

PART III: CONSUMER INFORMATION

**Pr ^{Pr} LOVASTATIN
Lovastatin Tablets, USP**

This leaflet is part III of a three-part “Product Monograph” published when 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 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

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 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. 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 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 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 telithromycin¹)
 - the antidepressant nefazodone¹
 - 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 nonmedicinal ingredients are:

Lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate and FD & C blue #2. LOVASTATIN 20 mg tablets also contain the non-medicinal ingredient FD & C blue #1. LOVASTATIN 40 mg tablets also contain the non-medicinal ingredient D & C yellow #10.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

Before taking LOVASTATIN, tell your physician or pharmacist if you:

- are pregnant, intend to become pregnant, are breastfeeding 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

¹ not marketed in Canada

- have a family history of muscular disorders

IMPORTANT: PLEASE READ

- 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. Slightly increased blood sugar can occur when you take 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. 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 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 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 LOVASTATIN. You should also tell any physician who is prescribing a new medication for you that you are taking LOVASTATIN.

Because taking 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, telithromycin¹, and fusidic acid [oral¹ or intravenous¹])
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir and saquinavir)
- boceprevir or telaprevir (drugs used to treat hepatitis C virus infection)
- the antidepressant nefazodone¹

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

¹ not marketed in Canada

- Avoid drinking large quantities of alcohol.

IMPORTANT: PLEASE READ

- **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
- 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 HMGCoA reductase inhibitors (“statins”), including 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 LOVASTATIN and if you have any symptoms of liver problems while you take 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 LOVASTATIN. This risk of muscle breakdown is greater for patients with abnormal kidney function.

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 physician or pharmacist | | Stop taking drug and seek immediate emergency attention |
|------------------|---|--|--------------|---|
| | | Only if severe | In all cases | |
| Un-known | Increased Blood Sugar: frequent urination, thirst and hunger | ✓ | | |

IMPORTANT: PLEASE READ

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| Rare | Allergic Reactions: rash, hives, swelling of the face, lips, tongue or throat difficulty swallowing or breathing | | | ✓ |
| | Brownish or discoloured urine | | ✓ | |
| | Liver problems: 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 LOVASTATIN, contact your physician or pharmacist.

HOW TO STORE IT

Store at room temperature (15 - 30°C). Protect from light.

Keep all medicines out of the reach of children.

Do not use outdated medicine.

REPORTING SUSPECTED SIDE EFFECTS

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Sanis Health Inc., at:
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