SIMVACOR
Pharma Dynamics (Pty) Ltd

APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

SIMVACOR 10 mg film coated tablet

SIMVACOR 20 mg film coated tablet

SIMVACOR 40 mg film coated tablet

Simvastatin

SIMVACOR contains sugar (each 10 mg tablet contains 67,92 mg lactose monohydrate, each 20 mg tablet contains 135,84 mg lactose monohydrate and each 40 mg tablet contains 271,68 mg lactose monohydrate)

Read all of this leaflet carefully before you start taking SIMVACOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- SIMVACOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SIMVACOR is and what it is used for

SIMVACOR contains simvastatin, one of a group of medicines called HMG-CoA-reductase inhibitors.

SIMVACOR is used, in combination with a cholesterol-lowering diet, to lower cholesterol and triglyceride (fat-like substances) levels in the blood. SIMVACOR works by blocking the enzyme that is needed by the body to make cholesterol, thereby reducing the amount of cholesterol in the blood. Using SIMVACOR may help to prevent medical problems caused by these substances clogging the blood vessels.

SIMVACOR may also be used to prevent certain types of heart problems in adults with risk factors for heart problems that are unresponsive to diet changes.

2. What you need to know before you take SIMVACOR

Do not take SIMVACOR:

- if you are hypersensitive (allergic) to simvastatin, other medicines that reduce cholesterol levels, or to any of the ingredients of SIMVACOR (see section 6)
- if you have an acute or chronic liver disease
- if you suffer from porphyria (a rare blood disorder)
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding)
- if you are taking medicine(s) with one or more than one of the following active ingredients:
    - itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections)
    - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections)
    - boceprevir or telaprevir (used to treat hepatitis C virus infection)
    - erythromycin, clarithromycin, or telithromycin (used to treat infections)
    - nefazodone (used to treat depression)
    - cobicistat (used to treat HIV infection)
    - gemfibrozil (used to lower cholesterol)
    - cyclosporin (used in organ transplant patients)

- danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- lomitapide (used to lower familial cholesterol).

Warnings and precautions

Take special care with SIMVACOR:

Memory loss and confusion have been reported with the use of statins like SIMVACOR. These events were generally not serious and went away once the medicine was no longer being taken.

If any of the following situations apply to you, you should tell your doctor before taking SIMVACOR:

- if you are trying to become pregnant
- if you drink large amounts of alcohol
- if you have a history of liver disease. Your doctor could do a blood test before you start taking SIMVACOR and if you develop any symptoms of liver problems while you take this medicine. This is to check how well your liver is working. Your doctor may also want you to have blood tests to check how well your liver is working after you start taking SIMVACOR

- if you are predisposed to developing kidney failure secondary to rhabdomyolysis (a breakdown of muscle tissue that releases a damaging protein into the blood), high blood pressure, severe metabolic, endocrine and electrolyte disorders, uncontrolled seizures (epilepsy), major surgery or trauma
- if you have severe kidney problems
- if you are due to have an operation, as you will need to stop taking SIMVACOR a few days before surgery
- if you are using any other medicines such as immunosuppressants, fibrates (except fenofibrate), lipid lowering doses of niacin, amiodarone, amlodipine, verapamil, diltiazem or daptomycin (also see Do not take SIMVACOR)
- if you are Asian
- if you have severe lung disease.

If you develop any unexplained muscle pain, tenderness or weakness during treatment with SIMVACOR you should notify your doctor or healthcare professional immediately. If you have any of the following conditions you may be at risk of developing muscle problems (causing the release of muscle pigment in the urine) that may lead to kidney failure:

- if you get convulsions or seizures that are not well-controlled
- if you have an electrolyte or metabolic enzyme deficiency or disorder

- if you suffer from a severe infection
- if you have low blood pressure
- if you recently had major surgery or suffered severe trauma.

The risk of muscle breakdown is greater at higher doses of SIMVACOR, particularly the 80 mg dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- if you are elderly (age ≥ 65 years)
- if you are female
- if you have kidney problems
- if you have uncontrolled hypothyroidism
- if you have personal or family history of muscle disorders
- if you previously experienced muscle disorders with statin or fibrate use
- if you consume large amounts of alcohol.

Your normal blood sugar levels may increase whilst taking SIMVACOR. While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes.
You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Children and adolescents

Safety and effectiveness of simvastatin as in SIMVACOR have been studied in 10 - 17-year-old boys and in girls who had started their menstrual period (menstruation) at least one year before. SIMVACOR has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Other medicines and SIMVACOR

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
If you are using any of the following medicines, please ask your doctor, pharmacist or other healthcare professional for advice:

- fibrates with an active ingredient like gemfibrozil and bezafibrate or nicotinic acid (used to lower cholesterol)
- erythromycin, clarithromycin or telithromycin (antibiotic)
- itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (antifungal medicine)
- HIV-protease inhibitors such as ritonavir, saquinavir and nelfinavir (used for HIV infections)
- nefazodone (a medicine for depression)
- hepatitis C antiviral medicines such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C virus infection)

- medicines with the active ingredient cobicistat (used to treat HIV infection)
- ciclosporin (medicine used to prevent organ rejection after organ transplant)
- danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- fusidic acid (prescribed for the treatment of serious or deep-seated infections), you will need to temporarily stop SIMVACOR. Your doctor will tell you when it is safe to restart SIMVACOR. Taking this medicine with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis)
- amiodarone (used to treat irregular heart beat)
- calcium channel blockers e.g. verapamil and diltiazem or amlodipine (used to treat high blood pressure and chest pains)
- lomitapide (used to treat a serious and rare genetic cholesterol condition)
- niacin (a form of vitamin B3). If you are Asian you should not use SIMVACOR with niacin)
- ticagrelor (antiplatelet medicine)
- colchicine (anti-gout medicine)

- daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin (such as SIMVACOR). Your doctor may decide that you stop taking SIMVACOR for a while
- rifampicin (medicine used to treat tuberculosis)
- warfarin (medicine that prevents the blood from clotting) may increase the risk of bleeding
- digoxin (medicine used for heart dysrhythmia or heart failure) co-administration may intensify the effect of digoxin
- colestipol and cholestyramine (medicines that control bile-acid and cholesterol) may weaken the effect of SIMVACOR.

SIMVACOR with food, drink and alcohol

SIMVACOR should not be taken with grapefruit juice or other grapefruit products because grapefruit increases the concentration of simvastatin in the body.

Do not use excessive amounts of alcohol while taking SIMVACOR because it can worsen the adverse effects of SIMVACOR on the liver.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using SIMVACOR.

SIMVACOR should not be used during pregnancy or by women who plan to become pregnant and should not be used during breastfeeding (see Do not take SIMVACOR).

An effective form of birth control should be used during treatment with SIMVACOR. Check with your doctor immediately if you think you have become pregnant while taking SIMVACOR.

Driving and using machines

SIMVACOR has no or negligible influence on the ability to drive and use machines.

SIMVACOR can cause headaches and dizziness. Do not drive or operate any machinery until you know how SIMVACOR affects you.

It is not always possible to predict to what extent SIMVACOR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SIMVACOR affects them.

SIMVACOR contains lactose

SIMVACOR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take SIMVACOR

Do not share medicines prescribed for you with any other person.
Always take/use SIMVACOR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Before prescribing medicine for your condition, your doctor will probably try to control your condition by planning a personal diet for you. Such a diet may be low in fats, sugars, and/or cholesterol. Many people are able to control their condition by carefully following their doctor's orders for proper diet and exercise.
Medicine is prescribed only when additional help is needed and is effective only when a schedule of diet and exercise is properly followed.
Remember that SIMVACOR will not cure your condition but it does help to control it. Therefore, you must continue to take SIMVACOR as directed, to keep your cholesterol levels down.

The tablets should be swallowed whole with a glass of water.

Do not crush or chew these tablets. SIMVACOR tablets can be taken with or without meals.

Adults:

To treat high cholesterol:

The usual adult starting dose is 10 mg SIMVACOR in the evening, depending on your specific condition.

To treat coronary heart disease:

The usual adult dosage is one SIMVACOR 20 tablet in the evening.

Dosage Adjustments:

The dose can be increased by your doctor to 80 mg SIMVACOR daily as a single dose in the evening.

If your doctor has prescribed SIMVACOR along with another medicine for lowering cholesterol containing any bile acid sequestrant, you should take SIMVACOR at least 1 hour before or 4 hours after taking cholestyramine.

A maximum daily dose of 10 mg SIMVACOR is recommended in patients taking ciclosporin, fibrates or niacin with this medicine.

Your doctor will tell you how long your treatment with SIMVACOR will last.

If you have the impression that the effect of SIMVACOR is too strong or too weak, tell your doctor or pharmacist.

If you take more SIMVACOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take SIMVACOR

If you forget to take SIMVACOR, take a dose as soon as you remember, then continue to take SIMVACOR at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking SIMVACOR

Talk to your doctor or pharmacist because your cholesterol may rise again.

4. Possible side effects

SIMVACOR can have side effects.

Not all side effects reported for SIMVACOR are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while using SIMVACOR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using SIMVACOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SIMVACOR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe muscle tenderness, weakness, pain and stiffness around the shoulders and hips
- changes in the way your heart beats, for example, if you notice it beating irregular and often very fast
- Lupus-Like Syndrome: Drug-induced lupus erythematosus (DIL) is a subset of lupus defined as a lupus-like syndrome that develops in temporal relation when you have taken some kind of medicine and resolves after you stop taking the medicine
- an inflammation of the blood vessels with symptoms including fever, fatigue, weight loss and muscle and joint pain
- unusual bruising

- pain or inflammation in the joints
- skin eruptions and swelling, rash, hives, sensitivity of skin to the sun, fever, flushing
- joint pain, arthritis
- shortness of breath and generally feeling unwell
- peripheral neuropathy (weakness, numbness and pain from nerve damage, usually in the arms, hands, legs and feet)
- interstitial lung disease (a group of disorders that cause progressive scarring of lung tissue)
- inflammation of the pancreas often with severe abdominal pain
- inflammation of the liver (hepatitis, jaundice) with the following symptoms: yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, feeling tired or weak, loss of appetite, liver failure
- myalgia (soreness and achiness in the muscles that can range from mild to severe)
- muscle cramps
- myopathy (disease where muscle fibres do not function properly)
- myositis (inflammation of the muscles, symptoms include weakness, swelling and pain)
- rhabdomyolysis presenting as muscle pain with elevated creatine phosphokinase and myoglobinuria leading to kidney failure
- muscle rupture

- tendinopathy (a condition in which the tissue connecting the muscle to the bone becomes inflamed), sometimes complicated by rupture
- immune-mediated necrotising myopathy (IMNM) (an autoimmune condition causing muscle cell death)
- increases in serum transaminases (alanine aminotransferase, aspartate aminotransferase, γ-glutamyl transpeptidase), elevated alkaline phosphatase, causing inflammation or damage in the liver
- increase in serum CK levels (it may mean you have a muscle injury or disease, such as muscular dystrophy or rhabdomyolysis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- abdominal pain and cramps, flatulence, nausea, vomiting, indigestion.

Less frequent side effects:

- anaemia (condition where the blood doesn’t have enough healthy red blood cells)
- diabetes
- increase in blood sugar levels

- problems sleeping, memory loss and confusion, forgetfulness, amnesia
- headache and/or dizziness, feeling extremely tired or weak, altered taste sensation, ‘pins and needles’
- blurred vision, visual impairment, sensitivity to light
- constipation, diarrhoea
- skin rash, alopecia (sudden hair loss, usually circular bald patches), lichenoid drug eruptions (violaceous, scaling papules and plaques that are typically symmetrical and widespread), eczema
- gynaecomastia (swollen male breast tissue caused by a hormone imbalance)
- asthenia (abnormal physical weakness or lack of energy) fluid retention (most commonly in the legs or arms), swelling.

The following side effects have been reported but the frequency for them to occur is not known:

- neutropenia (an abnormally low count of a type of white blood cell (neutrophils))
- depression, sleep disturbances (including nightmares)
- erectile dysfunction
- myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing)
- drooping of one or both eyelids or double vision (ocular myasthenia)
- respiratory infections, bronchitis, sinusitis

- weight gain.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of SIMVACOR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store SIMVACOR

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place.

Protect form light.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SIMVACOR contains

The active substance is simvastatin.

SIMVACOR 10 mg: Each film coated tablet contains simvastatin 10 mg.

SIMVACOR 20 mg: Each film coated tablet contains simvastatin 20 mg.

SIMVACOR 40 mg: Each film coated tablet contains simvastatin 40 mg.

The other ingredients are

Tablet cores:

Ascorbic acid, butylhydroxyanisole, citric acid anhydrous, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, starch pre-gelatinised.

Film coating:

Hypromellose, propylene glycol, talc and the colourant titanium dioxide

What SIMVACOR looks like and contents of the pack

SIMVACOR 10 mg: White, round (6 mm in diameter), slightly biconvex, bevel-edged, film coated tablet.

SIMVACOR 20 mg: White, round (8 mm in diameter), slightly biconvex, bevel-edged, film coated tablet.

SIMVACOR 40 mg: White, round (11 mm in diameter), slightly biconvex, bevel-edged, one side scored, film coated tablet.

SIMVACOR tablets are available in thermo formed PVC/PE/PVDC film and heat sealing aluminium foil blister packs of 28 or 30 tablets in an outer carton.

Holder of Certificate of Registration

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SIMVACOR 10 mg: NAM NS2 04/7.5/1660

BOT S2 1202043

SIMVACOR 20 mg: NAM NS2 04/7.5/1659

BOT S2 1202044

MOZ 2885

SIMVACOR 40 mg: NAM NS2 07/7.5/0166

MOZ 2886