PART III: CONSUMER INFORMATION

[Pr]PRAVASTATIN
pravastatin sodium

This leaflet is part III of a three-part "Product Monograph" published when PRAVASTATIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRAVASTATIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

PRAVASTATIN is available only with your physician's prescription. It is to be used as an adjunct to a medically recommended and carefully supervised diet for the long-term treatment of hypercholesterolemia and is not a substitute for such a diet. This has been shown to decrease the chances of experiencing a first or second heart attack, or stroke, and 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). In addition, depending on your condition, your physician may recommend an appropriate regimen of exercise, weight control and other measures.

What it Does:

PRAVASTATIN lowers the level of cholesterol, particularly Low Density Lipoprotein (LDL) cholesterol, in the blood. PRAVASTATIN reduces cholesterol production by the liver and induces some changes of cholesterol transport and disposition in the blood and tissues.

When it should not be used:

Do not use PRAVASTATIN if you:
- are pregnant, since its use in the event of pregnancy may harm the unborn. Only female patients who are highly unlikely to conceive can be candidates for PRAVASTATIN treatment. In the event of pregnancy during treatment, PRAVASTATIN should be discontinued and the physician should be informed.
- know that you are allergic to pravastatin or any of the non-medicinal ingredients of PRAVASTATIN.
- have liver disease.
- are less than 18 years of age. The safety of pravastatin sodium in this age group has not been established.

What the medicinal ingredient is:

Pravastatin sodium

What the non-medicinal ingredients are:

Lactose anhydrous, povidone, crospovidone, calcium phosphate dibasic anhydrous, sodium stearyl fumarate, microcrystalline cellulose, croscarmellose sodium, ferric oxide red (10 mg tablet), ferric oxide yellow (20 mg tablet), color yellow DC No.10 Aluminum Lake 18-24% and color FDC blue No.1 Aluminum Lake 11-13% (40 mg tablet).

What dosage forms it comes in:

10, 20 and 40 mg tablets

WARNINGS AND PRECAUTIONS

Use only as specifically directed. Do not alter the dosage unless ordered to do so by your physician. Check with your physician before discontinuing medication since this may result in an increase of your blood lipids.

Before taking PRAVASTATIN, tell your doctor or pharmacist if you:
- are breast-feeding or intend to breast-feed,
- have thyroid problems,
- have a family history of muscular disorders,
- have had any past problems with the muscles (pain, tenderness), after using an HMG-CoA reductase inhibitor ("statin") such as atorvastatin (Lipitor®)[3] fluvastatin (Lescol®)[4], lovastatin (Mevacor®)[5], pravastatin (PRAVASTATIN), rosuvastatin (Crestor®)[6] or simvastatin (Zocor®)[5], 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,
- suffer from alcohol abuse,
- are 65 years of age or older.

Pregnancy

Before using this medication, discuss the following with your doctor:

- Cholesterol compounds are essential elements for the development of a fetus.

[3] Lipitor® is a registered trademark of Pfizer Ireland Pharmaceuticals.
[4] Lescol® is a registered trademark of Sandoz Canada Inc.
[5] Mevacor® and Zocor® are registered trademarks of Merck & Co., Inc.
[6] Crestor® is a registered trademark of IPR Pharmaceuticals Inc.

- Cholesterol-lowering drugs can harm the fetus. If you are of child-bearing age, discuss with your doctor the potential hazards to the fetus and the importance of birth control methods.
- PRAVASTATIN should not be used by pregnant women. If you become pregnant, discontinue use immediately and discuss with your doctor.

Slightly increased blood sugar can occur when you take HMG-CoA reductase inhibitor ("statin"). Discuss with the doctor your risk of developing diabetes

INTERACTIONS WITH THIS MEDICATION

PRAVASTATIN may interact with other drugs, including those you take without a prescription. You must tell your doctor or pharmacist about all drugs, including prescription and non-prescription, herbal products and supplements, you are taking or planning to take before you take PRAVASTATIN.

You should tell your doctor if you are taking other cholesterol lowering medication such as fibrates (gemfibrozil, fenofibrate), niacin, or ezetimibe. If you take these drugs and PRAVASTATIN together, you may be at an increased risk of myopathy (muscle disease with aching or weakness).

If you are taking a bile acid-binding resin (such as cholestyramine, colestipol), your doctor will recommend that you take PRAVASTATIN either one hour or more before or at least four hours following the resin. Taking them together causes lower amounts of PRAVASTATIN in the blood, making it less effective.

If you are taking cyclosporine, your doctor may need to adjust the dose of PRAVASTATIN.

If you are taking certain antibiotics (such as azithromycin or clarithromycin) to treat an infection your doctor my need to adjust the dose of PRAVASTATIN.

Excessive alcohol intake should be avoided when taking PRAVASTATIN. Tell your doctor if you regularly drink *three or more* alcoholic drinks daily.

PROPER USE OF THIS MEDICATION

- Do not change the dose unless directed by a doctor.
- PRAVASTATIN should be taken as a single dose at bedtime, as prescribed by your physician.
- Your physician will monitor your clinical condition and your blood tests at regular intervals. It is important to have these check-ups done on schedule. Please keep your appointments accurately.
- Notify your physician about any illness which may develop during your treatment with PRAVASTATIN and about any new prescription or non-prescription medication you may take. If you require medical help for other reasons, inform the attending physician that you are taking PRAVASTATIN,
- Notify your physician if you are going to have major surgery or have sustained a severe injury,
- Notify your physician of any muscle pain, tenderness or weakness developing during treatment with PRAVASTATIN (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

Usual adult dose:
The recommended starting dose is 20 mg once daily at bed time. Patients who require a large dose reduction in cholesterol may be started at 40 mg once daily. The dose of 80 mg once daily should be reserved for patients who do not achieve their treatment goal with lower doses. PRAVASTATIN may be taken without regard to meals.

Overdose:

If you think you have taken too much PRAVASTATIN contact your doctor, pharmacist, hospital emergency department or regional Poison control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- abdominal pain, constipation, diarrhea, nausea, indigestion
- headache, dizziness
- skin rashes
- persistent cough
- trouble sleeping, insomnia, nightmares
- sexual problems
- depression, anxiety, nervousness

Muscle effects

Side effects such as muscle pain, muscle disease with aching or weakness, rhabdomyolosis (a muscle wasting disease), associated tenderness, and rare cases of rhabdomylosis leading to kidney failure have been reported with other drugs of this class, known as HMG-CoA reductase inhibitors ("statins"), including PRAVASTATIN.

As these muscle problems are on rare occasions serious, you should contact your physician promptly if you experience any of the side effects listed in the Table below.

IMPORTANT PLEASE READ

Pravastatin sodium can also cause abnormal blood test results. Your doctor 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 medical help
		Only if severe	In all cases	
Rare	- muscle pain that you cannot explain		√	
	- muscle tenderness or muscle weakness, or muscle cramping		√	
	- generalized weakness, especially if you do not feel well (ie. fever or fatigue)		√	
	- brownish or discoloured urine		√	
	- Symptoms of liver problems (upper belly pain, dark urine, itchy skin, nausea or vomiting, loss of appetite, pale stools, yellowing of skin or the whites of your eyes)			√
	- Cough and/or shortness of breath		√	
	- Severe Skin reaction with fever, sore mouth or throat, blistering and/or peeling of your skin or mucous membranes			√
Uncommon	- Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	- Memory problems: poor memory, forgetfulness, confusion, memory loss	√		
Common	Vision problems, blurred vision		√	
Unknown	- Increased Blood Sugar: Frequent urination, thirst and hunger	√		
	- Chest pain		√	

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

HOW TO STORE IT

PRAVASTATIN should be stored at room temperature (15-30°C). Protect from moisture and light.

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

This document plus the full product monograph, prepared for health professionals can be found by contacting Sanis Health Inc., at:
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or quality@sanis.com

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