

## PATIENT INFORMATION LEAFLET

**Please read this leaflet carefully before taking SIMVACOR 10 mg, 20 mg or 40 mg tablets.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine 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.

**Scheduling Status:** Schedule 4

### **Proprietary name, Strength and Pharmaceutical Form:**

**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

### **1.1 WHAT SIMVACOR TABLETS CONTAIN**

Active ingredient: Each film coated tablet contains simvastatin 10 mg, 20 mg, and 40 mg, respectively.

Inactive ingredients:

Each tablet contains the following antioxidants: Butylated hydroxyanisole 0.02% m/m, citric acid anhydrous 1,5 % m/m and ascorbic acid 2,5%.

Other ingredients include hypromellose, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, propylene glycol, purified talc, starch pre-gelatinised, titanium dioxide.

### **2. WHAT SIMVACOR ARE USED FOR**

**SIMVACOR** is used to lower cholesterol and triglyceride (fat-like substances) levels in the blood.

Simvastatin works by blocking the enzyme that is needed by the body to make cholesterol, thereby reducing the amount of cholesterol in the blood. Using this medicine 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.

### 3. BEFORE YOU TAKE SIMVACOR

#### **Do not take SIMVACOR**

- If you are hypersensitive (allergic) to simvastatin, other medicine that reduce cholesterol levels or any of the other ingredients of **SIMVACOR**.
- If you have an acute or chronic liver disease.
- If your liver enzymes have persistently high levels.
- If you are pregnant or breastfeeding a baby.

#### **Take special care with SIMVACOR:**

- If you use large amounts of alcohol.
- If your kidney function is impaired.
- If you have any muscle disorder or disease.
- If you develop any muscle tenderness or weakness during treatment with **SIMVACOR** you should notify your doctor or healthcare professional.

*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.

***Taking SIMVACOR TABLETS with food and drink:***

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

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

These tablets should not be taken with grapefruit juice or other grapefruit products because grapefruit increase 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 this medicine on the liver.

**Pregnancy and breast-feeding:**

**SIMVACOR should not be used during pregnancy or by women who plan to become pregnant.** An effective form of birth control should be used during treatment with this product. Check with your doctor immediately if you think you have become pregnant while taking this medicine.

**SIMVACOR should not be used during breast-feeding.**

**Driving and using machinery:**

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

**Using other medicines with SIMVACOR:**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **SIMVACOR** with these medicines may cause undesirable interactions.

Tell your doctor or pharmacist if you are taking any other medicines, including any you have

bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are using any of the following substances, please tell your doctor:

- Colestipol and cholestyramine (medicine that controls bile-acid and cholesterol)
- Digoxin (medicine used for heart arrhythmia or heart failure)
- Erythromycin and clarithromycin (antibiotic)
- Itraconazole and ketoconazole (antifungal medicine)
- Cyclosporin (medicine used to prevent organ rejection after organ transplant.)
- Fibrates or nicotinic acid
- Warfarin (medicine that prevents the blood from clotting)
- HIV-protease inhibitors

#### 4. HOW TO TAKE SIMVACOR

*Before prescribing medicine for your condition, your doctor will probably try to control your condition by prescribing 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 this medicine 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 dose of **SIMVACOR** will be different for different patients.*
- Always take **SIMVACOR** exactly as your doctor has instructed you.
- You should check with your doctor if you are unsure.
- If you have the impression that the effect of **SIMVACOR** is too strong or too weak, talk to your doctor or pharmacist.

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

The dose can be increased by your doctor to 80 mg simvastatin daily.

**If you take more SIMVACOR than you should:**

When an overdose is suspected contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what the person has taken.

**If you forget to take SIMVACOR:**

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

## 5. POSSIBLE SIDE EFFECTS

Like all medicines, **SIMVACOR** can cause side effects in some patients.

***Check with your doctor immediately if any of the following side-effects occur:***

The following side-effects have been reported less frequently:

- ♦ Cough
- ♦ Difficulty in swallowing or breathing
- ♦ Muscle tenderness, weakness or stiffness
- ♦ Swelling of face, lips or tongue.

The following side-effects have been reported but frequency is not determined:

- ♦ Blister, peeling or loosening of skin
- ♦ Dark coloured urine
- ♦ Severe diarrhoea

Other side-effects may occur that usually do not need medical attention. These side-effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side-effects continue or are bothersome:

The following side-effects have been reported frequently:

- ♦ Headache and/or dizziness
- ♦ Abdominal pain

- ♦ Constipation
- ♦ Nausea

The following side-effects have been reported but frequency is not determined:

- ♦ Weight gain
- ♦ Hair loss

**Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.**

## **6. STORING AND DISPOSING OF SIMVACOR**

- Store at or below 25 °C in a dry place. Protect from light.
- Keep the blisters in the carton until required for use.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.**
- Do not use the tablets after the expiry date printed on the container, blister or label.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)