

INFORMATION FOR THE PATIENT

Pr APO-LOVASTATIN

Lovastatin Tablets USP

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Full prescribing information is available to the physician and pharmacist.

APO-LOVASTATIN is the brand name of Apotex Inc. for the substance lovastatin available **only on prescription** from your physician. Lovastatin is one of a 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.

When it is necessary to lower cholesterol, physicians usually try to control the condition, known as hypercholesterolemia, with a carefully supervised diet. Also your physician may recommend other measures such as exercise and weight control. 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).

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.**

Do not use outdated medicine.

Store your tablets at room temperature (15°C - 30°C), away from heat and direct light. Keep all medicines out of the reach of children.

Read the following information carefully. **If you need any explanations, or further information, ask your physician or pharmacist.**

BEFORE TAKING THIS MEDICINE

This medicine may not be suitable for certain people. So, tell your physician if you think **any** of the following applies to you:

- You have previously taken lovastatin or any other medication in the same class - example, simvastatin (Zocor), pravastatin (Pravachol) or fluvastatin (Lescol) and were allergic, or had reacted badly to it.
- **You are pregnant or intend to become pregnant.** This medicine should **not** be used during pregnancy.
- You are breast-feeding, or intend to breast-feed.
- You have liver disease.

Your physician also needs to know if you are taking any other medication, whether on prescription or otherwise. It is particularly important to inform your physician if you are taking:

- cyclosporine (Sandimmune), gemfibrozil (Lopid), lipid-lowering doses of niacin (nicotinic acid), nefazodone (Serzone), corticosteroids, or an anticoagulant (e.g., warfarin), digoxin or erythromycin.

The safety of this medicine has not been established in adolescents and children.

PROPER USE OF THIS MEDICINE

- Take this medicine **exactly** as your physician ordered. It is usually recommended as a single dose with the evening meal or in two divided doses with the morning and evening meals.
- 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.**
- Carefully follow any measures that your physician has recommended for diet, exercise or weight control.
- It is important to continue taking the tablets as instructed. Do not alter the dosage or stop taking the medicine without consulting your physician.
- Keep your appointments regularly with your physician so that your blood can be tested and your progress checked at proper intervals. Your physician may also arrange for periodic eye examination by an ophthalmologist.
- **Do not consume grapefruit juice while taking APO-LOVASTATIN.**
- Avoid drinking large quantities of alcohol.
- **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 dental or other 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.

SIDE EFFECTS OF THIS MEDICINE - AND WHAT YOU SHOULD DO

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:**

- Aching muscles, muscle cramps, tiredness or weakness
- Fever
- Blurred vision

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

Some people may have other reactions. If you notice **any unusual effect**, check with your physician or pharmacist.

Active Ingredient: Each tablet of APO-LOVASTATIN contains lovastatin. It comes in two strengths: 20 mg (light blue), and 40 mg (light green).

Comments: Revisions made as per TPP request dated November 2, 1998.

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