

CONSUMER INFORMATION

 **ZOCOR[®]**

simvastatin tablets

This leaflet is part III of a three-part "Product Monograph" published when ZOCOR[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ZOCOR[®]. Contact your physician 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

ZOCOR[®] is the brand name for the substance - simvastatin, available **only on prescription** from your physician.

What the medication is used for:

Your physician has prescribed ZOCOR[®] 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), ZOCOR[®] should lessen the risk of heart attack or stroke.

You can also benefit from taking ZOCOR[®] 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 physician may recommend a diet to reduce cholesterol and other measures such as exercise and weight control.

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.

ZOCOR[®] 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 ZOCOR[®] if you are:

- allergic to any of its components
- diagnosed with active liver disease
- pregnant or breast-feeding

What the medicinal ingredient is:

Simvastatin

What the nonmedicinal ingredients are:

Ascorbic acid, butylated hydroxyanisole, citric acid, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc, and titanium dioxide. Tablets ZOCOR[®] 5 mg, 10 mg and 20 mg contain yellow ferric oxide. Tablets ZOCOR[®] 10 mg, 20 mg, 40 mg and 80 mg also contain red ferric oxide.

What dosage forms it comes in:

Tablet 5 mg (buff), 10 mg (peach), 20 mg (tan), 40 mg (brick red) and 80 mg (brick red)

WARNINGS AND PRECAUTIONS

Before taking ZOCOR[®], tell your physician 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 (MEVACOR[®]), pravastatin (Pravachol) or rosuvastatin (Crestor), or have developed an allergy or intolerance to them
- have kidney or liver problems
- have 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 physician the potential hazards to the fetus and the importance of birth control methods.
- become pregnant. ZOCOR[®] should not be used by pregnant women. If you become pregnant, discontinue use immediately and discuss with your physician.

INTERACTIONS WITH THIS MEDICATION

You should tell your physician about all drugs that you are using or plan to use, including those obtained without a prescription, while taking ZOCOR[®]. You should also tell any physician who is prescribing a new medication for you that you are taking ZOCOR[®].

Because taking ZOCOR[®] with any of the following drugs 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 physician if you are taking:

- cyclosporine (immunosuppressant)
- danazol
- antifungal agents (such as itraconazole or ketoconazole)
- fibrates/fibric acid derivatives (bezafibrate and gemfibrozil) (drug to treat lipids problems)
- the antibiotics (erythromycin, clarithromycin, telithromycin, and fusidic acid [oral or intravenous])
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir and saquinavir)
- the antidepressant nefazodone
- amiodarone (a drug used to treat an irregular heartbeat)
- verapamil or diltiazem (drugs used to treat high blood pressure, angina, or other heart conditions)

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

The safety of this medicine has not been established in adolescents and children.

PROPER USE OF THIS MEDICATION

Usual Dose:

- Take your medication exactly as your physician instructed. Do not change the dose unless directed by a physician. It is usually recommended as a single dose with the evening meal. Your physician may adjust your dose to a maximum of 80 mg a day, given as a single dose in the evening. It is important to continue taking the tablets as instructed. **Do not alter the dosage or stop taking the medicine without consulting your physician.**
- Carefully follow any measures that your physician has recommended for diet, exercise or weight control.
- When taking ZOCOR[®], you should avoid consuming very large amounts (over 1 liter daily) of grapefruit juice; however, typical consumption (one 250 mL glass daily) is unlikely to cause any problems.
- When taking ZOCOR[®] 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 physician 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 physician or pharmacist.
- Let your physician know if you suffer a severe injury, or severe infection.
- If you have to undergo any kind of surgery, tell your physician about the planned surgery; and also inform the physician in charge that you are taking this medicine.

Overdose:

Contact your physician immediately.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

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. Most people do not have any problem when taking this medicine; but if you notice any of the following reactions, **check with your physician as soon as possible:**

- Fever
- Blurred vision
- Muscle effects
- Liver problems (sometimes serious) (See SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM.)

Some other side effects that may occur, generally do not require medical attention, and may come and go during treatment. But if any of the following persist or become troublesome, **do check with your physician or pharmacist:**

- Constipation, diarrhea, gas, stomach upset, nausea
- Pain in the abdomen
- Headache
- Skin rash
- Memory loss
- Trouble sleeping

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptoms / effects	Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
	Only if severe	In all cases	
Rare	Allergic reactions		√
	Brownish or discoloured urine		√
	Symptoms of liver problems (abdominal pain, dark urine, itchy skin, nausea or vomiting, pale stools, yellowing of skin or eyes)		√
	Generalized weakness, especially if you do not feel well		√
	Unexplained muscle pain		√
	Muscle tenderness or muscle weakness		√

Side effects such as myalgia (muscle pain), myopathy (muscle disease with aching or weakness), rhabdomyolysis (a muscle wasting disease), associated tenderness, and rare cases of rhabdomyolysis leading to kidney failure have been reported with other drugs of this class, known as HMG-CoA reductase inhibitors ("statins"), including ZOCOR[®]. This risk of muscle breakdown is greater for patients taking higher doses of ZOCOR[®]. This risk of muscle breakdown is greater for patients with abnormal kidney function.

As these muscle problems are on rare occasions serious, you should contact your physician promptly if you experience any of the following:

- muscle pain that you cannot explain
- muscle tenderness or muscle weakness
- generalized weakness, especially if you do not feel well (i.e., fever or fatigue)
- brownish or discoloured urine

This is not a complete list of side effects. For any unexpected effects while taking ZOCOR[®], contact your physician 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 of children.

Do not use outdated medicine.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 1-866-234-2345

By toll-free fax: 1-866-678-6789

Online: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office
Marketed Health Products Safety and
Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

or Merck Frosst Canada Ltd. by:

Toll-free telephone: 1-800-567-2594

Toll-free fax: 1-877-428-8675

By regular mail:

Merck Frosst Canada Ltd.

P.O. Box 1005

Pointe-Claire - Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program or Merck Frosst. Do not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.merckfrosst.com> or by contacting the sponsor, Merck Frosst Canada Ltd., at: 1-800-567-2594

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