

## PART III: CONSUMER INFORMATION

**PRO-LOVASTATIN**  
Lovastatin Tablets, USP

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

PRO-LOVASTATIN is the brand name for the substance lovastatin available **only on prescription** from your physician.

#### What the medication is used for:

Your physician has prescribed PRO-LOVASTATIN 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. PRO-LOVASTATIN 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 classes 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 is 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 PRO-LOVASTATIN 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, 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<sup>1</sup>)
- the antidepressant nefazodone<sup>1</sup>
- medicines containing cobicistat
- the immunosuppressant cyclosporine

Ask your physician or pharmacist if you are not sure if your medicine is listed above.

#### What the medicinal ingredient is:

Lovastatin

#### What the non-medicinal ingredients are:

Butylated Hydroxyanisole, FD&C Blue No. 2 Aluminum Lake, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch, and the following:

**20 mg** tablets also contain: FD&C Blue No. 1 Lake

**40 mg** Tablets also contain: D&C Yellow No. 10 Aluminum Lake

#### What dosage form it comes in:

**Tablets:** 20 mg and 40 mg

### WARNINGS AND PRECAUTIONS

Before taking PRO-LOVASTATIN, 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, non-prescription 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, fluvastatin, pravastatin, rosuvastatin or simvastatin, 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 PRO-LOVASTATIN. Discuss with the physician 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 physician the potential hazards to the fetus and the importance of birth control methods.
- become pregnant. PRO-LOVASTATIN 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 PRO-LOVASTATIN, or at any time, if you experience any unexplained muscle pain, tenderness or weakness, you must report promptly to your physician.

Be sure to tell your physician or healthcare provider you are taking PRO-LOVASTATIN 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 PRO-LOVASTATIN. You should also tell any physician who is prescribing a new medication for you that you are taking PRO-LOVASTATIN.

Because taking PRO-LOVASTATIN with any of the following drugs or substances 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:

- antifungal agents (such as itraconazole, ketoconazole, posaconazole, or voriconazole)
- the antibiotics (erythromycin, clarithromycin, telithromycin<sup>1</sup>, and fusidic acid [oral<sup>1</sup> or intravenous<sup>1</sup>])
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- boceprevir or telaprevir (drugs used to treat hepatitis C virus infection)
- the antidepressant nefazodone<sup>1</sup>
- medicines containing cobicistat
- fibric acid derivatives (such as gemfibrozil and bezafibrate)
- cyclosporine (immunosuppressant)
- danazol
- verapamil or diltiazem (drugs used to treat high blood pressure or angina)
- amiodarone (a drug used to treat an irregular heartbeat)
- colchicine (a medicine used for gout)
- grapefruit juice (which should be avoided while taking PRO-LOVASTATIN)

It is also important to tell your physician if you are taking corticosteroids, anticoagulants (drug that prevents blood clots, such as warfarin, phenprocoumon or acenocoumarol), 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”.

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 PRO-LOVASTATIN, you should avoid consuming grapefruit juice.
- When taking PRO-LOVASTATIN 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

<sup>1</sup> not marketed in Canada

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
- Poor memory
- Memory loss
- Confusion
- 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.

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 lovastatin]), 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 PRO-LOVASTATIN.

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

See your physician 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 PRO-LOVASTATIN and if you have any symptoms of liver problems while you take PRO-LOVASTATIN.

**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 PRO-LOVASTATIN. This risk of muscle breakdown is greater for patients with abnormal kidney function.

PRO-LOVASTATIN can cause abnormal blood test results. Your physician will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Unkn own	<b>Increased Blood Sugar:</b> frequent urination, thirst and hunger	✓		
	<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat difficulty swallowing or breathing			✓
Rare	Brownish or discoloured urine		✓	
	<b>Liver problems:</b> upper belly pain, nausea, vomiting, loss of appetite, dark/brown urine, yellow skin and eyes, itchy skin, pale stools		✓	
	Generalized weakness, especially if you do not feel well		✓	
	Unexplained muscle pain		✓	
	Muscle tenderness or muscle weakness		✓	

*This is not a complete list of side effects. For any unexpected effects while taking PRO-LOVASTATIN, contact your physician or pharmacist.*

#### HOW TO STORE IT

Store between 15°C and 30°C and protect from light. Keep bottle tightly closed and blister in outer carton until all tablets are used.

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

**Do not use outdated medicine.**

**Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at [MedEffect](#);
  - By calling 1-866-234-2345 (toll-free);
  - By completing a Consumer Side Effect Reporting Form and sending it by:
    - Fax to 1-866-678-6789 (toll-free), or
    - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 0701E  
Ottawa, ON  
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*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**

This document plus the full product monograph, prepared for health professionals can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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