

PART III: CONSUMER INFORMATION

**Pr APO-ATORVASTATIN
(Atorvastatin Calcium Tablets)**

This leaflet is part III of a three-part “Product Monograph” published when APO-ATORVASTATIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-ATORVASTATIN. Contact your doctor or pharmacist if you/your child have any questions about the drug. Please read this information carefully.

ABOUT THIS MEDICATION

What the medication is used for:

Your doctor has prescribed these pills to help lower your cholesterol or other fats in the blood (such as triglycerides) and to prevent cardiovascular disease such as heart attacks. High levels of cholesterol and other fats can cause heart disease by clogging the blood vessels that feed blood and oxygen to the heart.

Children 10-17 years old with heterozygous familial hypercholesterolemia (high cholesterol inherited from one of the parents) and a family history of cardiovascular disease or 2 or more risk factors of cardiovascular disease, as determined by your doctor, can also benefit from taking APO-ATORVASTATIN.

APO-ATORVASTATIN is just part of the treatment your doctor will plan with you/your child to help keep you healthy. Depending on your/your child’s health and lifestyle, your doctor may recommend:

- a change in diet to control weight and reduce cholesterol, reduce intake of saturated fats and increase fiber
- exercise that is right for you/your child
- quitting smoking or avoiding smoky places
- giving up alcohol or drinking less

Follow your doctor’s instructions carefully.

What it does:

APO-ATORVASTATIN belongs to the class of medicines known as “statins”, more specifically called HMG-CoA reductase inhibitors. HMG-CoA reductase is an enzyme involved in regulating cholesterol levels in your body. Statins are used along with changes to exercise and diet to help control the amount of cholesterol produced by the body.

APO-ATORVASTATIN can help your body:

- Decrease LDL (bad) cholesterol, triglyceride levels and other lipids/fats in the blood.
- Increase HDL (good) cholesterol.
- Decrease the Total Cholesterol HDL-Cholesterol Ratio

(TC:HDL-C Ratio). This ratio represents the balance between bad and good cholesterol.

APO-ATORVASTATIN also reduces the risk of heart attacks and strokes in people with multiple risk factors for coronary heart disease such as high blood pressure and diabetes. When used by people who have suffered a heart attack in the past, APO-ATORVASTATIN reduces the risk of having another heart attack.

APO-ATORVASTATIN is only available by prescription after seeing a doctor.

When it should not be used:

Do not take APO-ATORVASTATIN if you/your child:

- Are/is allergic to any ingredient of this medication (see what the medicinal ingredient is and what the important non medicinal ingredients are).
- Have active liver disease or unexplained increases in liver enzymes.
- Are/is pregnant or breast-feeding.

What the medicinal ingredient is:

atorvastatin calcium propylene glycol solvate.

What the important nonmedicinal ingredients are:

APO-ATORVASTATIN tablets contain: calcium acetate, croscarmellose sodium, sodium carbonate, microcrystalline cellulose, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyethylene glycol, titanium dioxide.

What dosage forms it comes in:

Tablets are available in 4 strengths: 10 mg, 20 mg, 40 mg and 80 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Tell your doctor if you/your child have any muscle pain, tenderness, soreness or weakness during treatment with APO-ATORVASTATIN.

Before using this medicine:

Before taking APO-ATORVASTATIN, tell your doctor or pharmacist if you/your child:

- are/is pregnant, intend to become pregnant. Cholesterol compounds are essential elements for the development of a fetus. Cholesterol-lowering drugs can harm the fetus. Females of child-bearing age should discuss with their doctor the potential hazards to the fetus and the importance of birth control methods. APO-ATORVASTATIN should not be used by pregnant women. If you/your child become pregnant, discontinue use immediately and discuss with your doctor
- are/is breast-feeding or intend to breast-feed. This

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medicine may be present in breast milk.

- have thyroid problems
- have had a stroke or a mini stroke (TIA)
- regularly drink *three or more* alcoholic drinks daily
- are taking any other cholesterol lowering medication such as fibrates (gemfibrozil, fenofibrate), niacin or ezetimibe
- 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 (APO-ATORVASTATIN), fluvastatin (Lescol®), lovastatin (Mevacor®), pravastatin (Pravacol®), rosuvastatin (Crestor®) or simvastatin (Zocor®) or have developed an allergy or intolerance to them
- have kidney or liver problems
- have diabetes (as the dosage of APO-ATORVASTATIN may need to be adjusted)
- have undergone surgery or other tissue injury
- do excessive physical exercise

Atorvastatin was studied in boys and girls (girls who already started their period) 10-17 years at a dose of 10 and 20 mg. APO-ATORVASTATIN has not been studied in pre-pubertal patients or patients younger than 10 years of age. Adolescent girls should discuss with their doctor the potential hazards to the fetus and the importance of birth control while on APO-ATORVASTATIN therapy.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interaction with other drugs is possible. Tell your doctor or pharmacist if you are taking any other medications, including prescription, non-prescription and natural health products. In particular, these drugs may interact with APO-ATORVASTATIN:

- corticosteroids (cortisone-like medicines)
- cyclosporine (SANDIMMUNE®)
- gemfibrozil (LOPID®)
- fenofibrate (LIPIDIL MICRO®) or bezafibrate (BEZALIP®)
- lipid-lowering doses of niacin (nicotinic acid)
- erythromycin, clarithromycin or azole antifungal agents (ketoconazole or itraconazole)
- nefazodone (SERZONE®)
- indinavir sulfate (CRIXIVAN®), nelfinavir mesylate (VIRACEPT®), ritonavir (NORVIR®), saquinavir mesylate (INVIRASE™), lopinavir/ritonavir (e.g. KALETRA®)
- fusidic acid (e.g. FUSIDIN)
- digoxin
- diltiazem
- efavirenz, rifampin
- antacids (frequent use) and APO-ATORVASTATIN should be taken 2 hours apart
- grapefruit juice - especially if ingesting upwards of 1.2 litres of grapefruit juice at once

PROPER USE OF THIS MEDICATION

We often cannot see or feel the problems that high cholesterol causes until a lot of time has passed. That’s why it is important to take these pills just as prescribed. You/your child and your doctor will be watching your/your child’s cholesterol levels to get them down to a safe range. Here are some important tips.

- Follow the plan that you/your child and your doctor make for diet, exercise and weight control.
- Take APO-ATORVASTATIN as a single dose. It does not matter if APO-ATORVASTATIN is taken with food or without food, but it should not be taken with grapefruit juice. Your doctor will usually tell you/your child to take it in the evenings.
- Do not change the dose unless directed by a doctor.
- If you/your child get sick, have an operation, or need medical treatment, inform your doctor or pharmacist that you/your child are taking APO-ATORVASTATIN.
- If you/your child have to take any other medicine - prescription or non-prescription - while taking APO-ATORVASTATIN, talk to your doctor or pharmacist first.
- If you/your child have to see a different doctor for any reason, be sure to inform him/her that you/your child are/is taking APO-ATORVASTATIN.
- APO-ATORVASTATIN was prescribed for you/your child only. Don’t give these pills to anyone else.

Usual dose:

Adults: The recommended starting dose of APO-ATORVASTATIN is 10 or 20 mg once daily, depending on your required LDL-C reduction. Patients who need a large reduction in LDL-C (more than 45%) may be started at 40 mg once daily. The dosage range of APO-ATORVASTATIN is 10 to 80 mg once daily. The maximum dose is 80 mg/day.

The recommended dose of APO-ATORVASTATIN is 10 to 80 mg/day for people who have already suffered a heart attack.

Children (10-17 years old): the recommended starting dose of APO-ATORVASTATIN is 10 mg/day; the maximum recommended dose is 20 mg/day.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed Dose:

If you/your child miss taking a pill, take it as soon as possible. But if it is almost time for the next dose, skip the missed dose and just take the next dose. Don’t take a double dose.

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SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Most people do not have any problems with side effects when taking this medicine. However, all medicines can cause unwanted side effects. Check with your doctor or pharmacist promptly if any of the following persist or become troublesome:

- constipation/diarrhea/gas
- depression (in children)
- headache
- skin rash
- stomach pain or upset
- vomiting or throwing up

Very rarely, a few people may suffer from jaundice, (which may be manifested by yellowing of the skin and eyes), from a liver condition called hepatitis (inflammation of the liver).

Possible side effects reported with some statins:

- breathing problems including persistent cough and/or shortness of breath or fever
- cases of erectile dysfunction (difficulty to achieve or maintain an erection)
- sleep disturbances (difficulty sleeping or staying asleep), including insomnia and nightmares
- mood related disorders including depression

This is not a complete list of side effects. If you/your child notice anything unusual or any unexpected effects while taking APO-ATORVASTATIN, contact your doctor or pharmacist.

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

Symptom/Effect	Talk with your doctor or pharmacist		Stop taking the drug and seek emergency medical assistance
	Only if severe	In all cases	
Rare	Muscle pain that you cannot explain	√	
	Muscle tenderness or weakness	√	
	Generalized weakness, especially if you don't feel well	√	
	Brownish or discoloured urine	√	

HOW TO STORE IT

Always keep medicine well out of the reach of children.

Keep APO-ATORVASTATIN at room temperature (15-30°C), away from warm and damp places, like the bathroom or kitchen.

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 0701D
 - 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 side effects, contact your health professional. 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 DISpedia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at: <http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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