

# Simvacor

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using SIMVACOR?

SIMVACOR contains the active ingredient simvastatin. SIMVACOR is used to treat 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).

For more information, see Section [1. Why am I using SIMVACOR?](#) in the full CMI.

### 2. What should I know before I use SIMVACOR?

Do not use if you have ever had an allergic reaction to SIMVACOR or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use SIMVACOR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with SIMVACOR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use SIMVACOR?

- For adults, the recommended starting dose is 10mg or 20 mg per day, taken in the evening, which may need to be increased up to 80 mg daily to have the best effect

More instructions can be found in Section [4. How do I use SIMVACOR?](#) in the full CMI.

### 5. What should I know while using SIMVACOR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using SIMVACOR.</li><li>• Have your blood fats checked when your doctor says, to make sure SIMVACOR is working.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not give SIMVACOR to anyone else even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how SIMVACOR affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Drinking large quantities of alcohol may increase your chance of SIMVACOR causing liver problems.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25 degree Celsius. Protect from Moisture. Do not store it or any other medicine in the bathroom or near a sink</li></ul>

For more information, see Section [5. What should I know while using SIMVACOR?](#) in the full CMI.

### 6. Are there any side effects?

Common: constipation, diarrhoea, (wind), stomach upset or pain, feeling sick (nausea), headache, dizziness. Serious: swelling of the face, lips, mouth, tongue, and/or throat that may cause difficulty in swallowing or breathing, shortness of breath

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Simvacor

Active ingredient: *Simvastatin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SIMVACOR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SIMVACOR.**

Where to find information in this leaflet:

- [1. Why am I using SIMVACOR?](#)
- [2. What should I know before I use SIMVACOR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SIMVACOR?](#)
- [5. What should I know while using SIMVACOR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using SIMVACOR?

**SIMVACOR contains the active ingredient simvastatin.** SIMVACOR is used to lower cholesterol and triglyceride levels.

**SIMVACOR is used to treat 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).**

SIMVACOR may be used in these people, regardless of their cholesterol level 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.

### Cholesterol

Everyone has cholesterol and triglycerides in their blood. They are types of blood fat needed by the body for many things, including building cell walls, making bile acids (which help to digest food) and certain hormones. However, too much cholesterol can be a problem.

Your body makes cholesterol, but it also comes from food.

Normally, the body balances the cholesterol it makes with the cholesterol it gets from food. This means, if more cholesterol comes from food less is made by the body. However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol, it may 'stick' to the inside of your blood vessels. Instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas called plaque on the walls of blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and angina), and stroke.

In people with CHD, SIMVACOR may slow down the hardening of blood vessels and reduce the risk of developing new plaques.

There are different types of cholesterol, called LDL and HDL cholesterol. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol on the other hand, is the 'good' cholesterol, that is thought to remove the bad cholesterol from the blood vessels.

### Triglycerides

Triglycerides are an energy source for the body. However, as with cholesterol, too much triglycerides can be a problem.

### How SIMVACOR works

SIMVACOR belongs to a group of medicines known as HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver. In terms of good and bad cholesterol, SIMVACOR reduces the bad cholesterol and raises the good cholesterol.

SIMVACOR does not reduce the cholesterol and triglycerides that come from fat in food.

Therefore, when you are taking SIMVACOR, you also need to follow a low fat diet and other measures, such as exercise and weight control.

In most people, there are no symptoms of high cholesterol or triglycerides. Your doctor can measure your cholesterol and triglycerides with a simple blood test.

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 (see How to take SIMVACOR). SIMVACOR has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Your doctor may have prescribed SIMVACOR for another reason. Ask your doctor if you have any questions about why SIMVACOR has been prescribed for you.

SIMVACOR is not addictive.

## 2. What should I know before I use SIMVACOR?

### Warnings

#### Do not use SIMVACOR if:

- you are allergic to simvastatin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant. Or breastfeeding. Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.
- you have liver disease
- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides

Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the tongue or face or painful joints.

#### Check with your doctor if you:

- you have unexplained muscle pain, tenderness or weakness not caused by exercise. This is because on rare occasions, muscle problems can be serious including muscle breakdown resulting in kidney damage that can lead to death. Your doctor may do a blood test to check for certain muscle problems
- you are Asian
- you have ever had liver disease. Your doctor will do a blood test to make sure you have no problems with your liver.
- you have kidney disease or any other medical problems
- you drink alcohol regularly

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

SIMVACOR should not be used during pregnancy or while breastfeeding.

## 3. What if I am taking other medicines?

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

Some medicines should not be taken with SIMVACOR as they may increase the risk of muscle side effects with SIMVACOR. It is particularly important to tell your doctor if you are taking:

- nefazodone, used to treat depression
- medicines containing cobicistat (a drug used in the treatment of HIV infection)
- protease inhibitors, including indinavir, nelfinavir, ritonavir, saquinavir, used to treat HIV infection
- certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
- gemfibrozil, used to treat high cholesterol levels
- ciclosporin, used to suppress the immune system
- danazol
- erythromycin, clarithromycin, telithromycin and fusidic acid antibiotics used to treat infections
- ketoconazole, itraconazole, posaconazole and voriconazole, used to treat certain fungal infections

#### Some medicines may interfere with SIMVACOR and affect how it works.

Because taking SIMVACOR with any of the following drugs can increase the risk of muscle problems (see Side Effects), it is particularly important to tell your doctor if you are taking:

- other medicines to lower cholesterol levels, for example, other fibrates, nicotinic acid (also known as niacin)
- warfarin, or other drugs used to prevent blood clots
- colchicine, used for gout
- verapamil, diltiazem or amlodipine, used to treat high blood pressure, angina or other heart conditions
- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)
- amiodarone, used to treat irregular heart beat
- digoxin, used to treat heart failure
- Certain hepatitis C antiviral agents, such as elbasvir or grazoprevir
- daptomycin, a drug used to treat complicated skin and skin structure infections and bacteraemia

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SIMVACOR.**

## 4. How do I use SIMVACOR?

### How much to take

- Take SIMVACOR only when prescribed by your doctor.
- Your doctor will tell you how many tablets you need to take each day. This depends on your cholesterol and triglyceride levels and other factors, such as kidney disease.
- For adults, the recommended starting dose is 10mg or 20 mg per day, taken in the evening, which may need to be increased up to 80 mg daily to have the best effect.
- Because of the increased risk of muscle problems, the 80 mg dose is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.
- People with CHD or risk factors for CHD are usually started on 40 mg per day, taken in the evening.
- For children (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.
- SIMVACOR helps lower your cholesterol. It does not cure your condition. Therefore, you must continue to take as directed by your doctor if you expect to lower your cholesterol and keep it down. You may have to take cholesterol lowering medicine for the rest of your life. If you stop taking SIMVACOR, your cholesterol levels may rise again

### When to take SIMVACOR

- SIMVACOR should be used once a day in the evening.
- The liver produces its greatest amount of cholesterol when the body is at rest and when there is no dietary intake. For most people, this is at night, when asleep. Therefore, SIMVACOR is more effective when taken in the evening. A good time SIMVACOR would be after your evening meal. However, it does not matter whether you take it before or after food.
- Take SIMVACOR at about the same time each evening.
- Taking your tablet(s) at the same time each evening will have the best effect. It will also help you remember when to take the tablets.

### How to take SIMVACOR

- Swallow SIMVACOR with a glass of water

### If you forget to use SIMVACOR

SIMVACOR should be used regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

### If you use too much SIMVACOR

If you think that you have used too much SIMVACOR, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using SIMVACOR?

### Things you should do

- Have your blood fats checked when your doctor says, to make sure SIMVACOR is working.
- Changes to lifestyle that may help reduce the chance of coronary heart disease. Lowering high cholesterol can help reduce your chances of having coronary heart disease (CHD). However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking, diabetes, excess weight, family history of CHD, being a male and being a woman who has reached menopause.
- Some self-help measures suggested below may help your condition and help reduce your chances of having CHD. Talk to your doctor, pharmacist or dietician about these measures and for more information.
- **Diet:** continue the low fat diet recommended by your doctor dietician or pharmacist
- **Weight:** your doctor may advise you to lose weight if you are overweight
- **Exercise:** Make exercise: a part of your routine walking is good. Ask your doctor for advice before starting exercise
- **Smoking:** your doctor may advise you to stop smoking; or at least cut down.

### Call your doctor straight away if you:

- are about to be started on any new medicine
- become pregnant
- are about to have elective surgery. Your doctor may suggest stopping the tablets a few days before surgery

Remind any doctor, dentist or pharmacist you visit that you are using SIMVACOR.

### Things you should not do

- Do not stop using this medicine suddenly.
- Do not give SIMVACOR to anyone else even if they have the same condition as you.
- Do not drink grapefruit juice while taking this medicine. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including SIMVACOR

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how SIMVACOR affects you. SIMVACOR**

generally does not cause any problems with your ability to drive a car or operate machinery.

SIMVACOR may cause dizziness in some people

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol may increase your chance of SIMVACOR causing liver problems if drinking large quantities of alcohol

**Avoid drinking large quantities of alcohol..**

## Looking after your medicine

- Store below 25 degree Celsius. Heat and dampness can destroy some medicines.
- Keep your tablets in the blister pack until it is time to take them.
- If you take the tablets out of the blister pack, they may not keep well

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• constipation, diarrhoea, (wind), stomach upset or pain, feeling sick (nausea)</li> <li>• headache</li> <li>• dizziness</li> <li>• aching muscles, muscle tenderness or weakness not caused by exercise (in <b>very rare cases this may</b> not go away after stopping SIMVACOR)</li> <li>• brown/black coloured urine</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• tingling in the hands or feet</li> <li>• signs of anaemia, such as tiredness, being short of breath and looking pale</li> <li>• fever, generally feeling unwell</li> <li>• skin rash, itchiness</li> <li>• pinkish, itchy swellings on the skin, also called hives or nettlerash</li> <li>• painful, swollen joints</li> <li>• bruising more easily than normal</li> <li>• larger breasts than normal in men</li> <li>• swelling of the face, lips, mouth, tongue, and/or throat that may cause difficulty in swallowing or breathing</li> <li>• shortness of breath</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

On rare occasions, muscle problems can be serious including muscle breakdown resulting in kidney damage that can lead to death.

The risk of muscle problems is greater for:

- patients taking higher doses of SIMVACOR, particularly the 80 mg dose
- older patients (65 years of age and older)
- female patients
- patients with abnormal kidney function
- patients with thyroid problems

**Also tell your doctor if you notice:**

- hair loss
- muscle cramps
- trouble sleeping
- poor memory, memory loss, confusion
- feelings of depression
- blurred vision and impaired vision
- erectile dysfunction
- breathing problems including persistent cough and/or shortness of breath or fever
- gynaecomastia (breast enlargement in men) (very rare)
- muscle rupture (very rare)
- rash that occur on the skin or sores in the mouth (lichenoid drug eruptions) (very rare)

These are other side effects that have been reported for SIMVACOR.

Liver problems can also occur and may be serious. Your doctor will do blood tests to check your liver.

**Tell your doctor immediately if**

### you have the following symptoms of liver problems:

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What SIMVACOR contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• Simvastatin</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Microcrystalline cellulose</li><li>• Lactose monohydrate</li><li>• Pregelatinised maize starch</li><li>• Ascorbic acid</li><li>• Citric acid monohydrate</li><li>• Butylated hydroxyanisole</li><li>• Magnesium stearate</li><li>• Opadry complete film coating system Pink</li><li>• Opadry complete film coating system Brown</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What SIMVACOR looks like

- SIMVACOR 10 mg: Light pink coloured, oval, biconvex film-coated tablets, marked 'SVN 10' on one side and 'NEO' on the other side (AUST R 182910)
- SIMVACOR 20 mg: Tan coloured, oval, biconvex film-coated tablets, marked with 'SVN 20' on one side and 'NEO' on the other side. (AUST R 182911)
- SIMVACOR 40 mg: Pink coloured, oval, biconvex film coated tablets, marked 'SVN' 40 on one side and 'NEO' on the other side. (AUST R 182912)

- SIMVACOR 80 mg: Pink coloured, capsule shaped, biconvex film coated tablets marked with 'SVN 80' on one side and 'NEO' on the other side. (AUST R 182913)

SIMVACOR tablets are available in bottle pack of 180, 30 and 100 tablets.

### Who distributes SIMVACOR

#### Sponsor:

Cipla Australia Pty Ltd  
Level 1 / 132-136 Albert Road  
South Melbourne VIC 3205  
[drugsafety@cipla.com](mailto:drugsafety@cipla.com)  
Phone: 1 800 569 074

#### Distributor:

Pharmacor Ltd  
Unit 5/36 Campbell Ave  
CROMER NSW 2099

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