

AMLODIPINE 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 Amlodipine Sandoz?

Amlodipine Sandoz contains the active ingredient amlodipine besilate. Amlodipine Sandoz is used to treat high blood pressure and angina pectoris (chest pain due to the heart not getting enough oxygen). Amlodipine Sandoz is not for the relief of a sudden attack of angina.

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

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

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

3. What if I am taking other medicines?

Some medicines may interfere with Amlodipine 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 Amlodipine Sandoz?

- The usual dose of Amlodipine Sandoz is 5 mg each day. Your doctor may increase this to 10 mg each day.
- You must take Amlodipine Sandoz every day. Continue taking it for as long as your doctor tells you.
- Swallow the tablet whole with a full glass of water.

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

5. What should I know while using Amlodipine Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Amlodipine Sandoz.• Keep all your doctor's appointments so that your progress can be checked.• Tell your doctor immediately if you become pregnant while taking Amlodipine Sandoz.
Things you should not do	<ul style="list-style-type: none">• Do not take Amlodipine Sandoz to treat any other conditions unless your doctor tells you to.• Do not give this medicine to anyone else, even if they have the same condition as you.
Things to be careful of	<ul style="list-style-type: none">• Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice.
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 this medicine affects you.• Amlodipine Sandoz may cause dizziness or drowsiness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them.• Keep Amlodipine Sandoz in a cool dry place, away from moisture, heat, or sunlight where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects of Amlodipine Sandoz include headache, dizziness, flushing, tiredness, drowsiness or sleepiness, stomach pain or nausea. Serious side effects may also occur while taking Amlodipine Sandoz. Serious side effects include fast or irregular heart beats; chest pain (which may or may not be associated with exertion (angina) that lasts longer, is more severe or occurs more often); shortness of breath; symptoms of allergy (such as skin rash and/or tingling); and severe upper stomach pain, often with nausea and vomiting.

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.

Amlodipine Sandoz®

Active ingredient(s): *amlodipine besilate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Amlodipine Sandoz?

Amlodipine Sandoz contains the active ingredient amlodipine besilate. Amlodipine Sandoz belongs to a group of medicines called calcium channel blockers or calcium ion antagonists. It works by relaxing the blood vessels in your body, making it easier for your heart to pump blood around the body. It also widens the blood vessels leading to your heart and so helps to increase the supply of oxygen-rich blood to the heart.

Calcium channel blockers do not change the amount of calcium in your blood or bones.

Amlodipine Sandoz is used to:

- **lower high blood pressure (hypertension)**
There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems.
- **treat angina pectoris**
Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck, and sometimes to the shoulders and back. The pain of angina is due to a shortage of oxygen to the heart.
Amlodipine Sandoz is NOT for the relief of a sudden attack of angina. If such an attack occurs, you should take other medication that your doctor will have given to you.

Ask your doctor if you have any questions about why Amlodipine Sandoz has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Warnings

Do not use Amlodipine Sandoz if:

- you are allergic to amlodipine, other calcium channel blockers (e.g. felodipine, nifedipine or lercanidipine) or any of the ingredients listed at the end of this leaflet.
 - Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.
- Always check the ingredients to make sure you can use this medicine. Check with your doctor or pharmacist if you are unsure.
- **The expiry date on the pack has passed, or the package 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, or have had, any other medical conditions, including:
 - heart problems, including heart failure
 - liver problems
- take any medicines for any other condition
- have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

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.

This medicine may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Do not breast-feed if you are taking this medicine.

The active ingredient in Amlodipine Sandoz passes into breast milk. Your baby may be affected.

Use in Children

- Amlodipine Sandoz is not recommended for use in children as the safety and efficacy in this age group have not been established.

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 Amlodipine Sandoz and affect how it works. Tell your doctor if you are taking any of the following:

- other medicines used to treat angina, such as diltiazem
- some antibiotics, such as erythromycin, clarithromycin or rifampicin
- some antifungals, such as ketoconazole or itraconazole
- anti-proteases, medicines used to treat HIV infection, such as ritonavir
- simvastatin, a medicine used to lower cholesterol
- ciclosporin, tacrolimus, sirolimus or everolimus, medicines used to suppress the immune system
- temsirolimus, a medicine used to treat kidney cancer
- St John's Wort.

You may need different amounts of your medicine, or you may need to take different medicines or take your medicines at different times.

Your doctor and pharmacist have more information on medicine to be careful with or avoid while taking Amlodipine 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 Amlodipine Sandoz.

4. How do I use Amlodipine Sandoz?

Take Amlodipine Sandoz exactly as your doctor has prescribed.

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 box, ask your doctor or pharmacist to help.

How much to take

- The usual dose of Amlodipine Sandoz is 5 mg each day. Your doctor may increase this to 10 mg each day.
- Your doctor may prescribe another dose of Amlodipine Sandoz depending on your condition and how you respond to this medicine.

When to take Amlodipine Sandoz

- **Take your tablet about the same time each day, either morning or evening.**
- Taking it at the same time each day will have the best effect and also makes it easier to remember when to take it.

How to take Amlodipine Sandoz

- Swallow the tablet with a full glass of water.
- If you need to break Amlodipine Sandoz, hold the tablet with both hands and snap along the break line.



- Amlodipine Sandoz can be taken with or without food.

How long to take Amlodipine Sandoz

You must take Amlodipine Sandoz every day. 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 Amlodipine Sandoz

If you miss your dose at the usual time, and it is less than 12 hours before 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(s) 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 the dose you missed.

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

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

If you use too much Amlodipine Sandoz

If you take too much Amlodipine Sandoz, you may feel dizzy, light-headed or faint or have breathing difficulty and an irregular heartbeat.

If you think that you have used too much Amlodipine 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 Amlodipine Sandoz?

Things you should do

- If you become pregnant while taking Amlodipine Sandoz, tell your doctor immediately.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Amlodipine Sandoz.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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

Things you should not do

- Do not give Amlodipine Sandoz to anyone else, even if they have the same condition as you.
- Do not take Amlodipine Sandoz to treat any other complaints unless your doctor tells you to.

Things to be careful of

Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Amlodipine Sandoz. Drinking very large quantities (over 1.2 litres) of grapefruit juice each day while taking Amlodipine Sandoz may increase the effects of this medicine.

Driving or using machines

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

Amlodipine Sandoz may cause dizziness or light-headedness in some people, especially after the first dose or after the dose has been increased.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Things that would be helpful for your high blood pressure or angina

Some self-help measures suggested below may assist your condition. Your doctor or pharmacist can give you more information about these measures.

- Weight: Your doctor may suggest losing some weight. Some people may need a dietician to plan a suitable diet to help with weight loss.
- Exercise: Regular exercise helps lower blood pressure and strengthen the heart. It is important not to overdo it. Before commencing regular exercise you should consult your doctor who will suggest the most suitable exercise for you. If you feel uncomfortable when exercising or experience symptoms such as chest pain or breathlessness see your doctor.

- Alcohol: Your doctor may advise you to limit your alcohol intake.
- Salt: Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt at the table or in cooking.
- Smoking: Your doctor may advise you to stop smoking or at least cut down.

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.

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

Store it in a cool dry place below 25°C 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.

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

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
<p>These are more common side effects of Amlodipine Sandoz:</p> <ul style="list-style-type: none">• headache• dizziness• flushing• tiredness• drowsiness or sleepiness• stomach pain or nausea	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<p>These may or may not be due to Amlodipine Sandoz, but you should tell your doctor:</p> <ul style="list-style-type: none">• indigestion• sexual problems	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">changes in heart beat either fast or slowswelling of the ankles, feet, face or handstingling or numbness of the hands or feetdizziness or light-headedness on standing up from a sitting or lying positionunusual tiredness or weaknessmuscle cramps or achesjoint paineye pain or change in visionchanges in mood, feeling anxious or nervoussymptoms of liver disease such as itching, yellowing of the skin and eyes, and dark coloured urineunusual movements, including trembling and shaking of the hands, and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs	<p>Call your doctor immediately if you notice any of these serious side effects.</p> <p>These may be serious side effects that may need urgent medical attention.</p>

Very serious side effects	What to do
<ul style="list-style-type: none">fast or irregular heart beatschest painchest pain associated with exertion (angina) that lasts longer, is more severe or occurs more oftenshortness of breathsymptoms of allergy such as skin rash and/or itchingsevere upper stomach pain, often with nausea and vomiting.	<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>

If you are 65 years or older, you should be especially careful when you are taking Amlodipine Sandoz. Report any side effects promptly to your doctor.

Some people in this age group are more likely to experience side effects such as swelling of the feet and ankles, muscle cramps and dizziness.

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 Amlodipine Sandoz contains

Active ingredient (main ingredient)	amlodipine besilate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">sodium starch glycollatecalcium hydrogen phosphatemicrocrystalline cellulosemagnesium stearate

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

What Amlodipine Sandoz looks like

Amlodipine Sandoz 5 mg – white or almost white, oblong tablet, scored on one side and coded "5" on the other. Available in blisters of 30 tablets (Aust R 124578).

Amlodipine Sandoz 10 mg – white or almost white, oblong tablet, scored on one side and coded "10" on the other. Available in blisters of 30 tablets (Aust R 124582).

Who distributes Amlodipine Sandoz

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

This leaflet was prepared in November 2024.

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