems.

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

- medicines to prevent blood clots, such as **warfarin**, **phenprocoumon** or **acenocoumarol** (anticoagulants)
- **fenofibrate** (another medicine for lowering cholesterol)
- **niacin** (another medicine for lowering cholesterol)
- **rifampicin** (a medicine 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 Simvador.

Simvador 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 Simvador.

Pregnancy and breast-feeding

DO NOT take Simvador if you are pregnant, think you may be pregnant, or are trying to get pregnant, or if you get pregnant while taking Simvador **STOP** taking the medicine and see your doctor immediately.

You should stop taking simvador 1 month before trying to get pregnant.

Do not take Simvador if you are breastfeeding because it is not known if simvastatin passes into the breast milk.

Children

Safety and effectiveness of Simvador 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 Simvador). Simvador has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Driving and using machines

Simvador 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.

Important information about some of the ingredients of Simvador

Simvador 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 Simvador

Always take simvador exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. 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. Swallow the medicine with plenty of water. Remember to keep to a low-fat diet and to take physical exercise.

People with coronary heart disease (CHD)

The usual dose is 20mg – 40mg which you should take in the evening. Your doctor may increase the dose you take every 4 weeks. The maximum dose is 80mg.

People with high levels of blood fats (Hyperlipidaemia)

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

People with hereditary high cholesterol (homozygous familial hypercholesterolaemia)

The usual dose is 40mg taken in the evening. Your doctor may ask you to take 80mg each day in three doses through the day (20mg, 20mg and 40mg). This 80mg dose is only for patients who have very high levels of cholesterol in their blood or are at a high risk of developing heart problems who have not reached their cholesterol goal on lower doses.

Children (10-17 years)

The usual starting dose for children (10 -17 years old) 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 ciclosporin, danazol, fibrates or niacin and also if they have kidney problems.

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

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 Simvador works. You must take Simvador 2 hours before or 4 hours after you have taken colestyramine.

If you take more Simvador 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 Simvador

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.

4. Possible side effects

Like all medicines Simvador 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.

Stop taking Simvador and go to hospital at once if you have:

- a rare **allergic reaction** such as swelling of the face, tongue, lips and throat, difficulty breathing, severe itching of your skin with raised lumps, joint pain, sensitivity to the sun, general feeling of being unwell. You may need urgent medical attention.
- **Unexplained muscle problems** such as pain, tenderness or weakness. 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.
- Inflammation of the liver with yellowing of the skin and eyes, dark coloured urine or pale coloured stools).
- Inflammation of the pancreas often with severe abdominal pain.

Tell your doctor or pharmacist if any of the following side effects persist, get worse or if you notice any other side effects not listed.

- Diabetes. This is more likely if you have high blood pressure, high levels of sugar or fats in your blood or if you have a body mass index of more than 30kg/m². Your doctor will monitor you more closely if these factors apply to you:
- Low red blood cell count (anaemia)
- Numbness or weakness in the arms and legs
- Headache, tingling sensation, dizziness
- Gastrointestinal disturbances such as feeling or being sick, constipation, wind, diarrhoea, indigestion, stomach pain
- Rash, itching or hair loss
- Weakness
- Sleep disturbances such as difficulty sleeping and nightmares
- Poor memory, memory loss, confusion
- Sexual difficulties such as erectile dysfunction
- Depression
- Inflammation of the lungs causing difficulty in breathing, persistent cough and shortness of breath
- Tendon problems, sometimes complicated by rupture of the tendon

Side effects of unknown frequency: Muscle weakness that is constant.

Laboratory Values

Elevation 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme Website: 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 Simvador

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

Do not store them above 25°C.

Do not use these tablets after the expiry date which is stated on the pack.

The expiry date refers to the last day of that month.

Disposal

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 Simvador Tablets contain

The active substance is simvastatin.

The other ingredients are:

Lactose monohydrate, cellulose microcrystalline (E460), starch pregelatinised, citric acid monohydrate (E330), ascorbic acid (E300), butylhydroxyanisole (E320), isopropyl alcohol and magnesium stearate (E572), hydroxypropylcellulose (E463), hydroxypropylmethylcellulose (E464), titanium dioxide (E171), talc (E553b).

In addition Simvador 10mg, 20mg, 40mg, 80mg Tablets contain iron oxide red (E172), Simvador 10mg, 20mg, 80mg Tablets contain iron oxide yellow (E172) and Simvador 20mg, 40mg, 80mg Tablets contain iron oxide black (E172).

What Simvador Tablets look like and the contents of the pack

Simvador Tablets are available in four strengths.

- The peach coloured, oval-shaped, biconvex, film-coated tablets marked “10” on one side and breakline on the other side contain 10 mg Simvastatin.
- The tan coloured, oval-shaped, biconvex, film-coated tablets marked “20” on one side and breakline on the other side contain 20mg Simvastatin.
- The brick-red coloured, oval-shaped, biconvex, film-coated tablets marked “40” on one side and breakline on the other side contain 40mg Simvastatin.
- The brick-red coloured, capsule-shaped, biconvex, film-coated tablets marked “80” on one side and breakline on the other side contain 80mg Simvastatin.

Simvador Tablets are available in blister packs of 28 tablets.

Marketing Authorisation Holder & Manufacturer

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