

SIMVOR TABLETS

(Simvastatin 10/ 20/ 40 mg)

Consumer Medication Information Leaflet (RiMUP)

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This leaflet answers some common questions about **SIMVOR TABLETS**. It does not contain all the available information.

SIMVOR TABLETS contains simvastatin.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What **SIMVOR TABLETS** are used for

SIMVOR TABLETS are used in people who have coronary heart disease (CHD) or who are at high risk of CHD (for example, if they have diabetes, a history of stroke, or other blood vessel disease) to:

- help prolong life by reducing the risk of a heart attack
- reduce the risk of stroke
- reduce the need for surgery to increase blood flow to the heart
- reduce the need for hospitalisation due to angina.

SIMVOR TABLETS are used along with diet if you have:

- a raised cholesterol level in your blood (primary hypercholesterolaemia) or

elevated fat levels in your blood (mixed hyperlipidaemia)

- a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments.

Your doctor should exclude other causes of high cholesterol level before start therapy with **SIMVOR TABLETS**.

How **SIMVOR TABLETS** work

Simvastatin belongs to a group of medicines known as statins. Simvastatin is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, simvastatin raises levels of “good” cholesterol (HDL cholesterol).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

SIMVOR TABLETS are available in 10 mg, 20 mg & 40 mg tablets

This medicine is available only with a doctor’s prescription.

Before you use **SIMVOR TABLETS**

When you must not use it

Do not take **SIMVOR TABLETS if any of the following apply to you. If**

- You are allergic to simvastatin or to any of the inactive ingredients of this medicine (An allergic reaction may include rash, itching, swelling of face, lips, or hands/feet, or breathing difficulties)
- You are suffering from liver disease or your blood test reports show any unexplained, abnormal increase in liver enzymes
- You are pregnant or intend to become pregnant
- You are breast feeding

- You are taking any of the following medicines:

- Itraconazole, ketoconazole or posaconazole, voriconazole (medicines used to treat fungal infections)
- Nelfinavir, indinavir, ritonavir, saquinavir (medicines used to treat HIV infection)
- Cobicistat (medicines used to treat HIV infection) containing medicines
- Boceprevir and telaprevir (medicines used to treat hepatitis)
- Erythromycin, clarithromycin, telithromycin (medicines used to treat bacterial infections)
- Nefazodone (medicine used to treat depressed mood)
- Gemfibrozil (medicine used to lower the lipid level in blood)
- Cyclosporine (medicine used to suppress the immune system)
- Danazol (medicine used to treat breast and menstrual disorders)

If you are not sure whether to start taking this medicine, talk to your doctor or pharmacist.

Do not use after the use by (expiry) date printed on the pack.

The expiry date refers to the last day of that month.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor:

- If you have any of the following risk factors for muscle breakdown. symptoms includes unexplained muscle pain, tenderness, or weakness with or without passage of pink coloured urine; muscle breakdown may result in kidney damage. The risk of muscle breakdown would be greater if:

- You are using higher doses of simvastatin, particularly the 80 mg dose
 - You have problem(s) with your kidney(s)
 - You have under active thyroid gland (hypothyroidism)
 - You are an elderly person (more than 65 years old)
 - You are female
 - If you are receiving fibrates (such as gemfibrozil, bezafibrate) alone or along with **SIMVOR TABLETS**
 - You or your close members of your family have or had muscle problems
 - You consume large amounts of alcoholic beverages
- If you have or have had liver problem
 - If you have eye related problem (lens opacities)

If you have not told your doctor about any of the above, tell him/her before you take SIMVOR TABLETS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **SIMVOR TABLETS** may interfere with each other. These include:

- Itraconazole, ketoconazole, posaconazole, voriconazole and fluconazole (medicines used to treat fungal infections)
- Erythromycin, clarithromycin, or telithromycin (medicines used to treat bacterial infections)
- Fusidic acid (antibiotic used for skin infections)
- Nefazodone (medicine used for the treatment of depression)
- Indinavir, nelfinavir, ritonavir (medicines used to treat HIV infection; AIDS)
- Ciclosporin (medicine used to suppress the immune system)
- Danazol (medicine used to treat breast and menstrual disorders)
- Fibrates (cholesterol-lowering medicines such as gemfibrozil, and bezafibrate)
- Niacin or nicotinic acid (cholesterol-lowering medicine), when used in

large doses (i.e. greater than or equal to 1 g per day)

- Amiodarone, dronedarone ranolazine, verapamil, diltiazem, amlodipine (medicine used to treat heart problems)
- Digoxin (medicine used to treat heart problems)
- Anticoagulants (blood thinning drugs, such as warfarin)
- Colchicine (used to treat gout)
- Rifampicin (a medicine used to treat tuberculosis)
- Grapefruit juice (more than 1 quart daily)

Important information about some of the ingredients of SIMVOR TABLETS

This medicine contains small quantities of inactive ingredient called Lactose. If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicinal product.

SIMVOR TABLETS also contains butylated hydroxyanisole, it may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Ask your doctor or pharmacist if you are not sure whether you are taking any of these medicines. You may need different amounts of your medicines or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use SIMVOR TABLETS

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the PIL ask your doctor or pharmacist for help.

How much to use

Take **SIMVOR TABLETS** exactly as your doctor has prescribed.

The usual recommended dosage range of **SIMVOR TABLETS** is 5 mg to 40 mg taken once daily every evening. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day. Do not take more than 80 mg a day. Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have certain kidney conditions.

Keep taking **SIMVOR TABLETS** unless your doctor tells you to stop.

SIMVOR TABLETS may be used alone or in combination with other lipid lowering medicines such as bile acid sequestrants (e.g. cholestyramine, colestipol).

Swallow the tablets whole with a full glass of water.

SIMVOR TABLETS can be taken with or without food.

Follow all directions given to you by your doctor and pharmacist carefully. These instructions may differ from the information contained in this leaflet.

If you do not understand the directions on the pack, ask your doctor or pharmacist for help.

When to use it

Take your dose of **SIMVOR TABLETS**, as advised by your doctor. Take **SIMVOR TABLETS** in the evening.

How long to use it

Your doctor will advise you on how long you should continue to take your medicine.

If you forget to use it

It is important to take your medicine every day as regular treatment works better.

Do not take an extra dose, just take your normal amount of **SIMVOR TABLETS** at the usual time the next day.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you are taking more than the recommended dose of **SIMVOR TABLETS** please contact your doctor or pharmacist

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SIMVOR TABLETS.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

While you are using SIMVOR TABLETS

Things you must do

Always follow dietary advice given by your doctor or pharmacist.

Tell your doctor or pharmacist that you are taking **SIMVOR TABLETS** if you are about to be started on any new medicines.

If you are about to have elective surgery, tell your doctor that you are taking **SIMVOR TABLETS**.

Tell your doctor if you become pregnant or are trying to become pregnant or intend to breastfeed while you are taking SIMVOR TABLETS.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use SIMVOR TABLETS to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful drinking alcohol while taking **SIMVOR TABLETS**.

If you develop problems with your liver.

If you develop difficulty in breathing, cough, weakness, weight loss and fever. You might have interstitial lung disease.

If you develop unexplained muscle pain, tenderness, or weakness with or without passage of pink coloured urine. You might have rhabdomyolysis.

It is recommended to avoid large quantities of grapefruit juice (> 1 quart daily) while on therapy with **SIMVOR TABLETS**.

If you experience dizziness when taking **SIMVOR TABLETS**, do not drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SIMVOR TABLETS, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, **SIMVOR TABLETS** can have side effects, although not everybody gets them.

Ask your doctor or pharmacist to answer any questions you may have.

Serious Side Effects

If any of the following happen, stop taking **SIMVOR TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital

- hypersensitivity (allergic) reactions including:
 - swelling of the face, tongue and throat which may cause difficulty in breathing (angioedema)
 - pain or inflammation of the joints (polymyalgia rheumatica)
 - inflammation of the blood vessels (vasculitis)
 - unusual bruising, skin eruptions and swelling (dermatomyositis), hives, skin sensitivity to the sun, fever, flushing
 - shortness of breath (dyspnoea)

- lupus-like disease picture (including rash, joint disorders, and effects on blood cells)
- serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever
- a serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis)
- inflammation of the liver 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
- inflammation of the pancreas often with severe abdominal pain
- muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage.

If you have muscle problems that do not go away even after your doctor has told you to stop taking **SIMVOR TABLETS**, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Other side effects

Tell your doctor if you notice any of the following:

- digestive disturbances (abdominal pain, constipation, nausea)
- muscle pain, joint pain
- inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever
- headache, sleeplessness
- swelling
- abnormal heart rhythm
- inflammation of the stomach
- diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine
- spinning sensation
- skin rash
- urinary tract infections

Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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

After taking SIMVOR TABLETS

Storage

Keep **SIMVOR TABLETS** where children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Keep **SIMVOR TABLETS** in a cool, dry place where the temperature stays below 25 degrees C. Heat and dampness can destroy some medicines.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Keep **SIMVOR TABLETS** in the original blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Disposal

If your doctor tells you to stop taking **SIMVOR TABLETS**, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What **SIMVOR TABLETS** look like

Simvor Tablets 10mg

Light pink coloured film coated oval shaped tablets, debossed with '10' on one side and score line on the other side.

Simvor Tablets 20mg

Peach coloured film coated oval shaped tablets, debossed with '20' on one side and score line on the other side.

Simvor Tablets 40mg

Pink coloured film coated oval shaped tablets, debossed with '40' on one side and scoreline on the other side.

Ingredients

Active ingredient: Simvastatin USP

Inactive ingredients:

SIMVOR TABLETS contains:

Microcrystalline Cellulose,
Pregelatinised Starch,
Magnesium Stearate,
Purified Water,
Butylated Hydroxyanisole,
Isopropyl Alcohol,
Low Substituted Hydroxypropyl Cellulose,
Opadry Yellow OY-LS-54901,
Opadry Brown OY-LS-56504,
Opadry Pink OY-LS-54902,
Lactose

MAL NO:

Simvor Tablets 10mg
MAL20020472AZ

Simvor Tablets 20mg
MAL20020473AZ

Simvor Tablets 40mg
MAL06021199AZ

Manufacturer and Registration Holder	Product
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**RANBAXY (MALAYSIA) SDN.
BHD.**

Lot 23, Bakar Arang Industrial Estate,
08000 Sungai Petani, Kedah, Malaysia.

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