

PART III: CONSUMER INFORMATION**P^rLESCOL[®]
Fluvastatin sodium capsules****P^rLESCOL[®] XL****Fluvastatin sodium extended release tablets**

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

ABOUT THIS MEDICATION**What the medication is used for:**

LESCOL[®]/LESCOL[®] XL is to be used along with a medically recommended and carefully supervised diet for the long-term treatment of high cholesterol and fatty acids and is not a substitute for such a diet. In addition, depending on your condition, your physician may recommend an appropriate regimen of exercise, weight control and other measures.

LESCOL[®] may be prescribed by your physician if you suffer from coronary heart disease, and have undergone a percutaneous coronary intervention (PCI) (a medical procedure on your heart (or its vessels) that was performed through an incision on your leg or arm), to reduce your risk of developing any major heart problems, such as loss of heart muscle, nonfatal heart attack, or the need to perform other medical procedures on the heart or its vessels.

LESCOL[®]/LESCOL[®] XL is intended for children aged 10 years and older. Your doctor will advise you about the appropriate diet for your child.

What it does:

LESCOL[®]/LESCOL[®] XL lower the level of cholesterol, particularly low density lipoprotein (LDL) cholesterol, in the blood. LESCOL[®]/LESCOL[®] XL reduce cholesterol production by the liver and induce some changes of cholesterol transport and the way it is distributed in the blood and tissues.

When it should not be used:**Do not take LESCOL[®]/LESCOL[®] XL:**

- if you are hypersensitive (allergic) to fluvastatin or any of the other ingredients of LESCOL[®]/LESCOL[®] XL
- if you have an active liver disease, or unexplained, persistent elevations in liver function values (transaminases)
- if you are pregnant or breast-feeding
- LESCOL[®] and LESCOL[®] XL have not been studied in children under 9 years of age.

If any of these apply to you, **tell your doctor without taking LESCOL[®]/LESCOL[®] XL.**

What the medicinal ingredient is:

fluvastatin sodium.

What the non-medicinal ingredients are:

LESCOL[®] capsules contain: Calcium carbonate, gelatin, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium bicarbonate, talc and

titanium dioxide.

LESCOL[®] XL tablets contain: hydroxypropyl cellulose, hydroxypropyl methyl cellulose, iron oxide yellow (C.I. # 77492), magnesium stearate, microcrystalline cellulose, polyethylene glycol 8000, potassium bicarbonate, povidone and titanium dioxide (C.I. # 77891).

What dosage forms it comes in:

**LESCOL[®] Capsules 20 mg and 40 mg
LESCOL[®] XL Extended Release Tablets 80 mg**

WARNINGS AND PRECAUTIONS**Pregnancy**

LESCOL[®]/LESCOL[®] XL should not be used during pregnancy. Cholesterol is essential for the development of a baby. Cholesterol-lowering drugs can harm the baby. If you become pregnant while using LESCOL[®]/LESCOL[®] XL, stop using the medication immediately and contact your doctor.

BEFORE you use LESCOL[®]/LESCOL[®] XL talk to your doctor or pharmacist if you:

- have thyroid problems
- regularly drink *three or more* alcoholic drinks daily
- are taking any other cholesterol lowering medication such as fibrates (gemfibrozil, fenofibrate, bezafibrate), niacin or ezetimibe
- are taking any other medications, including prescription, nonprescription and natural health products as drug interactions are possible, in particular corticosteroids, cyclosporine (NEORAL[®]), fibrates (e.g. gemfibrozil [LOPID[®]]), oral anticoagulants (eg. warfarin [COUMADIN[®]]), phenytoin, oral hypoglycemics, non steroidal anti-inflammatory drugs, erythromycin, lipid lowering doses of niacin (nicotinic acid), nefazodone (SERZONE[®]) and colchicines
- have a personal or family history of muscular disorders
- had any past muscle problems (pain, tenderness), after using an HMG-CoA reductase inhibitor ("statin") such as atorvastatin (LIPITOR[®]), fluvastatin (LESCOL[®]/LESCOL[®] XL), lovastatin (MEVACOR[®]), pravastatin (PRAVACOLI[®]), rosuvastatin (CRESTOR[®]) or simvastatin (ZOCOR[®]) or have developed an allergy or intolerance to any of them
- have unexplained muscle pain, tenderness or weakness, as these might be early signs of potentially severe muscle degradation.
- have kidney disease
- have liver problems: liver function tests will normally be done before starting LESCOL[®]/LESCOL[®] XL, at dose increase and at various intervals during treatment to check for undesirable effects
- have severe metabolic, endocrine or electrolyte disorders such as decompensated diabetes and low blood potassium

Slightly increased blood sugar can occur when you take LESCOL[®]/LESCOL[®] XL. Discuss with the doctor your risk of developing diabetes.

- have undergone surgery or other tissue injury
- do excessive physical exercise
- have a serious infection
- have very low blood pressure (signs may include dizziness, lightheadedness)
- have congestive heart failure
- suffer from seizures
- are older than 70 years your doctor may want to clarify whether you have risk factors for muscular diseases. This may require specific blood tests
- In adolescents and children, the safety of LESCOL[®]/LESCOL[®] XL for a prolonged treatment period on their physical, intellectual and sexual maturation has not been established.

Your doctor will monitor your progress with LESCOL[®]/LESCOL[®] XL and may occasionally perform some tests to ensure your health and safety.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with LESCOL[®]/LESCOL[®] XL include:

- corticosteroids
- cholestyramine
- gemfibrozil/fenofibrate/bezafibrate/niacin
- cimetidine/ranitidine/omeprazole
- digoxin
- rifampicin
- warfarin and other coumarin derivatives
- phenytoin
- fluconazole
- oral hypoglycemic agents (e.g. tolbutamide, chlorpropamide, glyburide)
- non-steroidal anti-inflammatory drugs (NSAIDs)
- nefazodone
- alcohol
- spironolactone
- amlodipine
- cyclosporine

Notify your physician about any illness which may develop during your treatment with LESCOL[®]/LESCOL[®] XL and about any new prescription or nonprescription medication you may take. If you require medical help for other reasons, inform the attending physician that you are taking LESCOL[®]/LESCOL[®] XL.

In adolescents and children, no information on specific drug interactions with LESCOL[®]/LESCOL[®] XL is available.

PROPER USE OF THIS MEDICATION

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 fat substances in the blood.

Usual dose, limit to people older than 10 years old:

- If your doctor recommends you take only 1 dose of LESCOL[®] per day, take it in the evening or at bedtime or LESCOL[®] XL at any time of the day. If your doctor recommends taking divided doses (2 times per day), take one in the morning and one in the evening.
- LESCOL[®]/LESCOL[®] XL can be taken with or without food, but continue to take it the same way (either with *OR* without food) each time. Swallow LESCOL[®]/LESCOL[®] XL whole with a glass of water.
- Do not change the dose unless directed by a doctor.
- 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 if you are going to have major surgery or have sustained a severe injury.

Overdose:

If you take more LESCOL[®]/LESCOL[®] XL than you should, tell your doctor immediately or go to your nearest hospital.

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 forget to take LESCOL[®]/LESCOL[®] XL, take one dose as soon as you remember.

Do not take a double dose to make up for the one that you missed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients treated with LESCOL[®]/LESCOL[®] XL may experience side effects, although not everybody gets them.

Other side effects may occasionally occur which usually do not require stopping treatment. They may come and go during treatment without any particular danger, but you should mention them to your physician, without undue delay, if they become persistent or bothersome. Such adverse experiences include:

- abdominal pain/indigestion,
- constipation,
- diarrhea,
- nausea,
- headache,
- abnormal blood test values for muscle and liver,
- influenza,
- infections,

- poor memory, confusion and memory loss
- insomnia, and
- dizziness.

Possible side effects reported with some statins: liver failure (symptoms like nausea, vomiting, loss of appetite, yellow eyes or skin, confusion, euphoria or depression, mental slowing, slurred speech, sleep disturbances, tremors, easy bruising or bleeding), breathing problems including persistent cough and/or shortness of breath or fever, depression, erectile dysfunction, sleep disturbances, including insomnia and nightmares.

If any of these affect you severely, tell your doctor.

LESCOL®/LESCOL® XL can 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 right away		Stop taking drug and seek immediate medical attention
		Only if severe	In all cases	
Rare	Muscle pain that you cannot explain, muscle tenderness or muscle weakness		√	
	Skin rash, hives, swelling of the face, eyelids and lips			√
Very rare	Brownish or discoloured urine		√	
	Generalized weakness, especially if you do not feel well (ie. fever or fatigue)		√	
	Myositis (muscle inflammation), rhabdomyolysis (a muscle wasting disease)		√	
	Unusual tiredness or fever, yellowing of the skin and eyes, dark coloured urine (hepatitis)			√
	Severe abdominal pain (inflamed pancreas)		√	
	Skin swelling, rash, hives, dizziness, sensitivity to light (signs of severe allergic reaction)			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate medical attention
	Only if severe	In all cases	
Difficulty in breathing, swelling of the lips, throat, mouth, tongue or face (signs of severe allergic reaction)			√
Unknown	Increased Blood Sugar: frequent urination, thirst and hunger.	√	
	Unexplained muscle pain, tenderness or weakness	√	

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

HOW TO STORE IT

LESCOL® capsules: Do not store above 25°C. Store in a tight container. Protect from light and humidity.
 LESCOL® XL tablets: Store at room temperature between 15 and 30°C.

Keep all medicines out of the reach of children.

This medicine is prescribed for your specific medical problem and for your own use only. Do not give to other people.

Do not use outdated medicines. Discard them safely out of the reach of children or take them to your pharmacist who will dispose of them for you.

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.

NOTE: Should you require information related to the management of the side effect, please contact your health care professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.novartis.ca>

or by contacting the sponsor:

Novartis Pharmaceuticals Canada Inc.

385 Bouchard Blvd.

Dorval, Quebec, H9S 1A9

1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last revised: August 26, 2016

LESCOL is a registered trademark