

Simvastatin Sandoz®

simvastatin tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Simvastatin Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking this medicine against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Simvastatin Sandoz is used for

Simvastatin Sandoz is used to lower high cholesterol and triglyceride levels. It 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 in their

blood. It's a type of blood fat needed by the body for many things, such as building cell walls, making bile acids (which help to digest food) and some hormones.

Cholesterol is present in many foods and is also made in your body by the liver. If your body does not balance the amount of cholesterol it needs with the amount of cholesterol eaten, then your cholesterol levels become too high.

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 your 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.

If you have Coronary Heart Disease, your doctor has prescribed Simvastatin Sandoz to help prolong your life and to lessen the risk of a heart attack or further attacks, or stroke. This medicine may also decrease the risk of needing an operation to increase the blood flow to your heart.

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

Triglycerides

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

As there are mostly no symptoms of high cholesterol or triglycerides, you may not realise you have

increased levels. See your doctor if you are uncertain, as your cholesterol and triglycerides can be measured with a simple blood test.

How Simvastatin Sandoz works

Simvastatin Sandoz contains the active ingredient simvastatin. Simvastatin belongs to a group of medicines called HMG-CoA reductase inhibitors.

It works by reducing the amount of cholesterol made by the liver.

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

Simvastatin Sandoz reduces the 'bad' cholesterol and raises the 'good' cholesterol. In patients with CHD accompanied by high cholesterol levels, Simvastatin Sandoz may slow down the hardening of blood vessels and reduces the risk of new plaque development.

Simvastatin Sandoz affects only the cholesterol and triglycerides made by the liver in your body. It has no effect on cholesterol and triglycerides that come from fats in food. Therefore, Simvastatin Sandoz treatment should be accompanied by a diet that is low in fat and the used fats should be preferably unsaturated and of vegetable origin.

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.

There is no evidence that Simvastatin Sandoz is addictive.

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

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

Before you take Simvastatin Sandoz

When you must not take it

Do not take this medicine if you have an allergy to:

- simvastatin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- 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.

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

- liver disease

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

Do not take this medicine if you are pregnant or plan to become pregnant. Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

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

Do not breastfeed if you are taking this medicine.

It is not known if the active ingredient in Simvastatin Sandoz passes into breast milk. For safety reasons, it is not recommended to breastfeed your baby if you are taking this medicine.

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.

Before you start to take it

Tell your doctor if:

- you intend to become pregnant or plan to breast feed. Simvastatin Sandoz should not be used during pregnancy or while breast-feeding.
- 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.

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as simvastatin
- any foods, preservatives or dyes.

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

- kidney problems
- liver problems. Your doctor will do a blood test to make sure you have no problems with your liver.

Tell your doctor if you drink alcohol regularly.

Simvastatin Sandoz contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

If you have not told your doctor about any of the above, tell him/her before you start taking Simvastatin Sandoz.

Taking other medicines

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

Some medicines and Simvastatin Sandoz may interfere with each other. These include:

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

voriconazole, used to treat certain fungal infections.

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

Taking Simvastatin Sandoz with any of the medicines listed below can increase the risk of muscle problems. Tell your doctor if you take any of the following:

- other medicines used to lower cholesterol levels, e.g. fibrates (such as gemfibrozil) or nicotinic acid (also known as niacin)
- warfarin, or other drugs used to prevent blood clots
- colchicine, used to treat 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 heartbeat.
- digoxin, used to treat heart failure
- certain hepatitis C antiviral agents, such as elbasvir or grazoprevir.

Also tell your doctor if you are taking niacin or a niacin-containing product and you are Chinese.

These medicines may be affected by Simvastatin Sandoz, or may affect how well it works. You may need to take different amounts of your medicine, 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.

How to take Simvastatin Sandoz

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, ask your doctor or pharmacist for help.

How much to take

The amount of Simvastatin Sandoz to be taken 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. To have the best effect, this may need to be increased up to 80 mg daily.

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 the lower doses.

For people with CHD or risk factors for CHD, the usual starting dose is 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.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Simvastatin Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets with a full glass of water.

If you need to break Simvastatin Sandoz, hold the tablet with both hands and snap along the break line.

When to take Simvastatin Sandoz

Take your medicine 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 they are asleep. Therefore, Simvastatin Sandoz is more effective when taken in the evening. It does not matter whether you take it with or without food, but a good time would be after your evening meal.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take Simvastatin Sandoz

Your doctor will determine how long you have to take Simvastatin Sandoz.

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

This medicine helps to lower your cholesterol levels, but 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 medicines for the rest of your life. If you stop taking this medicine, your cholesterol levels may rise again.

If you forget to take it

Take your dose as soon as you remember, and continue to take it 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.

This may increase the chance of getting an unwanted side effect.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Simvastatin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Simvastatin Sandoz

Things you must do

If you become pregnant while taking Simvastatin Sandoz, stop taking it and tell your doctor immediately.

Have your blood fats checked when your doctor says so, to make sure this medicine is working.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Simvastatin Sandoz.

If you are going to have surgery, tell your doctor that you are taking Simvastatin Sandoz.

Your doctor may advise you to stop taking this medicine a few days before surgery.

Things you must not do

Do not stop taking Simvastatin Sandoz without your doctor's permission.

Do not take Simvastatin Sandoz to treat any other complaint unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how Simvastatin Sandoz affects you.

This medicine may cause dizziness or light-headedness in some people, especially after the first dose.

Avoid drinking large quantities of alcohol.

It may increase your chance of Simvastatin Sandoz causing liver problems.

Avoid drinking grapefruit juice.

Grapefruit juice contains some components that influence the metabolism of Simvastatin Sandoz. This increases the risk of Simvastatin Sandoz causing side effects, such as aching muscles, muscle tenderness or weakness, not caused by exercise.

Things that may help your condition

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, a 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 moderate exercise a part of your routine, e.g. walking, cycling or swimming. Ask your doctor for advice before starting exercise.

Smoking - your doctor will advise you to stop smoking.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Simvastatin Sandoz.

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 of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- constipation, diarrhoea, wind
- stomach upset or pain, feeling sick (nausea)
- headache
- dizziness
- nightmares
- memory loss
- sexual dysfunction.

These are the more common side effects of Simvastatin Sandoz.

Mostly, these are mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- 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.

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 Simvastatin Sandoz, particularly the 80mg dose
- older patients (65 years of age and older)
- female patients
- patients with abnormal kidney function
- patients with thyroid problems.

Tell your doctor immediately if you notice any of the following:

- tingling in the hands or feet
- yellowing of the skin and/or eyes, also called jaundice
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- larger breasts than normal in men
- bruising more easily than normal
- skin rash, itchiness
- fever, generally feeling unwell
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- painful, swollen joints.

These may be serious side effects of Simvastatin Sandoz. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Simvastatin Sandoz and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the limbs, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- shortness of breath
- itchy rash or hives.

These are the symptoms of an allergic reaction.

These are serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Also, tell your doctor if you notice:

- hair loss
- muscle cramps
- trouble sleeping
- poor memory, memory loss, confusion
- feelings of depression
- erectile dysfunction
- breathing problems including persistent cough and/or shortness of breath or fever.

These are other side effects that have been reported with Simvastatin Sandoz.

Liver problems can also occur and may be serious. Your doctor will do regular 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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Simvastatin Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light.

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

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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

Product description

What it looks like

Simvastatin Sandoz 5mg: yellow, oval, scored, convex, film-coated tablets, coded 'SIM 5' on one side.

Simvastatin Sandoz 10mg - pale pink, oval, scored, convex, film-coated tablets, coded 'SIM 10' on one side.

Simvastatin Sandoz 20mg - orange, oval, scored, convex, film-coated tablets, coded 'SIM 20' on one side.

Simvastatin Sandoz 40mg - pink, oval, scored, convex, film-coated tablets, coded 'SIM 40' on one side.

Simvastatin Sandoz 80mg - light green, oval, scored, convex, film-coated tablets, coded 'SIM 80' on one side.

They are available in blisters of 30 tablets.

Ingredients

Active ingredients:

Simvastatin Sandoz 5mg - 5mg simvastatin

Simvastatin Sandoz 10mg - 10mg
simvastatin

Simvastatin Sandoz 20mg - 20mg
simvastatin

Simvastatin Sandoz 40mg - 40mg
simvastatin

Simvastatin Sandoz 80mg - 80mg
simvastatin

Inactive ingredients:

- 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 20mg 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 80mg only).

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd ABN
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Australian Register Numbers

Simvastatin Sandoz 5 mg film-coated tablets: AUST R 114796 (blisters)

Simvastatin Sandoz 10 mg film-coated tablets: AUST R 114797 (blisters)

Simvastatin Sandoz 20 mg film-coated tablets: AUST R 114798 (blisters)

Simvastatin Sandoz 40 mg film-coated tablets: AUST R 114800 (blisters)

Simvastatin Sandoz 80 mg film-coated tablets: AUST R 98624 (blisters)