

PART III: CONSUMER INFORMATION

 **MEVACOR[®]**

lovastatin tablets

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

MEVACOR[®] is the brandname for the substance lovastatin available **only on prescription** from your physician.

What the medication is used for:

Your physician has prescribed MEVACOR[®] to help lower your elevated levels of cholesterol associated with normal or elevated triglycerides.

Elevated cholesterol can cause coronary heart disease (CHD) by clogging the blood vessels (atherosclerosis) that carry oxygen and nutrients to the heart. MEVACOR[®] is used to slow progression of atherosclerosis in the coronary arteries (blood vessels of the heart).

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:

Lovastatin is one of the class of medicines known as **Lipid Metabolism Regulators**. 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. Lovastatin is used to lower the levels of cholesterol (particularly Low Density Lipoprotein (LDL) cholesterol) and other fats in the blood. This may help prevent heart disease if caused by cholesterol clogging the blood vessels or slow the progression of atherosclerosis (hardening) of the arteries that nourish your heart, so-called coronary heart disease (CHD).

When it should not be used:

Do not take MEVACOR[®] if you are:

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

What the medicinal ingredient is:

Lovastatin

What the non-medicinal ingredients are:

Butylated hydroxyanisole, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch. Tablets MEVACOR[®] 20 mg also contain indigotine on alumina. Tablets MEVACOR[®] 40 mg contain indigotine, Quinoline yellow, both on alumina substratum.

What dosage forms it comes in:

Tablets 20 mg (light blue) and 40 mg (green).

WARNINGS AND PRECAUTIONS

Before taking MEVACOR[®], 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*), pravastatin (Pravachol*), rosuvastatin (Crestor*) or simvastatin (ZOCOR[®]), 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. MEVACOR[®] 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 MEVACOR®. You should also tell any physician who is prescribing a new medication for you that you are taking MEVACOR®.

Because taking MEVACOR® with any of the following drugs can increase the risk of muscle problems (see Side effects and what to do about them), it is particularly important to tell your physician if you are taking:

- cyclosporine (immunosuppressant)
- danazol
- antifungal agents (such as itraconazole or ketoconazole)
- fibric acid derivatives (bezafibrate, fenofibrate, and gemfibrozil) (drugs 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 (a drug used to treat high blood pressure or angina)
- large doses (more than 1 g/day) of niacin (nicotinic acid) (drug to treat lipids problems)

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

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 or in two divided doses with the morning and evening meals. Your physician may adjust your dose to a maximum of 80 mg/day, given in single doses with the evening meal or divided doses with the morning and evening meals. 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 MEVACOR®, 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 MEVACOR® 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.
- 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 dentist or the physician in charge that you are taking this or any other 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

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, dizziness
- Skin rash
- Memory loss
- Depression
- Erectile dysfunction

Possible side effects reported with some statins:

- Breathing problems including persistent cough and/or shortness of breath or fever.
- Sleep Disturbances, including insomnia and nightmares.
- Mood related disorders.

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	<ul style="list-style-type: none"> Allergic reactions 		✓
	<ul style="list-style-type: none"> Brownish or discoloured urine 		✓
	<ul style="list-style-type: none"> Generalized weakness, especially if you do not feel well 		✓
	<ul style="list-style-type: none"> Unexplained muscle pain 		✓
	<ul style="list-style-type: none"> 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 MEVACOR®.

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

Contact your physician promptly if you experience muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

This risk of muscle breakdown is greater for patients taking higher doses of MEVACOR®. This risk of muscle breakdown is greater for patients with abnormal kidney function.

This is not a complete list of side effects. For any unexpected effects while taking MEVACOR®, contact your physician or pharmacist.

HOW TO STORE IT

Store your tablets at room temperature (15°C - 30°C), in a tightly closed container, 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
- 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

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 1-866-496-9092, 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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