

INFORMATION FOR THE PATIENT

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APO-PRAVASTATIN

Pravastatin Sodium Tablets

The full product monograph is available to the physician and pharmacist.

APO-PRAVASTATIN is the proprietary name of Apotex Inc. for pravastatin sodium.

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

APO-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.

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 USING THIS MEDICATION, you should have told your physician if:

- you have already taken APO-PRAVASTATIN or any other lipid lowering agent of the same class - for example fluvastatin (Lescol), lovastatin (Mevacor), simvastatin (Zocor), atorvastatin (Lipitor), or cerivastatin (Baycol) - and have developed an allergy or intolerance to any of them,
- you suffer from liver disease,
- you are pregnant, intend to become pregnant or are breast feeding, or intend to breast-feed,
- you are taking any other medication, particularly corticosteroids, cyclosporine (Sandimmune), gemfibrozil (Lopid), and anticoagulant [e.g. warfarin (Warfilone)], erythromycin, or digoxin.

PROPER USE OF THIS MEDICINE

- APO-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.
- Avoid excessive alcohol intake.
- Notify your physician about any illness which may develop during your treatment with APO-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 APO-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 APO-PRAVASTATIN (see SIDE EFFECTS).
- The safety of APO-PRAVASTATIN in adolescents and children has not been established.
- APO-PRAVASTATIN is contraindicated during pregnancy 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 APO-PRAVASTATIN treatment. In the event of pregnancy during treatment, APO-PRAVASTATIN should be discontinued and the physician should be informed.

SIDE EFFECTS

Along with its intended action, any medication may cause unwanted effects.

Check with your physician as soon as possible if any of the following side effects occurs: aching muscles, muscle cramping, tiredness or weakness, fever and blurred vision.

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, constipation, diarrhea, nausea, headache, dizziness and skin rashes.

THIS MEDICINE IS PRESCRIBED FOR YOUR SPECIFIC MEDICAL PROBLEM AND FOR YOUR OWN USE ONLY. DO NOT GIVE TO OTHER PEOPLE.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

IF YOU NEED ANY FURTHER INFORMATION, ASK YOUR PHYSICIAN OR YOUR PHARMACIST.

WHO MANUFACTURES APO-PRAVASTATIN

Apotex Inc.
150 Signet Drive
Weston, Ontario
M9L 1T9

REMINDERS:

This medicine has been prescribed only for you. Do not give it to anybody else.

If you require any further information or advice please consult your doctor or pharmacist.

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