

PRAVASTATIN SANDOZ®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Pravastatin Sandoz?

Pravastatin Sandoz contains the active ingredient pravastatin sodium. Pravastatin sodium reduces the level of cholesterol in your blood and helps to protect you in other ways from heart attack or stroke. It is more effective if it is taken with a diet low in fat.

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

2. What should I know before I take Pravastatin Sandoz?

Do not use if you have ever had an allergic reaction to pravastatin sodium 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 take Pravastatin Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Pravastatin 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 take Pravastatin Sandoz?

- Pravastatin Sandoz should only be taken as directed by your doctor.
- Your doctor will decide on the dose, this will depend on many factors including your cholesterol level.

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

5. What should I know while taking Pravastatin Sandoz?

Things you should do	<ul style="list-style-type: none">• Call your doctor straight away if you suffer from an allergic reaction to Pravastatin Sandoz, so tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.• Call your doctor straight way if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine suddenly.• Do not give your medicine to anyone else even if they have the same condition as you have.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Pravastatin Sandoz affects you.• Pravastatin Sandoz may cause dizziness in some people. It generally does not interfere with your ability to drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in the original container. If you take it out of its original container it may not keep well.• Keep your medicine in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

There are a number of side effects associated with Pravastatin Sandoz. It is important to be aware of them so that you can identify any symptoms if they occur.

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.

PRAVASTATIN SANDOZ®

Active ingredient: *pravastatin sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Pravastatin 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 taking Pravastatin Sandoz.**

Where to find information in this leaflet:

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

1. Why am I taking Pravastatin Sandoz?

Pravastatin Sandoz contains the active ingredient pravastatin sodium. Pravastatin Sandoz is used to treat people who have had a heart attack or an episode of unstable angina, or who have high blood cholesterol levels. In these people Pravastatin Sandoz can reduce the risk of further heart disease, reduce the possibility of needing a bypass operation, or reduce the risk of having a stroke.

It lowers high blood cholesterol levels (Doctors call this hypercholesterolaemia). It is also used if your cholesterol levels are normal if you have had a heart attack or an episode of unstable angina.

It is used to treat heterozygous familial hypercholesterolaemia in children and adolescent patients aged 8 years and older as an adjunct to diet and lifestyle changes.

If you have had a heart attack, an episode of unstable angina or you have too much cholesterol in your blood, then you have an increased risk of a blood clot forming in your blood vessels and causing a blockage. Blood vessels that become blocked in this way can lead to further heart disease, angina or stroke.

Pravastatin Sandoz may be used to lower lipids in heart or kidney transplant patients, who are also being given immunosuppressive medicine.

It is used to treat long-term (chronic) conditions so it is important that you take your this medicine every day.

It is not addictive or habit forming.

It is only available upon prescription from your doctor.

2. What should I know before I take Pravastatin Sandoz?

Warnings

Do not take Pravastatin Sandoz if:

- you are or may become pregnant
- you are breast feeding
- you have ever had an allergic reaction to pravastatin sodium or any other ingredient listed at the end of this leaflet
- you have ever had liver disease
- you have had muscle pain from any other medicine used to treat high cholesterol.

Check with your doctor if you:

- are taking other medicines or treatment
- drink alcohol regularly
- have ever had liver problems
- have a problem with your kidneys
- are or may become pregnant
- are breastfeeding
- suffer from hormonal disorders
- suffer from central nervous system vascular lesions
- suffer from allergies
- suffer from homozygous familial hypercholesterolaemia, (a doctor will have told you this)
- have increased triglycerides in your blood (a doctor will have told you this also)
- suffer from muscle disease (including pain, tenderness or weakness).

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.

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 may interfere with Pravastatin Sandoz and affect how it works.

It is especially important that you tell your doctor if you are taking any of the following:

- any other medicine to lower cholesterol
- cyclosporin
- ketoconazole
- spironolactone
- cimetidine
- fibrate (e.g. gemfibrozil, fenofibrate)
- cholestyramine and colestipol
- antacids
- macrolide antibiotics (e.g. erythromycin, clarithromycin, roxithromycin)
- propranolol
- bile acid sequestrants
- digoxin
- warfarin or other coumarin anticoagulants
- lenalidomide
- fusidic acid
- colchicine
- nicotinic acid

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

4. How do I take Pravastatin Sandoz?

How much to take

- Pravastatin Sandoz should only be taken as directed by your doctor. Your doctor will decide on the dose, this will depend on many factors including your cholesterol level. The dose for lowering cholesterol is 10 – 80 mg, and is 40 mg for reducing the possibility of a stroke or heart attack.
- The recommended dose is 20 mg once daily for children 8 – 13 years of age and 40 mg once daily in adolescents 14 – 18 years of age, with heterozygous familial hypercholesterolemia. Follow the instructions provided and use Pravastatin Sandoz until your doctor tells you to stop.

When to take Pravastatin Sandoz

- Take your medicine once a day in the evening before bedtime.
- Taking it at the same time each day will have the best effect. It will also help you to remember when to take it.

How to take Pravastatin Sandoz

- Swallow the tablets with a glass of water or another liquid. The tablets can be broken in half. If you need to break Pravastatin Sandoz, hold the tablet with both hands and snap along the break line.
- Pravastatin Sandoz can be taken with or without food.

How to long to take Pravastatin Sandoz

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

- This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to use Pravastatin Sandoz

Pravastatin Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, 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.

If you use too much Pravastatin Sandoz

If you think that you have used too much Pravastatin 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 taking Pravastatin Sandoz?

Call your doctor straight away if you:

- suffer from an allergic reaction to Pravastatin Sandoz, so tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.
- have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.

Remind any doctor, dentist, pharmacist or other health professionals you visit that you are using Pravastatin Sandoz.

Things you should not do

- Do not stop taking this medicine suddenly.
- Do not give your medicine to anyone else even if they have the same condition as you have.

Driving or using machines

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

Pravastatin Sandoz may cause dizziness and visual disturbances in some people. It generally does not interfere with your ability to drive or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in the original container. If you take it out of its original container it may not keep well.
- Keep your medicine 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.

When to discard your medicine

The expiry date is printed on the pack. Do not take it after the expiry date or if the tablets have changed in appearance, colour or taste.

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
Nervous system related <ul style="list-style-type: none">• Dizziness.• Tiredness.• Headache or sleep disturbances including insomnia. Vision related <ul style="list-style-type: none">• Blurred or double vision. Gastrointestinal related <ul style="list-style-type: none">• Indigestion.• Nausea.• Vomiting.• Stomach pain or discomfort.• Diarrhoea.• Constipation.• Wind. Skin and hair related <ul style="list-style-type: none">• Itching.• Pimples.• Hives.• Rashes.	Speak to your doctor if you have any of these less serious side effects and they worry you. Your doctor may arrange blood tests

<ul style="list-style-type: none">• Scalp and hair problems (including hair loss). Urinary Related <ul style="list-style-type: none">• Bladder problems (painful or more frequent urination, having to pass urine at night). Genital Related <ul style="list-style-type: none">• Sexual dysfunction.	
--	--

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Unexplained muscle pain.• Muscle rupture.• Tenderness.• Weakness.• Muscle cramps.	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.

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.

If you take too much (overdose) or someone else has taken too much Pravastatin Sandoz, call your doctor immediately.

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 Pravastatin Sandoz contains

Active ingredient (main ingredient)	pravastatin sodium
Other ingredients (inactive ingredients)	microcrystalline cellulose, lactose monohydrate, dibasic sodium phosphate, croscarmellose sodium, sodium lauryl sulphate, povidone, iron oxide red CI77491, colloidal

	anhydrous silica, magnesium stearate
Potential allergens	lactose

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

What Pravastatin Sandoz looks like

Pravastatin Sandoz comes in four types of tablets:

Pravastatin Sandoz 10 mg - light brown, oval tablet, scored on both sides and marked with "P10" (Aust R 152451).

Pravastatin Sandoz 20 mg - light brown, oval tablet, scored on both sides and marked with "P20" (Aust R 152458).

Pravastatin Sandoz 40 mg - light brown, oval tablet, scored on both sides and marked with "P40" (Aust R 152450).

Pravastatin Sandoz 80 mg - light brown, oval tablet, marked with "HLP80" (Aust R 152452).

Available in blister packs of 30 tablets.

Not all strengths may be marketed.

Who distributes Pravastatin 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.