

## 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 SIMVAR?

SIMVAR contains the active ingredient simvastatin. SIMVAR is used to help lower cholesterol and triglyceride levels, its used in people who have coronary heart disease (CHD) and it is used in people with a high risk of CHD (e.g. diabetes, a history of stroke, or other blood vessel disease).

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

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

Do not use if you have ever had an allergic reaction to simvastatin 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 SIMVAR?](#) in the full CMI.

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

Some medicines may interfere with SIMVAR 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 SIMVAR?

- 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 pack, ask your doctor or pharmacist for help.
- Take this medicine only when prescribed by your doctor.

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

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

<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 SIMVAR.</li><li>• If you become pregnant while taking this medicine, stop taking it and tell your doctor immediately.</li><li>• Keep all your doctor's appointments so that your progress can be checked.</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 this medicine to anyone else, even if they have the same condition as you.</li><li>• Do not take your medicine to treat any other complaint unless your doctor tells you to.</li><li>• Do not stop taking your medicine or change the dosage without first checking with your doctor.</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 this medicine affects you.</li><li>• SIMVAR generally does not affect your ability to drive a car or operate machinery. However, this medicine may cause dizziness in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Avoid drinking large quantities of alcohol.</li><li>• Drinking large amounts of alcohol may increase the risk of liver problems.</li><li>• Avoid drinking grapefruit juice.</li><li>• Grapefruit juice can alter the metabolism of SIMVAR.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in its pack until it is time to take it.</li><li>• Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light and moisture.</li><li>• Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.</li><li>• Keep this medicine where children cannot reach it.</li></ul>

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

## 6. Are there any side effects?

Tell your doctor and pharmacist as soon as possible if you do not feel well while you are taking SIMVAR.

This medicine helps most people but may cause unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some side effects.

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.

# SIMVAR

Active ingredient: *simvastatin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SIMVAR. **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 SIMVAR.**

**Where to find information in this leaflet:**

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

## 1. Why am I using SIMVAR?

**SIMVAR contains the active ingredient simvastatin.**

SIMVAR 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, SIMVAR reduces the bad cholesterol and raises the good cholesterol.

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

**Therefore, when you are taking SIMVAR, 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.

**SIMVAR is used:**

- to help lower cholesterol and triglyceride levels
- in people who have coronary heart disease (CHD)
- in people with a high risk of CHD (e.g. diabetes, a history of stroke, or other blood vessel disease)

SIMVAR 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 high-fat diet, 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 attacks and angina) and stroke.

In people with CHD, SIMVAR 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 vessels. HDL cholesterol is the 'good' cholesterol that is thought to remove bad cholesterol from blood vessels.

**Triglycerides:**

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

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

SIMVAR is not addictive.

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

### Warnings

**Do not use SIMVAR if:**

- you are allergic to simvastatin, lactose, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the tongue or face, or painful joints.

**Do not take this medicine if you have or have had any of the following medical conditions:**

- liver disease or unexplained high levels of liver enzymes

- muscle pain, tenderness or weakness (myopathy) from other medicines used to treat high cholesterol or triglycerides

**Do not take this medicine if 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.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

- If you take this medicine after the expiry date has passed, it may not work.
- If it has expired or is damaged, return it to your pharmacist for disposal.

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

**Tell your doctor if:**

- **you intend to become pregnant or plan to breast-feed.**  
SIMVAR should not be used during pregnancy or while breastfeeding.
- **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.**
- **you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
- **you have or have had myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may lead to occurrence of myasthenia or aggravate the condition.**
- **you are taking niacin (also known as nicotinic acid) or a niacin-containing product, particularly if you are Chinese.**

**If you have not told your doctor about any of the above, tell them before you take any SIMVAR.**

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

Do not take this medicine if you are pregnant or there is a chance that you could become pregnant (e.g. not using adequate contraception).

- SIMVAR may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding.

- Your baby may absorb this medicine from breast milk, and therefore there is a possibility of harm to the baby.

## 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 must not be taken with SIMVAR as they may increase the risk of muscle side effects with this medicine. It is particularly important to tell your doctor if you are taking:

- nefazodone, used to treat depression
- gemfibrozil, used to treat high cholesterol levels
- ciclosporin, used to suppress the immune system
- danazol
- medicines known as 'CYP3A4 inhibitors', used to treat certain fungal infections (e.g. itraconazole, ketoconazole, posaconazole, voriconazole)
- medicines containing cobicistat (a drug used in the treatment of HIV infection)
- HIV protease inhibitors (e.g. indinavir, nelfinavir, ritonavir, saquinavir)
- certain hepatitis C virus protease inhibitors (e.g. boceprevir, telaprevir)
- antibiotics used to treat infections (e.g. erythromycin, fusidic acid, clarithromycin, telithromycin)

**Some medicines may interfere with SIMVAR and affect how it works.**

If you are taking any of the above, your doctor may suggest stopping this medicine temporarily or permanently.

Taking SIMVAR 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 used to lower cholesterol levels, such as other fibrates, niacin (also known as nicotinic acid)
- warfarin, ticagrelor and other medicines used to prevent blood clots
- colchicine, used for gout
- medicines used to treat high blood pressure, angina or other heart conditions (e.g. verapamil, diltiazem, amlodipine)
- lomitapide, used for 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 (e.g. elbasvir or grazoprevir)

- daptomycin, a drug used to treat complicated skin and skin structure infections and bacteraemia

These medicines may be affected by SIMVAR, may affect how well it works, or may increase the risk of side effects with this SIMVAR. You may need different amounts of your medicines, or you may need to take different medicines.

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

You should also tell any doctor who is prescribing a new medication for you that you are taking this medicine.

Grapefruit juice, especially in large amounts, may also interfere with the way SIMVAR works in your body. However, one glass of grapefruit juice per day is unlikely to have any effect.

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

## 4. How do I use SIMVAR?

### How much to take / use

- 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 pack, ask your doctor or pharmacist for help.
- Your doctor will tell you how much of this medicine you should take, depending on your condition and whether you are taking other medicines.
- For adults, the recommended starting dose is 10 mg 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 should only be used in patients at a high risk of heart problems who have not reached their cholesterol goal on lower doses.
- 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.

#### For people with CHD or risk of CHD:

- The usual starting dose is 40 mg per day, taken in the evening.

Swallow the tablets whole with a glass of water.

### When to take SIMVAR

- **Take SIMVAR 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, this medicine is more effective when taken in the evening. A good time would be after your evening meal. However, it does not matter whether you take it before or after food.
- **Take SIMVAR 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 long to take SIMVAR

Continue taking this medicine for as long as your doctor tells you.

SIMVAR helps to lower your cholesterol, but it does not cure your condition. It is important to keep taking your medicine even if you feel well. You may have to take cholesterol-lowering medicines for the rest of your life. If you stop taking this medicine, your cholesterol levels may rise again. Make sure you have enough to last over weekends and holidays.

### If you forget to use SIMVAR

SIMVAR should be used regularly at the same time each day. If you miss your dose at the usual time:

- If it is almost time for your next dose, skip the dose you missed and take your next dose at the usual time.
- Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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

### If you use too much SIMVAR

If you think that you have used too much SIMVAR, 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 SIMVAR?

### Things you should do

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking this medicine.**

**Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.**

**If you become pregnant while taking this medicine, stop taking it and contact your doctor immediately.**

**Keep all of your doctor's appointments so that your progress can be checked.**

**Have your blood fats checked when your doctor says, to make sure SIMVAR is working.**

**Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.**

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

Your doctor may suggest stopping the tablets a few days before surgery.

**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.

**Things you should not do**

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take your medicine to treat any other complaint unless your doctor tells you to.
- Do not stop taking your medicine or change the dosage without first checking with your doctor.

**Driving or using machines**

**Be careful driving or operating machinery until you know how SIMVAR affects you.**

SIMVAR generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, SIMVAR may cause dizziness in some people. Make sure you know how you react to SIMVAR before you drive a car or operate machinery.

**Drinking alcohol**

**Avoid drinking large quantities of alcohol.**

Drinking large amounts of alcohol may increase the risk of this medicine causing liver problems.

**Avoid drinking grapefruit juice.**

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including SIMVAR.

**Looking after your medicine**

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

**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.

**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.

Heat and dampness can destroy some medicines.

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

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Getting rid of any unwanted medicine**

If your doctor tells you to stop taking this medicine or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

SIMVAR helps most people with high cholesterol, but it may have unwanted side effects in a few people. 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

**Less serious side effects**

These are the more common side effects of SIMVAR. For the most part these have been mild and short-lived.

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• constipation, diarrhoea, wind</li><li>• stomach upset, such as feeling sick (nausea), vomiting, flatulence, pain, reflux</li><li>• headache</li><li>• dizziness</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

**Serious side effects**

These may be serious side effects of SIMVAR. Some of these may be symptoms of an allergic reaction to SIMVAR. You may need urgent medical attention. Serious side effects are rare.

Serious side effects	What to do
<ul style="list-style-type: none"> <li>tingling or numbness in the hands or feet</li> <li>signs of anaemia, such as tiredness, shortness of breath, looking pale</li> <li>fever, flushing and/or generally feeling unwell</li> <li>skin rash, itchiness</li> <li>pinkish, itchy swellings on the skin, also called hives or nettle rash</li> <li>painful, swollen joints</li> <li>bruising more easily than normal</li> <li>larger breasts than normal in men</li> <li>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 (symptoms of myasthenia)</li> <li>shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, mouth, tongue, throat and/or other parts of the body; rash, itching or hives on the skin (signs of an allergic reaction)</li> <li>dry cough, trouble breathing, high temperature, weight loss, feeling tired (signs of interstitial lung disease)</li> </ul> <p>Liver problems can also occur and may be serious. Your doctor will do blood tests to check your liver.</p> <ul style="list-style-type: none"> <li>feeling unusually tired or weak</li> <li>loss of appetite</li> <li>yellowing of the skin and/or eyes, also called jaundice</li> <li>dark urine (signs of a liver problem)</li> <li>sharp pain in the upper stomach (pancreatitis)</li> </ul> <p>On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.</p> <ul style="list-style-type: none"> <li>brown or dark coloured urine</li> <li>aching muscles, muscle tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping SIMVAR)</li> </ul> <p>The risk of muscle problems is greater for:</p>	<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>

<ul style="list-style-type: none"> <li>patients taking higher doses of SIMVAR, particularly the 80 mg dose</li> <li>older patients (65 years of age and older)</li> <li>female patients</li> <li>patients with abnormal kidney function</li> <li>patients with thyroid problems.</li> </ul> <p>Tell your doctor if you notice. These are other side effects that have been reported with SIMVAR.</p> <ul style="list-style-type: none"> <li>hair loss</li> <li>muscle cramps</li> <li>trouble sleeping</li> <li>poor memory, memory loss, confusion</li> <li>feelings of depression</li> <li>blurred vision and impaired vision</li> <li>erectile dysfunction</li> <li>breathing problems including persistent cough and/or shortness of breath or fever</li> <li>gynaecomastia (breast enlargement in men) (very rare)</li> <li>muscle rupture (very rare)</li> <li>rash that occur on the skin or sores in the mouth (lichenoid drug eruptions) (very rare)</li> </ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may also occur in some patients.

### 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 SIMVAR contains

<b>Active ingredient (main ingredient)</b>	simvastatin
<b>Other ingredients (inactive ingredients)</b>	butylated hydroxyanisole ascorbic acid citric acid monohydrate

	microcrystalline cellulose magnesium stearate lactose monohydrate pregelatinised maize starch Opadry Complete Film Coating System 20A230020 Pink (10 mg only) Opadry Complete Film Coating System 20A230019 Orange (20 mg only) Opadry Complete Film Coating System 20A240020 Pink (40 mg and 80 mg only)
<b>Potential allergens</b>	Contains sugars as lactose

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

## What SIMVAR looks like

### **SIMVAR 10 mg Tablets**

peach coloured, oval-shaped film-coated tablet, coded 'E33' on one side and plain on the other side.

Blister packs (PVC/PVDC/Al) of 30 tablets (AUST R 95949).

### **SIMVAR 20 mg Tablets**

SIMVAR 20 (20 mg) – tan coloured, oval-shaped film coated tablet with 'E34' marked on one side.

Blister packs (PVC/PVDC/Al) of 30 tablets (AUST R 95950).

### **SIMVAR 40 mg Tablets**

brick-red coloured, oval-shaped film coated tablet with 'E35' marked on one side.

Blister packs (PVC/PVDC/Al) of 30 tablets (AUST R 95953).

### **SIMVAR 80 mg Tablets**

brick-red coloured, capsule-shaped film coated tablet with 'E37' marked on one side.

Blister packs (PVC/PVDC/Al) of 30 tablets (AUST R 95954).

\*Not all strengths, pack types and/or pack sizes may be available.

## Who distributes SIMVAR

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in January 2024.