

PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrSIMVASTATIN

Simvastatin Tablets

Read this carefully before you start taking **SIMVASTATIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SIMVASTATIN**.

What is SIMVASTATIN used for?

SIMVASTATIN is used in adults and children (10 to less than 18 years of age). It is used in combination with a change in diet, to:

- lower the levels of cholesterol and fatty substances called triglycerides in the blood; and
- reduce blockages in the arteries

In adults, **SIMVASTATIN** can reduce the chance of experiencing health risks associated with Coronary Heart Disease (CHD) such as heart attack, stroke, or death.

How does SIMVASTATIN work?

Simvastatin belongs to a class of medicines known as “statins”, more specifically called HMG-CoA reductase inhibitors. Statins block an enzyme called HMG-CoA reductase from being made in your liver, which is involved in the production of cholesterol in your body. **SIMVASTATIN** is used along with a change in diet, to help control the amount of cholesterol in your blood. Medicines like this one are prescribed **along with**, and **not as a substitute for**, a special diet and other measures.

What are the ingredients in SIMVASTATIN?

Medicinal ingredient: Simvastatin

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

SIMVASTATIN comes in the following dosage forms:

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

Do not use SIMVASTATIN if:

- you are allergic to simvastatin or any non-medicinal ingredient in the formulation
- you are pregnant, think you may be pregnant, or intend to become pregnant; if you become pregnant, stop taking **SIMVASTATIN** immediately and talk to your healthcare professional.
- you are breastfeeding or intend to breastfeed.
- you have active liver disease.
- you are taking any of the following medicines:
 - certain antifungal medicines (itraconazole, ketoconazole, posaconazole, or voriconazole),

- certain medicines used to treat HIV (nelfinavir, ritonavir, or saquinavir)
- certain medicines used to treat hepatitis C virus (boceprevir or telaprevir),
- certain antibiotics (erythromycin, clarithromycin, or telithromycin),
- medicines containing cobicistat,
- nefazodone, used to treat depression,
- gemfibrozil, used for lowering cholesterol,
- cyclosporine, used to prevent organ transplant rejection,
- danazol, used to treat endometriosis or fibrocystic breast disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SIMVASTATIN. Talk about any health conditions or problems you may have, including if you:

- have diabetes or are at risk of having diabetes
- have thyroid problems
- regularly drink **three or more** alcoholic drinks daily
- had any past problems with the muscles (pain, tenderness), after using medicines such as atorvastatin, fluvastatin, lovastatin, pravastatin or rosuvastatin
- do excessive physical exercise
- have kidney or liver problems
- have undergone surgery or other tissue injury or if you have a planned surgery
- are taking any other cholesterol lowering medication such as fibrates (fenofibrate), niacin or ezetimibe
- are Asian
- are 65 years of age or older
- feel weak or frail
- have or have had myasthenia gravis (a disease causing general muscle weakness including the eye muscles and in some cases, muscles used for breathing) as statins may lead to occurrence of myasthenia or aggravate the condition.

Other warnings you should know about:

Pregnancy: SIMVASTATIN should not be taken during pregnancy as it may harm your unborn baby. If you are a woman who could become pregnant, your healthcare professional will ask you to use a highly effective birth control method while taking SIMVASTATIN. If you discover you are pregnant while taking SIMVASTATIN, stop taking the medicine and contact your healthcare professional **right away**.

Muscle disorders (myopathy or rhabdomyolysis): SIMVASTATIN increases your risk of developing a severe muscle disorder. If you experience any unexplained muscle pain, tenderness or weakness, especially with a fever, tell your healthcare professional **right away**.

Testing and check-ups: Your healthcare professional may do blood tests before you start SIMVASTATIN and regularly during your treatment. These tests will check:

- the amount of cholesterol and other fats in your blood
- your liver function

Depending on your test results, your healthcare professional may adjust your dose, temporarily stop, or discontinue your treatment with SIMVASTATIN.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not use SIMVASTATIN if you are taking any of the following:

- certain antifungal medicines (itraconazole, ketoconazole, posaconazole, or voriconazole),
- certain medicines used to treat HIV (nelfinavir, ritonavir, or saquinavir),
- certain medicines used to treat hepatitis C virus (boceprevir or telaprevir),
- certain antibiotics (erythromycin, clarithromycin, or telithromycin),
- medicines containing cobicistat,
- nefazodone, used to treat depression,
- gemfibrozil, used for lowering cholesterol,
- cyclosporine, used to prevent organ transplant rejection,
- danazol, used to treat endometriosis or fibrocystic breast disease.

Taking SIMVASTATIN with any of these medications may cause a serious drug interaction. Ask your healthcare professional if you are unsure.

The following may interact with SIMVASTATIN:

- Fibrates, used to lower fat levels in the blood (such as fenofibrate or bezafibrate)
- Amiodarone, used to treat an irregular heartbeat
- Verapamil, diltiazem, or amlodipine, used to treat high blood pressure, angina, or other heart conditions
- Lomitapide, used to treat a serious and rare genetic cholesterol condition
- Niacin
- Daptomycin, used to treat complicated skin and bacterial infections in the blood
- Colchicine, used for gout
- Cholestyramine, used to lower cholesterol
- Anticoagulants, medications that prevent blood clots, such as warfarin or coumarin
- Digoxin, used to treat heart problems
- Avoid drinking grapefruit juice while taking **SIMVASTATIN**

How to take SIMVASTATIN:

- Take SIMVASTATIN exactly as your healthcare professional tells you to.
- It is recommended to take SIMVASTATIN in the evening, with a meal.
- Carefully follow any measures that your healthcare professional has recommended for diet, exercise or weight control.
- When taking SIMVASTATIN, avoid consuming grapefruit juice.
- Keep regular appointments with your healthcare professional so that your blood can be tested and your progress checked at proper intervals.

Usual dose:

The dose of SIMVASTATIN prescribed to you depends on your condition and/or your blood cholesterol level. Your healthcare professional may change your dose depending on your response to SIMVASTATIN.

- For **adults**, the usual dosage is 5 mg to 40 mg once a day in the evening.
- For **children** (10 to less than 18 years old), the usual dosage is 10 mg to 40 mg once a day in the evening. The maximum recommended dose is 40 mg a day.

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. However, if it is too close to the time of your next dose, skip the missed dose and take your next dose as scheduled. Do not take a double dose.

What are possible side effects from using SIMVASTATIN?

These are not all the possible side effects you may have when taking SIMVASTATIN. If you experience any side effects not listed here, tell your healthcare professional.

- Persistent cough and/or shortness of breath
- Erectile dysfunction
- Acid reflux
- Constipation,
- Diarrhea
- Gas,
- Nausea
- Abdominal pain or discomfort
- Vomiting
- Confusion
- Dizziness
- Headache
- Memory loss
- Poor memory
- Hair loss
- Itchy skin
- Rash on the skin or inside the mouth (Lichen rash)
- Trouble sleeping
- Weakness

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	
RARE			
Allergic reactions: Difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			✓
Liver Disorder: yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite			✓
Muscle Disorders: Myopathy (muscle pain): aching muscles, tenderness or weakness that you cannot explain Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine. These muscle disorders can be accompanied with fever or feeling unwell.		✓	
Myasthenia Gravis (muscle weakness): General: difficulty in speaking, chewing, and swallowing or weakness of arms and legs and in some cases, muscles used when breathing Ocular (eye): weak, drooping eyelid(s) causing vision changes			✓

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			
<p>Blood Disorders:</p> <p>Anaemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness</p> <p>Leukopenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms</p> <p>Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness</p>		✓	
<p>Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse</p>		✓	
<p>Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue</p>	✓		
<p>Interstitial lung disease (disease that inflames or scars lung tissue): shortness of breath when at rest that gets worse with exertion, dry cough</p>		✓	
<p>Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen</p>		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.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.

Storage:

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.

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 Patient Medication 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.

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