

Ezetimibe/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 Ezetimibe/Simvastatin Sandoz?

Ezetimibe/Simvastatin Sandoz contains the active ingredients ezetimibe and simvastatin. Ezetimibe/Simvastatin Sandoz is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

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

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

Do not use if you have ever had an allergic reaction to Ezetimibe/Simvastatin Sandoz 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 Ezetimibe/Simvastatin Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ezetimibe/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 Ezetimibe/Simvastatin Sandoz?

- The recommended dose is one Ezetimibe/Simvastatin Sandoz 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening.
- For the best effect take Ezetimibe/Simvastatin Sandoz at about the same time each day.

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

5. What should I know while using Ezetimibe/Simvastatin Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Ezetimibe/Simvastatin Sandoz.• If you become pregnant while taking Ezetimibe/Simvastatin Sandoz, tell your doctor.• Have any blood tests your doctor requests to make sure Ezetimibe/Simvastatin Sandoz is right for you.
Things you should not do	<ul style="list-style-type: none">• Do not give Ezetimibe/Simvastatin Sandoz to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Side effects have been reported that may affect your ability to drive or operate machinery. Be careful driving or operating machinery until you know how Ezetimibe/Simvastatin Sandoz affects you.
Drinking alcohol	<ul style="list-style-type: none">• Drinking large quantities of alcohol while taking Ezetimibe/Simvastatin Sandoz may increase your chance of getting liver problems.
Looking after your medicine	<ul style="list-style-type: none">• Keep Ezetimibe/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 Ezetimibe/Simvastatin Sandoz?](#) in the full CMI.

6. Are there any side effects?

Common side effects of Ezetimibe/Simvastatin Sandoz are diarrhoea and muscle pain.

Allergic reactions to ezetimibe, simvastatin or other ingredients of Ezetimibe/Simvastatin Sandoz occur very 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.

Ezetimibe/Simvastatin Sandoz®

Active ingredient(s): *ezetimibe and simvastatin*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Ezetimibe/Simvastatin Sandoz?

Ezetimibe/Simvastatin Sandoz contains the active ingredients ezetimibe and simvastatin.

Ezetimibe/Simvastatin Sandoz helps to lower cholesterol and triglyceride levels.

Ezetimibe/Simvastatin Sandoz is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

Cholesterol

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called 'bad' cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries.

This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called 'good' cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How Ezetimibe/Simvastatin Sandoz works

Ezetimibe/Simvastatin Sandoz reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.

Ezetimibe/Simvastatin Sandoz works by decreasing the absorption of cholesterol in the small intestine and by reducing the amount of cholesterol made in the liver. Ezetimibe/Simvastatin Sandoz does not help you lose weight.

If you have heart disease and a history of heart attack or hospitalisation for unstable angina (chest pain), Ezetimibe/Simvastatin Sandoz reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Your doctor may have prescribed Ezetimibe/Simvastatin Sandoz for another reason. Ask your doctor if you have any questions about why Ezetimibe/Simvastatin Sandoz has been prescribed for you.

Ezetimibe/Simvastatin Sandoz is not addictive.

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

Warnings

Do not use Ezetimibe/Simvastatin Sandoz if:

- you are allergic to ezetimibe, 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 face, lips, mouth, tongue or throat.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant or breast feeding. Ezetimibe/Simvastatin Sandoz is contraindicated (i.e. should not be used) during pregnancy and breastfeeding. If you take this medicine during pregnancy and breastfeeding, your baby may absorb this medicine and it may affect your baby's normal development causing foetal malformations (birth defects) or irreversible damage.
- you have active liver disease or repeated blood tests indicating possible liver problems.
- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- you are taking certain medicines such as gemfibrozil, ciclosporin, danazol, fusidic acid and strong CYP3A4 inhibitors like itraconazole and ketoconazole. Please see Section [3. What if I am taking other medicines?](#) in this CMI for more information.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have kidney disease, diabetes or any other medical conditions
- 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, or have had, any medical conditions, including liver disease or liver problems. Your doctor will do a blood test to make sure you have no problems with your liver.
- 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.
- are taking niacin or a niacin-containing product.
- 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. Ezetimibe/Simvastatin Sandoz should not be used during pregnancy.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. Ezetimibe/Simvastatin Sandoz should not be used while breast feeding.

Use in children and adolescents

- Ezetimibe/Simvastatin Sandoz is used in children and adolescents (10 to 17 years of age) to treat familial hypercholesterolaemia, a type of high cholesterol that is hereditary (i.e. passed on through families).
- Ezetimibe/Simvastatin Sandoz is not recommended for use in children under 10 years of age, as there have been no studies of its effects in this age group.
- Your doctor will assess whether Ezetimibe/Simvastatin Sandoz is suitable for your child. Depending on the pubertal development of your child, Ezetimibe/Simvastatin Sandoz may not be suitable for him or her.

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 Ezetimibe/Simvastatin Sandoz. If you are taking any of them, your doctor may suggest stopping

Ezetimibe/Simvastatin Sandoz temporarily or permanently. These include:

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

Some medicines and Ezetimibe/Simvastatin Sandoz may interfere with each other. These medicines may be affected by Ezetimibe/Simvastatin Sandoz, may affect how well it works, or may increase the risk of side effects with Ezetimibe/Simvastatin Sandoz. You may need different amounts of your medicine, or you may need to take different medicines or take your medicines at different times. These include:

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

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

4. How do I use Ezetimibe/Simvastatin Sandoz?

How much to take

- The recommended dose in adults (18 years and over) is one Ezetimibe/Simvastatin Sandoz 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening. Your

doctor will adjust your Ezetimibe/Simvastatin Sandoz dose depending on your response.

- The recommended dose in adolescents (10 to 17 years of age) with familial hypercholesterolaemia is one Ezetimibe/Simvastatin Sandoz 10/10, 10/20 or 10/40 tablet once a day, in the evening. The maximum recommended dose in adolescents is 10/40 mg.
- Because of the increased risk of muscle problems, the Ezetimibe/Simvastatin Sandoz 10/80 tablet is only for patients at high risk of heart disease problems who have not yet reached their cholesterol goal on lower doses.
- Swallow Ezetimibe/Simvastatin Sandoz with a glass of water.
- Follow the instructions provided and take Ezetimibe/Simvastatin Sandoz until your doctor tells you to stop.

When to take Ezetimibe/Simvastatin Sandoz

- Ezetimibe/Simvastatin Sandoz should be taken 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, Ezetimibe/Simvastatin Sandoz is more effective when taken in the evening.
- Take Ezetimibe/Simvastatin Sandoz about the same time each day. A good time would be after your evening meal. However, it does not matter whether you take it before or after food.
- Taking Ezetimibe/Simvastatin Sandoz at the same time each day will have the best effect. It will also help you remember when to take your dose.
- Your doctor may ask you to take Ezetimibe/Simvastatin Sandoz with other cholesterol lowering agents such as bile acid sequestrants. If you are taking a bile acid sequestrant, such as colestyramine, take your Ezetimibe/Simvastatin Sandoz either at least two hours before or four hours after taking the bile acid sequestrant.

How long to take Ezetimibe/Simvastatin Sandoz

- Ezetimibe/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 Ezetimibe/Simvastatin Sandoz, your cholesterol levels may rise again.

If you forget to use Ezetimibe/Simvastatin Sandoz

Ezetimibe/Simvastatin Sandoz should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet as you would normally.

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

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

If you use too much Ezetimibe/Simvastatin Sandoz

If you think that you have used too much Ezetimibe/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 Ezetimibe/Simvastatin Sandoz?

Things you should do

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

Have your blood fats checked when your doctor says, to make sure Ezetimibe/Simvastatin Sandoz is working. Even if you are taking medicines to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

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

If you are about to have elective surgery, tell your doctor that you are taking Ezetimibe/Simvastatin Sandoz. Your doctor may suggest stopping the tablets a few days before surgery.

Things you should not do

- Do not give Ezetimibe/Simvastatin Sandoz to anyone else, even if they have the same condition as you.

Things to be careful of

- Grapefruit juice should be avoided while taking Ezetimibe/Simvastatin Sandoz. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Ezetimibe/Simvastatin Sandoz.

Things that may help your condition

High cholesterol can be treated in two main ways.

Lifestyle Changes

This includes a cholesterol-lowering diet, increasing physical activity, and weight management. Ask your doctor for advice before increasing physical activity.

Medicines

Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol.

Driving or using machines

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

There have been side effects reported with Ezetimibe/Simvastatin Sandoz that may affect your ability to drive or operate machinery. Individual responses to Ezetimibe/Simvastatin Sandoz may vary.

Drinking alcohol

Avoid drinking large quantities of alcohol.

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

Looking after your medicine

- Keep Ezetimibe/Simvastatin Sandoz in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

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

Store it 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. If you take this medicine after the expiry date has passed, it may not work.

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
Muscle/skeleton related: <ul style="list-style-type: none">• Muscle aches	Speak to your doctor if you have any of these less serious

Gastrointestinal-related: <ul style="list-style-type: none">• Nausea• Stomach irritation• Diarrhoea Heart and circulation-related: <ul style="list-style-type: none">• Hypertension• Hot flush Metabolism and nutrition-related: <ul style="list-style-type: none">• Decreased appetite Head and nervous system-related: <ul style="list-style-type: none">• Headache• Dizziness Respiratory-related: <ul style="list-style-type: none">• Cough General conditions: <ul style="list-style-type: none">• Feeling tired• Pain	side effects and they worry you. <p>These are the more common side effects of Ezetimibe/Simvastatin Sandoz or of either ezetimibe or simvastatin.</p>
Mood-related: <ul style="list-style-type: none">• Depression• Trouble sleeping Head and nervous system-related: <ul style="list-style-type: none">• Tingling or numbness of the hands or feet• Poor memory• Confusion Eye-related: <ul style="list-style-type: none">• Blurred vision and impaired vision 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, that may also occur with fatigue, unexplained weight loss or fever Muscle/skeleton related: <ul style="list-style-type: none">• Muscle rupture (very rare) Skin-related: <ul style="list-style-type: none">• Rash that occurs on the skin or sores in the mouth (lichenoid drug eruptions) (very rare)	Tell your doctor if you notice any of these. <p>These are rare side effects of ezetimibe or simvastatin.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing 	<p>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.</p>
<ul style="list-style-type: none"> skin rash and hives severe skin problems dark coloured urine light coloured bowel motions joint pain bleeding or bruising more easily than normal steady abdominal pain with nausea and vomiting. 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>Liver problems can also occur and may be serious. Your doctor may do blood tests to check your liver. Symptoms may include:</p> <ul style="list-style-type: none"> feel tired or weak loss of appetite upper belly pain dark urine yellowing of the skin or the white of your eyes <p>On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death. Symptoms may include:</p> <ul style="list-style-type: none"> unexplained muscle aches, tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping Ezetimibe/Simvastatin Sandoz). <p>The risk of muscle breakdown is greater at higher doses of Ezetimibe/Simvastatin Sandoz, particularly the 10/80 mg dose and is greater for older patients (65 years of age and older), female patients, patients with kidney problems, and patients with thyroid problems.</p>	<p>Tell your doctor immediately if you notice any of these side effects.</p> <p>These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.</p>

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

In adolescent patients (10 to 17 years of age) there have been no studies longer than 1 year of the effect of taking Ezetimibe/Simvastatin Sandoz on bone development, growth, social and emotional development, or fertility.

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 Ezetimibe/Simvastatin Sandoz contains

Active ingredient (main ingredient)	ezetimibe 10 mg per tablet simvastatin 10, 20, 40 or 80 mg per tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> butylated hydroxyanisole citric acid croscarmellose sodium hypromellose lactose monohydrate ascorbic acid magnesium stearate microcrystalline cellulose propyl gallate iron oxide yellow iron oxide red iron oxide black
Potential allergens	lactose monohydrate

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

What Ezetimibe/Simvastatin Sandoz looks like

Ezetimibe/Simvastatin Sandoz comes in four types of tablets:

Ezetimibe/Simvastatin Sandoz 10/10 – 10 mg Ezetimibe/10 mg Simvastatin: Light tan, mottled, round, biconvex, 6 mm tablets with markings “511” on one side. Available in blister packs of 5, 10 and 30 tablets (Aust R 279097).

Ezetimibe/Simvastatin Sandoz 10/20 – 10 mg Ezetimibe/20 mg Simvastatin: Light tab, mottled, round, biconvex, 8 mm tablets with markings “512” on one side. Available in blister packs of 5, 10 and 30 tablets (Aust R 279102).

Ezetimibe/Simvastatin Sandoz 10/40 – 10 mg Ezetimibe/40 mg Simvastatin: Light tan, mottled, round, biconvex, 10

mm tablets with markings "513" on one side. Available in blister packs of 5, 10 and 30 tablets (Aust R 279098).

Ezetimibe/Simvastatin Sandoz 10/80 – 10 mg Ezetimibe/80 mg Simvastatin: Light tab, mottled, capsule shaped, biconvex, 17.5 x 7.55 mm tablets with markings "515" on one side. Available in blister packs of 5, 10 and 30 tablets (Aust R 279117).

Not all pack sizes may be available in Australia.

Who distributes Ezetimibe/Simvastatin Sandoz

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

This leaflet was prepared in December 2025.

® Registered Trade Mark. The trade marks mentioned in this material are the property of their respective owners.