

# SIMVASTATIN-TIH

## 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 SIMVASTATIN-TIH?

SIMVASTATIN-TIH contains the active ingredient simvastatin. SIMVASTATIN-TIH 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 SIMVASTATIN-TIH?](#) in the full CMI.

### 2. What should I know before I use SIMVASTATIN-TIH?

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 SIMVASTATIN-TIH?](#) in the full CMI.

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

Some medicines may interfere with SIMVASTATIN-TIH 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 SIMVASTATIN-TIH?

- 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 SIMVASTATIN-TIH?](#) in the full CMI.

### 5. What should I know while using SIMVASTATIN-TIH?

<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 SIMVASTATIN-TIH.</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>• SIMVASTATIN-TIH 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 SIMVASTATIN-TIH.</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 SIMVASTATIN-TIH?](#) 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 SIMVASTATIN-TIH.

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.

# SIMVASTATIN-TIH

Active ingredient: *simvastatin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SIMVASTATIN-TIH. **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 SIMVASTATIN-TIH.**

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

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

## 1. Why am I using SIMVASTATIN-TIH?

**SIMVASTATIN-TIH contains the active ingredient simvastatin.** SIMVASTATIN-TIH belongs to a group of medicines known as HMG-CoA reductase inhibitors.

SIMVASTATIN-TIH works by reducing bad (LDL) cholesterol made by the liver and raises the good (HDL) cholesterol. It may slow the hardening of blood vessels and reduce the risk of developing new plaque.

SIMVASTATIN-TIH does not reduce the cholesterol and triglycerides that come from fat in food. Therefore, you also need to follow a low-fat diet and other measures, such as exercise and weight control, while you are taking SIMVASTATIN-TIH.

**SIMVASTATIN-TIH 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)

SIMVASTATIN-TIH can reduce the risk of a heart attack or stroke, reduce the need for surgery to increase blood flow to the heart, and can reduce the need for hospitalisation due to angina.

**Cholesterol:**

Everyone has cholesterol and triglycerides in their blood. The body uses them for many things, such as building cell walls and hormones.

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

Too much cholesterol or triglycerides can be a problem. 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. High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

There are usually no symptoms of high cholesterol or triglycerides. Your doctor can measure your cholesterol and triglycerides with a blood test.

There are two 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 are an energy source for the body.

## 2. What should I know before I use SIMVASTATIN-TIH?

### Warnings

**Do not use SIMVASTATIN-TIH 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.

**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 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 if you are taking the following medicines:**

- gemfibrozil
- cyclosporin
- danazol
- CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, posaconazole, voriconazole)
- HIV protease inhibitors (e.g. indinavir, nelfinavir, ritonavir, saquinavir)
- hepatitis C virus protease inhibitors (e.g. boceprevir, telaprevir)
- some antibiotics (e.g. fusidic acid, erythromycin, clarithromycin, telithromycin and fusidic acid)

- antibiotics used to treat infections)
- nefazodone
- ketoconazole, itraconazole, posaconazole and voriconazole, used to treat certain fungal infections.

**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 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.

#### **Check with your doctor if you:**

- have allergies to any other medicines, foods, preservatives or dyes.

**Tell your doctor if you have or have had any of the following medical conditions:**

- liver disease
- kidney disease
- thyroid problems
- unexplained muscle pain, tenderness or weakness not caused by exercise

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

**Tell your doctor if you become pregnant or plan to breast feed.**

**Tell your doctor if you are Asian.**

**Tell your doctor if you are taking niacin (also known as nicotinic acid) or a niacin-containing product, particularly if you are Chinese.**

**Tell your doctor if**

- you have not told your doctor about any of the above, tell them before you start taking this medicine.
- 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.

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).

- SIMVASTATIN-TIH 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 SIMVASTATIN-TIH 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
- cyclosporin, 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, used for 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 SIMVASTATIN-TIH and affect how it works.**

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

Taking SIMVASTATIN-TIH 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 SIMVASTATIN-TIH, may affect how well it works, or may increase the risk of side effects with this SIMVASTATIN-TIH. 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 SIMVASTATIN-TIH 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 SIMVASTATIN-TIH.**

## **4. How do I use SIMVASTATIN-TIH?**

### **How much to take / use**

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ to 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 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 SIMVASTATIN-TIH**

- SIMVASTATIN-TIH should be taken at the same time each day, preferably 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, such as after your evening meal, however it can be taken without food.
- Taking it at the same time each day will have the best effect and will also help you remember when to take it.

### **How to long to take SIMVASTATIN-TIH**

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

SIMVASTATIN-TIH 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 SIMVASTATIN-TIH**

SIMVASTATIN-TIH should be used regularly at the same time each day. If you miss your dose at the usual time, 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 SIMVASTATIN-TIH**

If you think that you have used too much SIMVASTATIN-TIH, 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 SIMVASTATIN-TIH?**

### **Things you should do**

**If you are about to be started on any new medicine, remind 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 tell your doctor immediately.**

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

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

**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 before you drive or use any machines or tools until you know how SIMVASTATIN-TIH affects you.**

SIMVASTATIN-TIH generally does not affect your ability to drive a car or operate machinery. However, this medicine may cause dizziness in some people. Make sure you know how you react to this medicine before you drive a car or operate machinery.

### Drinking alcohol

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

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

Avoid drinking grapefruit juice.

Grapefruit juice can alter the metabolism of SIMVASTATIN-TIH.

### Looking after your medicine

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>• stomach upset, such as nausea, vomiting, constipation, diarrhoea, 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

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• tingling or numbness in the hands or feet</li> <li>• tiredness, shortness of breath, looking pale (signs of anaemia)</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>• shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, 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> <li>• feeling unusually tired or weak; loss of appetite; yellowing of the skin and/or eyes, also called jaundice; dark urine (signs of a liver problem)</li> <li>• sharp pain in the upper stomach (pancreatitis)</li> <li>• brown or dark coloured urine, severe muscle aching all through the body, muscle weakness (muscle breakdown)</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> <p>Rarely, muscle breakdown can be serious and result in kidney damage or lead to death. The risk of muscle problems is greater for:</p> <ul style="list-style-type: none"> <li>• patients taking higher doses of SIMVASTATIN-TIH, such as 80 mg</li> <li>• older patients (65 years of age and older)</li> </ul>

<ul style="list-style-type: none"> <li>female patients</li> <li>patients with abnormal kidney function</li> <li>patients with thyroid problems.</li> <li>Tell your doctor if you notice:</li> <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 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 SIMVASTATIN-TIH 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 20A54692 Pink (10 mg only)

	Opadry 20A56767 Brown (20 mg only) Opadry 20A54535 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 SIMVASTATIN-TIH looks like

#### SIMVASTATIN-TIH 10 mg Tablets

Light pink coloured, oval, biconvex film-coated tablets, marked 'SVN 10' on one side and 'NEO' on the other side.

Blister packs (PVC/PVDC/Al) of 30 tablets (AUST R 211952).

#### SIMVASTATIN-TIH 20 mg Tablets

Tan coloured, oval, biconvex film-coated tablets, marked with 'SVN 20' on one side and 'NEO' on the other side.

Blister packs (PVC/PVDC/Al) of 30 tablets (AUST R 211953).

#### SIMVASTATIN-TIH 40 mg Tablets

Pink coloured, oval, biconvex film-coated tablets, marked 'SVN 40' on one side and 'NEO' on the other side.

Blister packs (PVC/PVDC/Al) of 30 tablets (AUST R 211954).

#### SIMVASTATIN-TIH 80 mg Tablets

Pink coloured, capsule-shaped, biconvex film-coated tablets marked with 'SVN 80' on one side and 'NEO' on the other side.

Blister packs (PVC/PVDC/Al) of 30 tablets (AUST R 211955).

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

### Who distributes SIMVASTATIN-TIH

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 February 2024.