

PART III: CONSUMER INFORMATION

 **ZOCOR**<sup>®</sup>

simvastatin tablets

This leaflet is part III of a three-part "Product Monograph" published when ZOCOR<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> should lessen the risk of heart attack or stroke.

You can also benefit from taking ZOCOR<sup>®</sup> 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.

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). ZOCOR<sup>®</sup> has not been studied in children under the age of 10 years. For more information, talk to your physician.

**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<sup>®</sup> 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<sup>®</sup> if you are:

- allergic to any of its components
- diagnosed with active liver disease
- pregnant or breast-feeding
- taking any of the following medicines:
  - certain antifungal medicines (such as itraconazole, ketoconazole, or posaconazole)
  - HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
  - certain antibiotics (such as erythromycin, clarithromycin, or telithromycin)
  - antidepressant nefazodone
  - gemfibrozil (a fibric acid medicine for lowering cholesterol)
  - cyclosporine
  - danazol.

Ask your doctor 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 hydroxyanisole, citric acid monohydrate, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc, and titanium dioxide. Tablets ZOCOR<sup>®</sup> 5 mg, 10 mg and 20 mg contain yellow ferric oxide. Tablets ZOCOR<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup>), 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<sup>®</sup> should not be used by pregnant women. If you become pregnant, discontinue use immediately and discuss with your physician.

When starting or increasing the dose of ZOCOR<sup>®</sup>, or at any time, if you experience any unexplained muscle pain, tenderness or weakness, you must report promptly to your doctor.

Be sure to tell your doctor you are taking ZOCOR<sup>®</sup> before undergoing any major elective surgery or if you have any other new major medical issues.

### **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<sup>®</sup>. You should also tell any physician who is prescribing a new medication for you that you are taking ZOCOR<sup>®</sup>.

Because taking ZOCOR<sup>®</sup> 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:

- antifungal agents (such as itraconazole, ketoconazole, or posaconazole)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- the antibiotics erythromycin, clarithromycin, telithromycin, and fusidic acid (intravenous or oral)
- the antidepressant nefazodone
- cyclosporine (immunosuppressant)
- danazol
- fibrates/fibric acid derivatives (bezafibrate and gemfibrozil) (drugs 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).

It is also important to tell your doctor if you are taking corticosteroids, anticoagulants (drugs that prevent 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. Also tell your doctor if you are taking niacin or a niacin-containing product and are Chinese.

While taking ZOCOR<sup>®</sup>, you should avoid drinking large quantities of grapefruit juice (more than 1 liter daily).

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 physician instructed. Do not change the dose unless directed by a physician. It is usually recommended as a single dose with the evening meal. For adults, your physician may adjust your dose to a maximum of 80 mg a day, given as a single dose in the evening. Because of the increased risk of muscle problems, the 80 mg dose is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses. It is important to continue taking the tablets as instructed. **Do not alter the dosage or stop taking the medicine without consulting your physician.**
- 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 physician has recommended for diet, exercise or weight control.

- When taking ZOCOR<sup>®</sup>, 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<sup>®</sup> 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.

In case of drug overdose, contact a health care practitioner, 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. 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
- 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.

| 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 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 ZOCOR<sup>®</sup>. This risk of muscle breakdown is greater for patients taking higher doses of ZOCOR<sup>®</sup>, 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.

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<sup>®</sup>, 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

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-800-369-3090, or
  - Mail to: Merck Canada Inc.  
Pharmacovigilance  
P.O. Box 1005  
Pointe-Claire–Dorval, QC H9R 4P8

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program or Merck do not provide medical advice.*

## MORE INFORMATION

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

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