

VASCOR® Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about VASCOR

VASCOR for oral use is available as 10 mg, 20 mg and 40 mg tablets, containing respectively 10 mg, 20 mg and 40 mg simvastatin.

VASCOR is a lipid-lowering agent, inhibitor of (HMG-CoA) reductase, an enzyme involved in the biosynthesis of cholesterol.

Studies have established that elevated plasma levels of total cholesterol, LDL-cholesterol (bad cholesterol) and apolipoprotein B (Apo B) as well as decreased levels of HDL-cholesterol (good cholesterol) promote human atherosclerosis and they are risk factors for developing cardiovascular disease.

Simvastatin has been shown to reduce total cholesterol, LDL-cholesterol, apolipoprotein B, VLDL and triglycerides and to increase HDL-cholesterol.

- *In patients at high risk of coronary events* (due to existing coronary heart disease (CHD), diabetes, peripheral vessel disease, history of stroke or other cardiovascular disease), VASCOR is indicated to reduce the risk of total mortality by reducing coronary death; to reduce the risk of myocardial infarction and stroke; and to reduce the need for coronary and non-coronary revascularization procedures.

- VASCOR is indicated as an adjunct to diet for *the treatment of hyperlipidemia*:

- to reduce elevated total cholesterol, LDL-cholesterol, Apo B and triglycerides and to increase HDL-cholesterol in patients with primary hyperlipidemia or mixed dyslipidemia.

- to reduce elevated triglycerides in patients with hypertriglyceridemia

- to reduce elevated triglycerides and VLDL-cholesterol in patients with primary dysbetalipoproteinemia

- to reduce total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments.

- VASCOR is indicated as an adjunct to diet to reduce elevated total cholesterol, LDL-cholesterol and Apo B in adolescent patients (10-17 years of age) *with heterozygous familial hypercholesterolemia*.

The way to take VASCOR

Take VASCOR as directed by your doctor. Do not discontinue the treatment without consulting your physician.

VASCOR should be used in addition to a standard cholesterol-lowering diet restricted in saturated fat and cholesterol.

The dosage is individualized according to the baseline LDL cholesterol level, and the patient's response. The dosage range is 5-80 mg/day.

VASCOR may be taken without regard to meals.

The recommended usual starting dose is 10 to 20 mg once a day in the evening; Patients who require a large reduction in LDL-C may be started at 40 mg/day in the evening.

For cardiovascular prevention, the recommended usual starting dose is 20 to 40 mg once a day in the evening.

Dosage is then adjusted according to the clinical context and to the cholesterol levels in the blood.

In patients with homozygous familial hypercholesterolemia, the recommended dosage is 40 mg/day in the evening or 80 mg/day in 3 divided doses of 20 mg, 20 mg, and an evening dose of 40 mg.

For adolescent patients (10-17 years of age) with heterozygous familial hypercholesterolemia, the recommended usual starting dose is 10 mg once a day in the evening. The recommended dosing range is 10-40 mg/day; the maximum recommended

dose is 40 mg/day. Dosage should be adjusted according to the recommended goal of therapy.

Duration of treatment

The duration of treatment will be decided by your doctor. Do not discontinue therapy of your own accord; you may require continuous treatment for quite some time. You should be periodically reassessed to determine the need for maintenance therapy with an appropriate dose.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- known hypersensitivity to any of the components
- active liver disease or unexplained persistent elevations of serum transaminases
- pregnancy and lactation
- concomitant use with itraconazole, ketoconazole, erythromycin, clarithromycin, telithromycin, HIV protease inhibitors, nefazodone, or large quantities of grapefruit juice

Precautions

- This drug must be used with caution in case of severe renal insufficiency, reduction in dosage and monitoring may be necessary.
- Consult your doctor at the first appearance of unexplained muscle pain, tenderness or weakness during the treatment.
- It is recommended that serum lipid levels and liver function tests be performed before initiation of treatment, and periodically thereafter.
- This drug should be used with caution in patients who consume substantial quantities of alcohol and/or have a past history of liver disease.
- Safety and effectiveness in children younger than 10 years of age have not yet been established.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Concomitant use with itraconazole, ketoconazole, erythromycin, clarithromycin, telithromycin, HIV protease inhibitors, nefazodone is contra-indicated.

Dosage adjustment of the drug is necessary in patients taking amiodarone, danazol, verapamil, cyclosporine, fibrates or niacin.

Use with caution with digoxin and oral anticoagulants.

Adverse reactions

This drug is usually well tolerated. In rare cases, it may cause headache, abdominal pain, constipation, nausea, diarrhea, rash, dyspepsia, flatulence, and asthenia.

Rarely reported adverse reactions include muscle cramps, myalgia, rhabdomyolysis, hypersensitivity reactions, hepatitis, pancreatitis, peripheral neuropathy, increases in serum transaminases or in CK levels.

Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

VASCOR 10, simvastatin 10 mg, pack of 30 tablets

VASCOR 20, simvastatin 20 mg, pack of 30 tablets

VASCOR 40, simvastatin 40 mg, pack of 30 tablets

Revision date: 03/2009

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