

SIMVACOR[®] FILM COATED TABLET

Simvastatin (20mg, 40mg)

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What SIMVACOR is used for

SIMVACOR is used for lowering of high blood cholesterol level when the response to fat/cholesterol restricted diet and other non-pharmacological measures alone has not been sufficient. SIMVACOR is also used in Coronary Heart Disease (CHD) patients to reduce the risk of death and complications of stroke.

How SIMVACOR works

SIMVACOR is a cholesterol lowering agent of statin group which is 3-Hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor. It works by inhibiting the enzyme (HMG-CoA reductase) which is essential for production of cholesterol in the body hence lowering the LDL-Cholesterol (bad cholesterol) and triglycerides (other fats). Besides that, it also helps to raise the level of HDL-cholesterol (good cholesterol).

Before you use SIMVACOR

- When you must not use it
Do not take SIMVACOR if:
 - You have known hypersensitivity to any component of SIMVACOR.
 - You are having any active liver disease or unexplained persistent elevations of serum transaminases, as simvastatin may affect the liver function.
 - You are taking any of the following medicines:

- certain antifungal medicines (such as itraconazole, ketoconazole, posaconazole, or voriconazole)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
- certain antibiotics (such as erythromycin, clarithromycin, or telithromycin)
- antidepressant nefazodone
- medicines containing cobicistat
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- cyclosporine
- danazol

Ask your doctor if you are not sure if your medicine is listed above.

Pregnancy and lactation

Do not take SIMVACOR if you are pregnant, trying to get pregnant or think you may be pregnant. If you become pregnant while taking SIMVACOR, stop taking it and contact your doctor immediately.

Do not take SIMVACOR if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

- Tell your doctor or pharmacist before taking SIMVACOR:
- if you are allergic to any medicines or if you have any other medical conditions.
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition.

Use in children

Safety and effectiveness have been studied in 10-17 year old boys and in girls, who had started their menstrual

period at least one year before (refer "How to use SIMVACOR"). SIMVACOR has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. There may be an interaction between simvastatin and some other medications because taking SIMVACOR with any of the following drugs or substances can increase the risk of muscle problems (refer "Side Effects"), it is particularly important to tell your doctor if you are taking:

- antifungal agents (such as itraconazole, ketoconazole, posaconazole, or voriconazole)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- boceprevir or telaprevir (drugs used to treat hepatitis C virus infection)
- the antibiotics erythromycin, clarithromycin, telithromycin, and fusidic acid
- the antidepressant nefazodone
- medicines containing cobicistat
- cyclosporine
- danazol
- fibric acid derivatives (such as gemfibrozil and bezafibrate)
- amiodarone (a drug used to treat an irregular heartbeat)
- verapamil, diltiazem, or amlodipine (drugs used to treat high blood pressure, angina, or other heart conditions)
- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)
- grapefruit juice (which should be avoided while taking SIMVACOR)

How to use SIMVACOR

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

The recommended dose is 5-80mg depending on your condition(s) and doctor recommendation(s). Any necessary dose change should be according to doctor's recommendation(s) and supervision.

- When to use it

SIMVACOR should be taken orally on a regular daily basis preferably in the evening, with evening meal.

- How long to use it

Continue taking SIMVACOR for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause unexplained muscle pain, tenderness or weakness particularly if accompanied by feeling of unwell (malaise) or fever may occur.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking SIMVACOR.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not start taking this medicine or change the dosage without first checking with your doctor.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give SIMVACOR to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

SIMVACOR should be taken with caution in patients with past history of liver disease and consume substantial quantities of alcohol. Patient receiving concomitant therapy of immunosuppressive drugs (cyclosporine), gemfibrozil or lipid lowering doses of niacin with SIMVACOR is contraindicated. Concurrent use of fibrates may cause severe myositis (muscle inflammation) and myoglobinuria (presence of muscle protein in urine).

Side effects

Like all medicines, SIMVACOR can cause side effects, although not everybody gets them. Possible common side effects include digestive disturbances and skin rash. Less common are weakness and headache. Still less common are muscle pain, tenderness or weakness (that in very rare cases may not go away after stopping SIMVACOR), liver problems (sometimes serious), anaemia, poor memory, memory loss, confusion, trouble sleeping, depression, erectile dysfunction, breathing problems including persistent cough and/or

shortness of breath or fever, and hypersensitivity (allergic reactions which may have a number of symptoms, including joint pain, fever, and shortness of breath).

Side effects with unknown frequency:

- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of SIMVACOR

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Keep in a tight container.

Protect from light and moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Simvacor Film Coated Tablet 20mg:
An orange brown elliptical film coated tablet, one side impressed with score and the other side with a mark



Simvacor Film Coated. Tablet 40mg:
A pale orange red elliptical film coated tablet, one side impressed with score and the other side with a mark “



- Ingredients

- Active ingredient(s)

- Simvastatin

- Inactive ingredients

- Starch
- Microcrystalline Cellulose
- Lactose
- Hydroxypropyl Cellulose
- Magnesium Stearate
- Talc
- Butylated Hydroxyanisole
- Citric Acid
- Tween
- Ascorbic Acid
- Opadry II Pink (Simvacor Film Coated Tablet 40mg) / Opadry II Brown (Simvacor Film Coated Tablet 20mg)

- MAL number(s):

Simvacor Film Coated Tablet 20mg:
MAL17107031AZ

Simvacor Film Coated Tablet 40mg:
MAL17107032AZ

Manufacturer and Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd.
Lot 3, 5, 7 & 12 & 14, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

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