PATIENT INFORMATION LEAFLET

SIMVACOR®

SIMVASTATIN

10mg Film-Coated Tablets

Kleva pharmaceuticals

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm, them, even if their symptoms are the same as yours.

In this leaflet:

1. What Simvacor® is and what it is used for
2. Before you take Simvacor®
3. How to take Simvacor®
4. Possible side effects
5. Storing Simvacor®
6. Further information

Simvacor® 10mg film coated tablets
Simvastatin

- The active substance is: Simvastatin 10 mg.
- The other ingredients are: Excipients: Lactose monohydrate, microsrystalline cellulose, pregelatinized maize starch, butylhydroxyanisole, ascorbic acid, citric acid monohydrate, magnesium stearate. *Coating:* Hypromellose, Hyprolose, Titanium dioxide E171.

The Marketing Authorization Holder and Manufacturing Authorization Holder for Simvacor® is:

Kleva SA 189, Parnithos Ave. 13671, Athens-Greece.

1. WHAT SIMVACOR® IS AND WHAT IT IS USED FOR

Simvacor® is available as pale pink, round, scored tablets in PVC/aluminium blisters. Each blister strip contains 3 blister strips (30 tablets) and a patient information leaflet.

Simvacor® is a hypolipidaemic agent and belongs to a group of medicines known as “statins” or “HMG-CoA reductase inhibitors”. Simvastatin reduces cholesterol and fatty substances called triglycerides in the blood. If levels of cholesterol in the bloodstream are too high it can be deposited on the walls of the blood vessels, causing a blockage. This process is called atherosclerosis. Atherosclerosis may provoke chest pain (angina pectoris) and heart attack. If you suffer from coronary heart disease, the drug may be administered by your Physician in order to decelerate the atherosclerosis process, to diminish the rate of cardiac incidents and to diminish the risk of heart attack. Simvacor® is administered as an adjunct to diet when response to diet or other non-pharmacological measures have proved inadequate.

Simvacor® reduces the amount of cholesterol in the blood. It significantly reduces the level of LDL (bad) cholesterol and triglycerides and raises HDL (good) cholesterol, LDL cholesterol is called “bad” because it is the cholesterol that blocks your arteries. HDL cholesterol, on the other hand is thought to remove cholesterol from the blood vessels and is, therefore considered to be “good” cholesterol.

Simvacor® was prescribed to you to reduce the health risks associated with coronary heart disease. If you have or are at risk of developing coronary heart disease (because you have diabetes, have had a stroke, or other blood vessel disease), Simvacor® may prolong your life by reducing the risk of heart disease by helping to keep your arteries clear, even if your cholesterol levels are normal.

2. BEFORE YOU TAKE SIMVACOR®

Prior to initiating therapy with Simvacor®, secondary causes for hypercholesterolaemia (e.g. obesity, thyroid disorders, insufficiently controlled diabetes, nephritic syndrome, dysproteinanaemias, obstructive liver disease, other drug therapy, alcoholism) should be dealt with.

Do not take Simvacor® :
- If you are hypersensitive (allergic) to simvastatin or any of the other ingredients of Simvacor®
- If you are a patient with active liver disease or unexplained persistent elevations of serum transaminases
- If you are taking the anti-fungal drugs, itraconazole and ketoconazole
- If you are taking the antibiotics known as macrolides (such as erythromycin, clarithromycin, roxithromycin or telithromycin)
- If you are taking the antidepressant nefazodone
- If you are taking a medicine for the treatment of HIV infections (HIV protease inhibitor)
- If you are pregnant or breast-feeding

Take special care with Simvacor®:
Simvastatin, like other HMG-CoA reductase inhibitors, occasionally cause myopathy (miscle problems), which is manifested as muscle pain, sensitivity or weakness. Sometimes rhabdomyolysis (muscle breakdown) occurs, which may result in kidney damage. The risk of muscle breakdown is increased by high levels of HMG-CoA reductase inhibitors in the blood.

Patients with rare genetical conditions of lactose intolerance, absence of Lapp lactase or malabsorption of glucose-galactose, should not take Simvacor®,.

The risk of muscle problems is increased in certain patients. Tell your doctor if any of the following applies to you:
- antifungals
- antibiotics known as mcrolides (such as erythromycin, clarithromycin, roxithromycin or telithromycin)
- nefazodone (antidepressant)
- HIV protease inhibitors such as indinavir, ritonavir and saquinavir (medicines used for the treatment of HIV infections)
- ciclosporin (a drug that suppresses the immune system)
- fibrates (other cholesterol lowering medicines such as bezafibrate, clofibrate, fenofibrate and gemfibrozil)
- amiodarone (a medicine used to treat irregular heartbeat)
- verepamil or diltiazem (drugs used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions)
- niacin or nicotinic acid (cholesterol lowering medicine) in large doses (greater or equal to 1g daily).
- coumarin anticoagulants such as warfarin (drugs that are used to prevent blood clots)
- danazol

Transcient discontinuation of Simvacor®, is recommended when treatment with oral antifungal drugs or with antibiotics such as erythromycin or clarithromycin is necessary. The concomitant administration of niacin or nicotinic acid is indicated only after evaluation of benefit/risk ratio and under close supervision. Concomitant treatment with fibrates is recommended.

The risk of myopathy and rhabdomyolisis was increased with the concomitant administration of danazol with higher Simvastatin doses.

3. HOW TO TAKE SIMVACOR®

Simvacor® is subject to medical prescription. Always take Simvacor® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will recommend a cholesterol lowering diet before prescribing Simvacor® you should continue following this diet during treatment with the drug.

The usual dose range is 5 mg to 80 mg in a single dose at night. It is recommended that Simvacor® is taken in the evening or at night so that it will be working when the body is producing more cholesterol. The 80mg dose is only recommended in patients with severe hypercholesterolaemia and high risk cardiovascular complications. A marked response to

simvastatin is seen within two weeks and the maximum therapeutic response occurs within four to six weeks. Your doctor may prescribe lower doses, particularly if you are taking certain medications listed above or you have certain kidney conditions.

Hypercholesterolaemia: the recommended starting dose is 10-20 mg once daily taken in the evening. If a greater reduction of LDL cholesterol is required, the recommended starting dose is 20-40mg taken in the evening.

Homozygous familial Hypercholesterolaemia: the recommended dosage is 40 mg daily, administered in the evening or 80 mg daily administered in divided doses (20 mg morning and noon and 40 mg in the evening).

Coronary heart disease: Patients with coronary heart disease can be treated with a starting dose of 20-40 mg daily given as a single dose in the evening. Adjustment of dosage, if required, should be made as specified above.

Concomitant therapy: Simvacor® is effective alone or in combination with bile acid sequesters (such as cholestyramine and colestipol). Simvacor® must be given 2 hours before or 4 hours after the bile acid sequester. In patients taking other hypolipidaemic agents like fibrates, with Simvacor® r, the maximum recommended dosage is 10 mg daily. If Simvacor® r is concomitantly given with immunosuppressive agents like ciclosporin) the starting dosage is 5 mg daily and the total dosage should not exceed 10mg daily. In patients takingamiodarone or verapamil with Simvacor® the maximum dosage of simvastatin is 20 mg daily.

Dosage in renal insufficiency: Because Simvacor® does not undergo significant renal excretion, modification of dosage should not be necessary in patients with moderate renal insufficiency. In patients with severe renal insufficiency, dosages above 10 mg daily should be carefully considered. Such patients should be closely monitored.

Elderly: No adjustment of dosage is required.

If you have the impression that the effect of Simvacor® is too strong or too weak, talk to your doctor or pharmacist.

If you take more Simvacor® than you should:
In case of overdose it is necessary to ask for your physician's or pharmacist's advice. A few cases of overdosage have been reported. All patients recovered without sequelae. There is no special treatment in case of overdosage. Symptomatic treatment as well as supporting measures should be adopted.

If you forget to take Simvacor®:
You must take Simvacor® following your doctor's instruction. Do not take a double dose to make up for forgotten individual doses. If you forget to take a dose, take it as soon as you remember, but if it almost time for your next dose skip the one you forgot.

Effects when treatment with Simvacor® is stopped:
If you stop taking Simvacor® , the level of cholesterol in your blood may rise again

4. POSSIBLE SIDE EFFECTS

Like all medicines, Simvacor® can have side effects. Simvacor® is generally well tolerated. Side effects are usually mild and transient in nature. The following side effects were reported rarely:

Stomach upsets (such as sickness, constipation, diarrhea, flatulence, indigestion and abdominal pain), weakness, headache, dizziness, numbness or loss of sensation in the arms and legs, hair loss, rash, itchiness, liver disease (possibly presenting as yellowing of the eyes and or skin, itchiness of the skin, dark coloured urine, pale coloured stools), muscle damage, or an allergic reaction to simvastatin. The allergic reaction may include some of the following: swelling of the face, tongue or throat (in which case you should contact your doctor immediately), joint pains, joint and blood vessel inflammation, unusual bruising, skin eruptions, swelling, hives , skin sensitivity to the sun, a high temperature, flushing, difficulty in breathing or tiredness.

Contact your doctor promptly if you experience muscle aches and pains, tenderness, weakness or cramps. This is because on rare occasions muscle damage can be serious.

If any of these side effects occur, or you have other unusual symptoms or feelings, stop taking the tablets and contact your doctor immediately.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING SIMVACOR®

Keep out of the reach and sight of children.
Do not store above 25C. Store in the original container in order to protect from moisture.
Do not use after the expiry date stated on the box.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the Marketing Authorization Holder.
KLEVA SA., 189, Parnithos Ave., Acharnai 136.71, Attiki, Greece

Kleva pharmaceuticals

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