

Simvastatin Sandoz®

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 Sandoz?

Simvastatin Sandoz contains the active ingredient simvastatin. Simvastatin Sandoz helps to lower cholesterol and triglyceride levels.

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

2. What should I know before I use Simvastatin Sandoz?

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 Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Simvastatin Sandoz 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 Sandoz?

- Take Simvastatin Sandoz once a day in the evening.
- Your doctor will tell you how many tablets you need to take each day.

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

5. What should I know while using Simvastatin Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Simvastatin Sandoz.• Have your blood fats checked when your doctor says, to make sure Simvastatin Sandoz is working• If you are about to have elective surgery, tell your doctor that you are taking Simvastatin Sandoz.
Things you should not do	<ul style="list-style-type: none">• Grapefruit juice should be avoided while taking Simvastatin Sandoz. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Simvastatin Sandoz.
Driving or using machines	<ul style="list-style-type: none">• Simvastatin Sandoz may cause dizziness in some people. Make sure you know how you react to Simvastatin Sandoz before you drive a car or operate machinery
Drinking alcohol	<ul style="list-style-type: none">• Avoid drinking large quantities of alcohol. Tell your doctor if you drink alcohol. Drinking large quantities of alcohol may increase your chance of Simvastatin Sandoz causing liver problems.
Looking after your medicine	<ul style="list-style-type: none">• Keep Simvastatin Sandoz in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects of Simvastatin Sandoz are constipation, diarrhoea, wind, stomach upset or pain, feeling sick (nausea), headache, trouble sleeping, rash.

Allergic reactions to Simvastatin Sandoz occur rarely.

Serious side effects are rare, but may need urgent medical attention.

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 Sandoz®

Active ingredient(s): *simvastatin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Simvastatin Sandoz. **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 Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Simvastatin Sandoz?

Simvastatin Sandoz contains the active ingredient **simvastatin**. Simvastatin Sandoz helps to lower cholesterol and triglyceride levels.

Simvastatin Sandoz is 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).

Simvastatin Sandoz 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, Simvastatin Sandoz 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 Simvastatin Sandoz works

Simvastatin Sandoz 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, Simvastatin Sandoz reduces the bad cholesterol and raises the good cholesterol.

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

Therefore, when you are taking Simvastatin Sandoz, 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 Simvastatin Sandoz). Simvastatin Sandoz has not been studied in children under the age of 10 years. For more information, talk to your doctor.

2. What should I know before I use Simvastatin Sandoz?

Warnings

Do not use Simvastatin Sandoz if:

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

- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides
- the packaging is torn or shows signs of tampering

Check with your doctor if 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.
- are Asian
- have ever had liver disease. Your doctor will do a blood test to make sure you have no problems with your liver
- have kidney disease
- drink alcohol regularly
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- 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.
- have any other medical conditions
- take any medicines for any other 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

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.

Simvastatin Sandoz should not be used during pregnancy or while breast-feeding.

Your baby may absorb this medicine in the womb or 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 should not be taken with Simvastatin Sandoz as they may increase the risk of muscle side effects with Simvastatin Sandoz.

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

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

Some medicines and Simvastatin Sandoz may interfere with each other. Because taking Simvastatin Sandoz with any of the following drugs can increase the risk of muscle problems (see Section [6. Are there any 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, ticagrelor 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

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Simvastatin Sandoz.

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

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 Sandoz.

4. How do I use Simvastatin Sandoz?

How much to take

- Take Simvastatin Sandoz 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 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 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.
- Swallow Simvastatin Sandoz with a glass of water.
- Follow the instructions provided and use Simvastatin Sandoz until your doctor tells you to stop.
- Simvastatin Sandoz helps lower your cholesterol. It does not cure your condition. Therefore, you must continue to take it 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 Simvastatin Sandoz, your cholesterol levels may rise again.

When to take Simvastatin Sandoz

- Take Simvastatin Sandoz 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, Simvastatin Sandoz 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 Simvastatin Sandoz 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.

If you forget to use Simvastatin Sandoz

Simvastatin Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

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 are not sure whether to skip the dose, talk to your doctor or pharmacist. If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you use too much Simvastatin Sandoz

If you think that you have used too much Simvastatin Sandoz, 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 Sandoz?

Call your doctor straight away and stop taking Simvastatin Sandoz if you become pregnant while you are taking Simvastatin Sandoz.

Things you should do

- Have your blood fats checked when your doctor says, to make sure Simvastatin Sandoz is working.
- If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Simvastatin Sandoz.
- If you are about to have elective surgery, tell your doctor that you are taking Simvastatin Sandoz. Your doctor may suggest stopping the tablets a few days before surgery.

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

Things you should not do

- Do not give Simvastatin Sandoz to anyone else, even if they have the same condition as you.
- Grapefruit juice should be avoided while taking Simvastatin Sandoz. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Simvastatin Sandoz.

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Simvastatin Sandoz affects you.

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

Drinking alcohol

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of Simvastatin Sandoz causing liver problems.

Looking after your medicine

- 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.
- Keep Simvastatin Sandoz in a cool dry place where the temperature stays below 25°C.

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
Gastrointestinal-related: <ul style="list-style-type: none"> • diarrhoea, constipation, wind • stomach upset or pain, feeling sick (nausea) 	Speak to your doctor if you have any of these less serious side effects

Muscle/skeleton-related: <ul style="list-style-type: none"> • muscle cramps • muscle rupture (very rare) Eye-related: <ul style="list-style-type: none"> • blurred vision and impaired vision Skin-related: <ul style="list-style-type: none"> • hair loss • rash that occurs on the skin or sores in the mouth (lichenoid drug eruptions) (very rare) Head and nervous system-related: <ul style="list-style-type: none"> • headache • dizziness • poor memory, memory loss, confusion • tingling in the hands and feet Mood-related: <ul style="list-style-type: none"> • trouble sleeping • feelings of depression Reproductive system or breast-related: <ul style="list-style-type: none"> • erectile dysfunction • gynaecomastia (breast enlargement in men) (very rare) Respiratory-related: <ul style="list-style-type: none"> • breathing problems including persistent cough and/or shortness of breath or fever Blood-related: <ul style="list-style-type: none"> • signs of anaemia, such as tiredness, being short of breath, and looking pale 	effects and they worry you.
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Serious side effects

Serious side effects	What to do
Muscle/skeleton-related: <ul style="list-style-type: none"> • aching muscles, muscle tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping Simvastatin Sandoz) • brown/black coloured urine • muscle rupture (very rare) <p>On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.</p> <p>The risk of muscle problems is greater for:</p> <ul style="list-style-type: none"> • patients taking higher doses of Simvastatin Sandoz, particularly the 80 mg dose • older patients (65 years of age and older) • female patients 	Tell your doctor immediately, if you notice any of these serious side effects.

<ul style="list-style-type: none"> patients with abnormal kidney function patients with thyroid problems. <p>Liver-related:</p> <p>Liver problems can also occur and may be serious. Your doctor will do blood tests to check your liver.</p> <p>Symptoms of liver problems include:</p> <ul style="list-style-type: none"> feeling tired or weak loss of appetite upper belly pain dark urine yellowing of your skin or the whites of your eyes 	
<p>Allergic reaction:</p> <ul style="list-style-type: none"> swelling of the face, lips, mouth, tongue, and/or throat that may cause difficulty in swallowing or breathing shortness of breath 	<p>Tell your doctor immediately, or go to accident and Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
<p>Blood-related:</p> <ul style="list-style-type: none"> bruising more easily than normal <p>Skin-related:</p> <ul style="list-style-type: none"> skin rash, itchiness pinkish, itchy swellings on the skin, also called hives or nettle rash <p>Muscle/skeleton-related:</p> <ul style="list-style-type: none"> painful, swollen joints 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). <p>Reproductive system or breast-related:</p> <ul style="list-style-type: none"> larger breasts than normal in men <p>General conditions:</p> <ul style="list-style-type: none"> fever, generally feeling unwell 	<p>Tell your doctor immediately if you notice any of these side effects. These may be serious side effects of Simvastatin Sandoz. Some of these may be symptoms of an allergic reaction to Simvastatin Sandoz. You may need urgent medical attention.</p>

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. 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 Sandoz contains

Active ingredient (main ingredient)	simvastatin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> pregelatinised maize starch lactose monohydrate microcrystalline cellulose butylated hydroxyanisole ascorbic acid citric acid monohydrate magnesium stearate hypromellose purified talc titanium dioxide iron oxide yellow (Simvastatin Sandoz 5 mg, 10 mg and 20 mg only) iron oxide red (Simvastatin Sandoz 10 mg, 20 mg and 40 mg only) indigo carmine aluminium lake (Simvastatin Sandoz 80 mg only) quinoline yellow aluminium lake (Simvastatin Sandoz 80 mg only).
Potential allergens	sugars as lactose monohydrate

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

What Simvastatin Sandoz looks like

Simvastatin Sandoz 5 mg - yellow, oval, scored, convex, film-coated tablets, coded 'SIM 5' on one side. Available in blisters of 30 tablets (Aust R 114796).

Simvastatin Sandoz 10 mg - pale pink, oval, scored, convex, film-coated tablets, coded 'SIM 10' on one side. Available in blisters of 30 tablets (Aust R 114797).

Simvastatin Sandoz 20 mg - orange, oval, scored, convex, film-coated tablets, coded 'SIM 20' on one side. Available in blisters of 30 tablets (Aust R 114798).

Simvastatin Sandoz 40 mg - pink, oval, scored, convex, film-coated tablets, coded 'SIM 40' on one side. Available in blisters of 30 tablets (Aust R 114800).

Simvastatin Sandoz 80 mg - light green, oval, scored, convex, film-coated tablets, coded 'SIM 80' on one side. Available in blisters of 30 tablets (Aust R 98624).

Not all presentations may be available in Australia.

Who distributes Simvastatin Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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