

INFORMATION FOR THE PATIENT

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APO-SIMVASTATIN

Simvastatin Tablets USP
Lipid Metabolism Regulator

The Product Monograph is available upon request to physicians and pharmacists.

APO-SIMVASTATIN is the brand name of Apotex Inc. for the substance simvastatin, available **only on prescription** from your physician. Simvastatin is one of a class of medicines known as HMG-CoA reductase inhibitors. 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. Simvastatin is used to lower the levels of cholesterol (particularly Low Density Lipoprotein (LDL) cholesterol) and fatty substances called triglycerides in your blood.

Your physician has prescribed APO-SIMVASTATIN to reduce the amount of cholesterol and triglycerides in your blood. Elevated cholesterol can cause coronary heart disease (CHD) by clogging the blood vessels which carry oxygen and nutrients to the heart. If you have CHD and elevated cholesterol levels, your physician has prescribed APO-SIMVASTATIN to help reduce the risk of dying from coronary heart disease, to lessen the risk of a heart attack or stroke, and to decrease the risk of needing a surgical procedure to increase the blood flow to your heart.

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Do not use outdated medicine.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 in a tightly closed container 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 simvastatin or any other medication in the same class - example, atorvastatin (Lipitor), fluvastatin (Lescol), lovastatin (Mevacor) or pravastatin (Pravachol) - and were allergic, or reacted badly to it.
- You have liver disease.
- You are pregnant or intend to become pregnant. This medicine should not be used in women who are pregnant, trying to become pregnant or suspect that they are pregnant. If you become pregnant while taking APO-SIMVASTATIN, stop taking it and contact your physician immediately.
- You are breast-feeding or intend to breast-feed.

TAKING APO-SIMVASTATIN WITH OTHER MEDICINES

You should tell your physician about all drugs that you are using or plan to use, including those obtained without a prescription, while taking APO-SIMVASTATIN. You should also tell any physician who is prescribing a new medication for you that you are taking APO-SIMVASTATIN. Because taking APO-SIMVASTATIN with any of the following drugs can increase the risk of muscle problems (see Side effects of this medicine - and what you should do), it is particularly important to tell your physician if you are taking:

- cyclosporine (immunosuppressant)
- antifungal agents (itraconazole or ketoconazole)
- fibric acid derivatives (bezafibrate, fenofibrate, and gemfibrozil) (drug to treat lipids problems)
- the antibiotics (erythromycin and clarithromycin)
- HIV protease inhibitors (indinavir, nelfinavir, ritonavir and saquinavir)
- the antidepressant nefazodone
- amiodarone (a drug used to treat an irregular heartbeat)
- verapamil (a drug used to treat high blood pressure or angina)
- large doses (more than 1 g/day) of niacin (nicotinic acid) (drug to treat lipids problems)

It is also important to tell your doctor if you are taking corticosteroids, anticoagulants (drug that prevents blood clots, such as warfarin) or digoxin (a drug used to treat heart problems).

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.
- When taking APO-SIMVASTATIN, you should avoid consuming very large amounts (over 1 liter daily) of grapefruit juice, typical consumption (one 250-mL glass daily) is unlikely to cause any problems.
- 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.
- Avoid drinking large quantities of alcohol.
- **Do not start taking any other medicines** unless you have discussed the matter with your physician or pharmacist.
- Let your physician know if you suffer a severe injury, or severe infection.
- If you have to undergo any kind of surgery, tell your physician about the planned surgery; and also inform the physician in charge that you are taking this medicine.
- Store your tablets at room temperature (15°C-30°C), in a tightly closed container, away from heat and direct light, and out of damp places, such as the bathroom or kitchen.

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

Since muscle problems are on rare occasions serious, you should contact your physician promptly if you experience muscle pain, tenderness, or weakness.

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
Skin rash

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

INGREDIENTS

Active ingredient: Each tablet of APO-SIMVASTATIN contains simvastatin. It comes in five strengths: 5 mg (light yellow), 10 mg (light pink), 20 mg (peach), 40 mg (dusty rose) and 80 mg (dusty rose).

Non-medical ingredients (alphabetical): butylated hydroxyanisole, croscarmellose sodium, hydroxyethyl cellulose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80 and titanium dioxide. Apo-Simvastatin 5 and 20 mg tablets also contain yellow ferric oxide. Apo-Simvastatin 10, 20, 40 and 80 mg tablets also contain red ferric oxide.



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