

Sivacor[®]

Simvastatin

Composition:

Sivacor 10mg: Each film coated tablet contains 10mg Simvastatin.

Sivacor 20mg: Each film coated tablet contains 20mg Simvastatin.

Properties:

Sivacor is Simvastatin which is a mevinic acid-derivative, an antilipemic agent. Simvastatin is a prodrug that competitively and reversibly inhibits HMG-CoA (3-hydroxy-3-methyl-glutaryl-coenzyme A) reductase, the enzyme that catalyses the conversion of HMG-CoA to mevalonate which is the rate-limiting step in cholesterol synthesis. Simvastatin undergoes extensive first pass hepatic metabolism following oral administration and only a small proportion of the dose reaches the systemic circulation. Sivacor reduces total cholesterol, low-density lipoprotein (LDL) - cholesterol, and very-low-density lipoprotein (VLDL) - cholesterol concentrations in plasma. Sivacor also tends to reduce triglycerides and to increase high-density lipoprotein (HDL) - cholesterol concentrations.

Indications:

Sivacor is indicated as an adjunct to dietary therapy for the reduction of elevated total and LDL - cholesterol levels in patients with primary hypercholesterolemia particularly in type IIa and type IIb hyperlipoproteinemias (hypercholesterolemia and combined hypertriglyceridemia), if diet and other measures are not sufficient, in patients with coronary heart disease (CHD) or at high risk of CHD.

Sivacor is also given to reduce the risk of CHD mortality, cardiovascular events and stroke, and to reduce the need for coronary and non-coronary revascularization procedures.

Contraindications:

Hypersensitivity to Simvastatin. Liver disease of unexplained persistent elevations of serum transaminase levels. Pregnancy and lactation.

Precautions and Warnings:

Hepatic Effect: It is recommended that liver function tests be performed before, at 6 and 12 weeks after initiation of therapy or increase in dose and periodically thereafter. Special attention should be paid for patients with elevated serum transaminase levels.

Muscle Effect: Therapy with Sivacor should be discontinued if elevated creatine kinase (CK) levels occur or if myopathy is diagnosed.

Pediatric Use: Safety and effectiveness in children and adolescents have not been established. Treatment in these two groups is not recommended at this time.

Geriatric Use: If evidence of severe renal impairment exists or develops, appropriate adjustments in dosage should be made and the patient should be closely monitored.

Renal Impairment: Sivacor should be administered with caution in patients with severe renal impairment.

Treatment with Sivacor should be stopped a few days prior to surgical procedures.

Drug Interactions:

Simvastatin is metabolized by CYP3A4 but has no CYP3A4 inhibitory activity; therefore it is not expected to affect the plasma concentrations of other drugs metabolized by CYP3A4. Potent inhibitors of CYP3A4 increase the risk of myopathy/rhabdomyolysis by reducing the elimination of simvastatin. Potent inhibitors of CYP3A4 include itraconazole, Ketoconazole, Erythromycin, Clarithromycin, Telithromycin, HIV protease inhibitors, Nefazodone, Cyclosporine, and large quantities of grapefruit juice (>1 quart daily). Therefore, concomitant administration of these drugs with Sivacor should be avoided. The risk of myopathy is increased by concomitant administration of Sivacor with gemfibrozil and to a lesser extent by other fibrates and niacin (nicotinic acid) (>1 g/day).

The risk of myopathy/rhabdomyolysis is increased by concomitant administration of amiodarone or verapamil with higher doses of simvastatin.

Sivacor slightly enhances the anticoagulant effect of warfarin. Prothrombin time should be determined prior to starting therapy with Sivacor in patients on coumarin anticoagulants. Concomitant use with digoxin may cause a slight elevation of serum digoxin concentration.

Side Effects:

Mild effects include gastrointestinal disturbances such as abdominal pain, constipation and flatulence. Less common side effects are headache and weakness. The following side effects have been reported rarely: nausea, vomiting, diarrhea, muscle pain, muscular weakness, tenderness of the muscles, alopecia, pancreatitis, paresthesia, peripheral neuropathy, pruritis, rash, liver problems, dizziness or fatigue. Also rarely, a hypersensitivity reaction may occur.

Dosage and Administration:

The patient should be placed on a standard cholesterol-lowering diet before receiving Sivacor and should continue on this diet during the treatment. The usual starting dose is 10mg given once daily in the evening. The dosage should be individualized according to baseline LDL - cholesterol levels and according to the goals of therapy and the patient's response to a maximum of 80mg daily given as a single dose in the evening. Adjustments of dosages should be done at intervals of 4 weeks or more. In patients with CHD or at high risk of CHD the starting dose may be 20mg once daily taken in the evening.

Adjustment of dosage, if required, should be made as specified above. The recommended dosage for patients with homozygous familial hypercholesterolemia is 40mg a day in the evening or 80mg a day, divided in 3 doses of 20mg, 20mg, and an evening dose of 40mg, in which Sivacor should be used as adjunct to other lipid-lowering treatments.

Sivacor should be administered with caution in patients with severe renal impairment, initiating therapy with the drug under close monitoring at a dosage of 5mg daily. Modification of dosage should not be necessary in patients with mild to moderate renal insufficiency. In patients taking immunosuppressive drugs concomitantly with Sivacor, therapy should begin with 5mg and should not exceed 10mg per day. If Sivacor is used in combination with gemfibrozil, the dose of Sivacor should not exceed 10 mg/day.

In patients taking amiodarone or verapamil concomitantly with Sivacor, the dose should not exceed 20 mg/day.

Presentation Available:

Sivacor is available as 10mg film coated tablet in 10 and 30 tablets pack. Sivacor is available as 20mg film coated tablet in 10 and 30 tablets pack.

This is a Medicament :

- Keep all medicaments away from children.
- A medicament is a product that affects your health, and its consumption contrary to instructions is dangerous.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the treatment before consulting your doctor.
- Do not repeat the same prescription without consulting your doctor.

