
PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

Simvastatin
Tablets USP
Lipid-lowering Agents



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PHARMACIST ONLY MEDICINES KEEP OUT OF REACH OF CHILDREN

Simvastatin Tablets USP Lipid-lowering Agents

PACKAGE LEAFLET: INFORMATION FOR THE USER Simvastatin 10mg, 20mg, 40mg and 80mg Tablets (simvastatin)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Simvastatin Tablets are and what they are used for
2. Before you take Simvastatin Tablets
3. How to take Simvastatin Tablets
4. Possible side effects
5. How to store Simvastatin Tablets
6. Further information

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

The active substance in your medicine is called simvastatin. Simvastatin belongs to a group of medicines known as statins or “HMG-CoA reductase inhibitors”. These work by reducing the amount of cholesterol and other fatty substances, called triglycerides, in your blood. Cholesterol is important for the body to work properly but if cholesterol levels are too high (hypercholesterolaemia), it can build up on the walls of the arteries (atherosclerosis) which can lead to a blockage of the blood vessels. This can lead to angina (crushing chest pain) and a heart attack.

High cholesterol in your blood may be caused by many factors, including a diet high in cholesterol and fats, certain existing diseases, inherited disease and lack of exercise.

Your doctor may have prescribed Simvastatin Tablets as an addition to dietary measures because:

- You have high levels of cholesterol (hypercholesterolaemia) or triglycerides (mixed dyslipidaemia) in your blood, which have not been lowered by diet, weight loss or exercise, or
 - You have been told that you have inherited a condition called homozygous familial hypercholesterolaemia (a rare illness which runs in the family and causes a high level of cholesterol in the blood), or
 - You are suffering from coronary heart disease (CHD) or you are at risk of developing CHD because you have diabetes, have had a stroke, or other blood vessel disease. Simvastatin may prolong your life by reducing the risk of heart disease by helping to keep your arteries clear, even if your cholesterol levels are normal.
- Your doctor will also advise you of how to reduce the levels of cholesterol in your blood by eating a low fat diet throughout your treatment with Simvastatin Tablets.

2. BEFORE YOU TAKE SIMVASTATIN TABLETS

Do not take Simvastatin Tablets

- If you are allergic (hypersensitive) to simvastatin
- If you are allergic to any of the other ingredients of Simvastatin Tablets (these are listed in section 6 Further Information).
- If you are pregnant or planning to become pregnant.
- If you are breast-feeding
- If you have liver problems
- If you are taking any of the following medicines:
 - antifungal medicines called itraconazole or ketoconazole
 - certain medicines for the treatment of HIV infections such as indinavir, nelfinavir, ritonavir, or saquinavir

- nefazodone (an antidepressant medicine)
- antibiotics such as erythromycin, clarithromycin or telithromycin.

Check with your doctor or pharmacist before taking

Simvastatin Tablets if you:

- Have severe respiratory failure.

Take special care with Simvastatin Tablets

Simvastatin may increase the risk of myopathy in some patients, which results in muscle pain, tenderness and weakness. The doctor may perform a blood test to check the condition of your muscles before and after starting treatment with Simvastatin Tablets.

Talk to your doctor BEFORE taking the tablets if any of the following apply to you, as you may have a greater risk of myopathy:

- **if you experience unexplained muscle pain, tenderness or weakness, or if you have ever suffered from an illness called myopathy (muscle disease)**
- if you have ever had muscle problems during treatment with cholesterol lowering medicines called ‘statins’ (such as pravastatin or atorvastatin) or “fibrates” (such as bezafibrate and gemfibrozil)
- if you drink substantial amounts of alcohol or if you have a past history of liver disease. Your doctor may conduct some blood tests to check your liver before and after starting treatment
- if you have any kidney or thyroid problems
- if you or close family members have a hereditary muscle disorder
- if you are more than 70 years old.

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.

Children

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

Taking other medicines

There are certain medicines that you must not take with Simvastatin Tablets. These are listed opposite under “Do not take Simvastatin Tablets”.

The risk of muscle problems can be greater if Simvastatin Tablets are taken with certain medicines. Other medicines may be affected by simvastatin. They, in turn, may affect how well simvastatin works.

You should tell your doctor if you are taking any of the following medicines:

- medicines used to suppress the immune system such as ciclosporin
- niacin or nicotinic acid in doses greater than or equal to 1g per day (these are medicines used to lower cholesterol)
- medicines used to lower cholesterol called “fibrates” such as gemfibrozil, fenofibrate or bezafibrate
- amiodarone a medicine used to treat an irregular heart beat
- medicines such as verapamil or diltiazem, which are used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions
- medicines used for thinning the blood to prevent blood clots, such as warfarin
- danazol (a steroid medicine used to treat endometriosis and breast cysts in women)
- fusidic acid, a medicine for bacterial infections.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Simvastatin Tablets with food and drink

Grapefruit juice contains some substances that can change the way Simvastatin Tablets work. You should **AVOID** drinking grapefruit juice whilst being treated with Simvastatin Tablets.

Pregnancy and breast-feeding

Do not take Simvastatin Tablets if you are pregnant, trying to become pregnant or think you may be pregnant. If you become pregnant while taking Simvastatin Tablets, stop taking it immediately and contact your doctor.

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

Driving and using machines

This medicine can make you feel dizzy. If this happens, you should not drive or operate machinery until you feel better. Important information about some of the ingredients of

Simvastatin Tablets:

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Simvastatin Tablets.

Simvastatin 80mg Tablets contain a colourant known as Allura Red AC (E129) which may cause allergic reactions.

3. HOW TO TAKE SIMVASTATIN TABLETS

Always take Simvastatin Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. You should stay on a cholesterol-lowering diet while taking Simvastatin.

The dose is 1 Simvastatin 10 mg, 20 mg, 40 mg, or 80 mg tablet by mouth once a day.

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

The 80 mg dose is only recommended in for adult patients with very high cholesterol levels and at high risk of heart disease problems. Your doctor may prescribe lower doses, particularly if you are taking certain medicines listed in section 2 overleaf or you have certain kidney conditions.

If you have the inherited condition called homozygous familial hypercholesterolaemia (a rare illness which runs in the family and causes a high level of cholesterol in the blood) your doctor may prescribe 3 doses to be taken throughout the day.

If you are taking bile acid sequestrants (drugs also used to lower cholesterol such as Cholestyramine, Colesevelam or Colestipol) you should not take Simvastatin Tablets within 2 hours before or 4 hours after taking the bile acid sequestrant.

Do not take more or less than your doctor has prescribed.

If you take more Simvastatin Tablets than you should, or if someone accidentally swallows some tablets, contact your doctor or pharmacist as soon as possible or go to your nearest hospital casualty department immediately. Remember to take the pack and any remaining tablets with you.

If you forget to take Simvastatin Tablet(s), do not worry. Simply take your next dose when it is due. Do not take a double dose to make up for a forgotten dose.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Simvastatin can cause side effects, although not everybody gets them. Rarely, patients have developed muscle wasting or inflammation, and very rarely this has progressed to become a serious potentially lifethreatening condition (called ‘rhabdomyolysis’). If you have muscle aches, weakness, tenderness or pain and particularly at the same time, you feel unwell or have a high temperature, stop taking simvastatin and tell your doctor immediately.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), joint pains, joint and blood vessel inflammation, unusual bruising, skin eruptions, swelling, hives, skin sensitivity to the sun, a high temperature, or flushing.

Laboratory values:

Elevations in some laboratory blood tests of liver function (transaminases) and a muscle enzyme (CK) have been observed. The following side effects have been reported rarely (less than 1 in 1000 but greater than 1 in 10,000):

- pancreatitis (inflammation of the pancreas)
- liver disease - possibly presenting as yellowing of the eyes and/or skin (jaundice), itchiness of the skin, dark coloured urine, pale coloured stools
- stomach upsets (such as sickness, constipation, diarrhoea, flatulence (wind), indigestion and stomach pains)
- weakness
- headache
- dizziness
- hair loss
- rash
- itchiness
- numbness or loss of sensation in the arms and legs
- feeling or being sick
- tingling or pins and

needles

(paresthaesia)

• anaemia (low red blood cell count).

The following side effects have been reported very rarely (less than 1 in 10,000):

•liver failure. The following side effects have been reported with some statins:

• 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. If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SIMVASTATIN TABLETS

Keep out of the reach and sight of children.

This medicine does not require any special storage conditions.

Do not use Simvastatin Tablets after the expiry date which is stated on the carton and on each blister strip of tablets after [Exp]. The expiry date refers to the last day of that month.

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. FURTHER INFORMATION

What Simvastatin Tablets contain:

• The active substance is simvastatin. Each tablet contains

10mg, 20mg, 40 mg or 80mg of simvastatin.

• The other ingredients in the tablet core are lactose monohydrate, microcrystalline cellulose, pre-gelatinised starch, ascorbic acid, citric acid monohydrate, butylated hydroxyanisole (E320), talc, magnesium stearate.

• The other ingredients in the tablet film-coat are polydextrose, hypromellose, titanium dioxide (E171), triacetin and macrogol.

• The colourants used in the different strengths of tablets are as follows; the 10mg tablets contain iron oxide red (E172), the 40mg tablets contain iron oxide red (E172) and the 80mg tablets contain allura red AC lake (E129).

What Simvastatin Tablets look like and contents of the pack:

Simvastatin 10mg film-coated Tablets are shield-shaped, pink tablets marked with "SV 10" on one side and ">>" on the other side.

Simvastatin 20mg film-coated Tablets are round, white tablets marked with a score line with "SV/20" on one side and ">>" on the other side.

Simvastatin 40mg film-coated Tablets are shield-shaped, pink tablets marked with "SV 40" on one side and ">>" on the other side.

Simvastatin 80mg Tablets are capsule-shaped, pink tablets marked with "SV 80" on one side and ">>" on the other side.

Simvastatin 10mg, 20mg, 40mg & 80mg Tablets are available in:

Blister packs of 7, 10, 14, 15, 28, 30, 50, 56, 60, 98 and 100 tablets and HDPE containers of 30, 50, 100 and 1000 tablets.

Not all pack sizes may be marketed.

Shelf life: 36 months Storage: Store in a cool, dry and dark place.

Marketing Authorisation Holder

Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

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