

PART III: CONSUMER INFORMATION

PrSIMVASTATIN

Simvastatin Tablets, USP

5 mg, 10 mg, 20 mg, 40 mg and 80 mg

This leaflet is part III of a three-part "Product Monograph" published when SIMVASTATIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SIMVASTATIN. Contact your doctor, nurse or pharmacist if you have any questions about the drug.

Remember - This medicine is prescribed for the particular condition that you have. **Do not give this medicine to other people, nor use it for any other condition.**

ABOUT THIS MEDICATION

SIMVASTATIN is the brand name for the substance - simvastatin, available **only on prescription** from your doctor.

What the medication is used for:

Your doctor has prescribed SIMVASTATIN to lower the levels of cholesterol and fatty substances called triglycerides in your blood and to reduce the health risks associated with Coronary Heart Disease (CHD).

Elevated cholesterol can cause CHD by clogging the blood vessels (atherosclerosis) that carry oxygen and nutrients to the heart.

If you have CHD or other signs of atherosclerosis such as previous stroke, symptoms of peripheral vascular disease, or diabetes (regardless of the amount of cholesterol in your blood), SIMVASTATIN should lessen the risk of heart attack or stroke.

You can also benefit from taking SIMVASTATIN if you have high levels of cholesterol with or without associated high triglycerides (primary hypercholesterolemia, or combined hyperlipidemia) and homozygous familial hypercholesterolemia (high cholesterol inherited from both parents).

As part of your treatment plan to lower cholesterol, and depending on your health and lifestyle, your doctor, nurse or pharmacist may recommend a diet to reduce cholesterol and other measures such as exercise and weight control.

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 Proper Use of this Medication). Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor, nurse or pharmacist.

What it does:

Simvastatin is one of the class of medicines known as HMG-CoA reductase **inhibitors**. They **inhibit**, in other words block, an enzyme that is necessary for the body to make cholesterol. In this way, less cholesterol is produced in the liver. Medicines like this one are prescribed **along with**, and **not as a substitute for**, a special diet and other measures. Simvastatin is used to lower the levels of cholesterol [particularly low-density lipoprotein cholesterol (LDL-C)] and fatty substances called triglycerides in your blood.

SIMVASTATIN reduces the amount of cholesterol in your blood. Elevated cholesterol can cause CHD by clogging the blood vessels that carry oxygen and nutrients to the heart.

When it should not be used:

Do not take SIMVASTATIN if you are:

- allergic to simvastatin or any non-medicinal ingredient in the formulation
- diagnosed with active liver disease
- pregnant or breast-feeding
- taking any of the following medicines:
 - certain antifungal medicines (such as itraconazole, ketoconazole, posaconazole, or voriconazole)
 - HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
 - certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
 - certain antibiotics (such as erythromycin, clarithromycin, or telithromycin)
 - antidepressant nefazodone
 - medicines containing cobicistat
 - gemfibrozil (a fibric acid medicine for lowering cholesterol)
 - cyclosporine
 - danazol.

Ask your doctor, nurse or pharmacist if you are not sure if your medicine is listed above.

What the medicinal ingredient is:

Simvastatin

What the nonmedicinal ingredients are:

Ascorbic acid, butylated hydroxy anisole, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc, and titanium dioxide.

SIMVASTATIN tablets 5 mg, 10 mg, 20 mg, 40 mg and 80 mg also contain iron oxide black, iron oxide red, and iron oxide yellow.

What dosage forms it comes in:

Tablets: 5 mg, 10 mg, 20 mg, 40 mg and 80 mg.

WARNINGS AND PRECAUTIONS

Before taking SIMVASTATIN, tell your doctor, nurse or pharmacist if you:

- are pregnant, intend to become pregnant, are breast-feeding or intend to breast-feed
- have thyroid problems
- regularly drink *three or more* alcoholic drinks daily
- are taking any other cholesterol lowering medication such as fibrates (gemfibrozil, fenofibrate), niacin or ezetimibe
- are taking any other medications, including prescription, nonprescription and natural health products as drug interactions are possible
- have a family history of muscular disorders
- had any past problems with the muscles (pain, tenderness), after using an HMG-CoA reductase inhibitor (“statin”) such as atorvastatin (Lipitor®), fluvastatin (Lescol®), lovastatin, pravastatin (Pravachol®) or rosuvastatin (Crestor®), or have developed an allergy or intolerance to them
- have kidney or liver problems
- have diabetes. Slightly increased blood sugar can occur when you take SIMVASTATIN. Discuss with your doctor, nurse or pharmacist your risk of developing diabetes
- have undergone surgery or other tissue injury
- do excessive physical exercise
- are of childbearing age. Cholesterol compounds are essential elements for the development of a fetus. Cholesterol-lowering drugs can harm the fetus. If you are of childbearing age, discuss with your doctor, nurse or pharmacist the potential hazards to the fetus and the importance of birth control methods.
- become pregnant. SIMVASTATIN should not be used by pregnant women. If you become pregnant, discontinue use immediately and discuss with your doctor, nurse or pharmacist
- are Asian.

When starting or increasing the dose of SIMVASTATIN, or at any time, if you experience any unexplained muscle pain, tenderness or weakness, you must report promptly to your doctor, nurse or pharmacist.

Be sure to tell your doctor, nurse or pharmacist you are taking SIMVASTATIN before undergoing any major elective surgery or if you have any other new major medical issues.

INTERACTIONS WITH THIS MEDICATION

You should tell your doctor, nurse or pharmacist about all drugs that you are using or plan to use, including those obtained without a prescription, while taking SIMVASTATIN. You should also tell any doctor who is prescribing a new medication for you that you are taking SIMVASTATIN.

Because taking SIMVASTATIN with any of the following drugs or substances can increase the risk of muscle problems (see Side effects of this medicine - and what you should do), it is

particularly important to tell your doctor, nurse or pharmacist if you are taking:

- antifungal agents (such as itraconazole, ketoconazole, posaconazole, or voriconazole)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- Hepatitis C antiviral agents (such as boceprevir, telaprevir, elbasvir or grazoprevir)
- the antibiotics erythromycin, clarithromycin, telithromycin, and fusidic acid (intravenous or oral)
- the antidepressant nefazodone
- medicines containing cobicistat
- cyclosporine (immunosuppressant)
- danazol
- fibrates/fibric acid derivatives (bezafibrate and gemfibrozil) (drug to treat lipids problems)
- amiodarone (a drug used to treat an irregular heartbeat)
- verapamil, or diltiazem, or amlodipine (drugs used to treat high blood pressure, angina, or other heart conditions)
- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)
- daptomycin (a drug used to treat complicated skin and skin structure infections and bacterial infections in the blood, including certain heart valve infections)
- grapefruit juice (which should be avoided while taking SIMVASTATIN).

It is also important to tell your doctor, nurse or pharmacist if you are taking corticosteroids, anticoagulants (drug that prevents blood clots, such as warfarin), colchicine (a medicine used for gout), digoxin (a drug used to treat heart problems), niacin, or fenofibrate, another fibric acid derivative.

Some of these have already been listed in the above section “When it should not be used”.

PROPER USE OF THIS MEDICATION

Usual Dose:

- Take your medication exactly as your doctor, nurse or pharmacist instructed. Do not change the dose unless directed by your doctor. It is usually recommended to be taken with the evening meal. Because of the increased risk of muscle problems, taking 80 mg each day is only recommended for patients who have been taking this amount for a long time with no muscle problems or for patients at high risk of heart disease problems who have problems taking other statins. It is important to continue taking the tablets as instructed. **Do not alter the dosage or stop taking the medicine without consulting your doctor, nurse or pharmacist.**

- 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.
- Carefully follow any measures that your doctor, nurse or pharmacist has recommended for diet, exercise or weight control.
- When taking SIMVASTATIN, you should avoid consuming grapefruit juice.
- When taking SIMVASTATIN concurrently with cholestyramine or any other resin, an interval of at least two hours should be maintained between the two drugs.
- Keep your appointments regularly with your doctor, nurse or pharmacist so that your blood can be tested and your progress checked at proper intervals.
- Avoid drinking large quantities of alcohol.
- **Do not start taking any other medicines** unless you have discussed the matter with your doctor, nurse or pharmacist.
- Let your doctor, nurse or pharmacist know if you suffer a severe injury, or severe infection.
- If you have to undergo any kind of surgery, tell your doctor, nurse or pharmacist about the planned surgery; and also inform the doctor in charge that you are taking this medicine.

Overdose:

If you think you, or a person you are caring for, have taken too much SIMVASTATIN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss taking a tablet at its usual time, take it as soon as possible. But, if it is too close to the time of your next dose: take only the prescribed dose at the appointed time. **Do not take a double dose.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, any medication may cause unwanted effects.

The following side effects that may occur, generally do not require medical attention, and may come and go during treatment. If any of the following persist or become troublesome, **do check with your doctor, nurse or pharmacist:**

- Constipation, diarrhea, gas, stomach upset, nausea
- Pain in the abdomen
- Headache
- Skin rash
- Poor memory
- Memory loss
- Confusion
- Trouble sleeping
- Depression
- Erectile dysfunction
- Breathing problems including persistent cough and/or shortness of breath or fever.

Possible side effects reported with other statins:
Sleep disturbances, including nightmares.

Side effects such as myalgia (muscle pain), myopathy (muscle disease with aching or weakness) [that in very rare cases may not go away after stopping SIMVASTATIN], rhabdomyolysis (a muscle wasting disease or muscle breakdown), associated tenderness, and rare cases of muscle breakdown resulting in kidney damage that can lead to death have been reported with other drugs of this class, known as HMG-CoA reductase inhibitors (“statins”), including SIMVASTATIN. This risk of muscle breakdown is greater for patients taking higher doses of SIMVASTATIN, particularly the 80 mg dose. This risk of muscle breakdown is also greater for older patients (65 years of age and older), female patients, patients with abnormal kidney function, and patients with thyroid problems.

See your doctor regularly to check your cholesterol level and to check for side effects. Your doctor should do blood tests to check your liver before you start taking SIMVASTATIN and if you have any symptoms of liver problems while you take SIMVASTATIN.

SIMVASTATIN can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM				
Symptoms / effects		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Unknown	Increased blood sugar: frequent urination, thirst and hunger	√		
Rare	Allergic reactions: swelling of the face, eyelids, lips, tongue and/or throat that may cause difficulty in swallowing, sudden shortness of breath, flushing, sensitivity to light, skin reactions including hives			√
	Brownish or discoloured urine		√	
	Liver Disorder: belly pain, dark urine, itchy skin, nausea or vomiting, loss of appetite, pale stools, yellowing of skin or the whites of your eyes			√
	Generalized weakness, especially if you do not feel well or have a fever		√	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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Symptoms / effects	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Unexplained muscle pain		√	
Muscle tenderness or muscle weakness		√	
Blurred vision		√	

This is not a complete list of side effects. For any unexpected effects while taking SIMVASTATIN, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store your tablets at room temperature (15°C - 30°C), in the original package, away from heat and direct light, and out of damp places, such as the bathroom or kitchen.

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

Do not use outdated medicine.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about SIMVASTATIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sivem.ca, or by calling 1-855-788-3153