

BLOOMS AMLODIPINE

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 Blooms Amlodipine?

Blooms Amlodipine contains the active ingredient amlodipine besilate. Blooms Amlodipine is used to treat high blood pressure and angina pectoris. Blooms Amlodipine is not for the relief of a sudden attack of angina.

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

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

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

3. What if I am taking other medicines?

Some medicines may interfere with Blooms Amlodipine 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 Blooms Amlodipine?

- The usual dose of Blooms Amlodipine is one 5 mg tablet each day. Your doctor may increase this to one 10 mg tablet each day. Your doctor may prescribe another dose of Blooms Amlodipine depending on your condition and how you respond to this medicine.
- Swallow the tablet whole with a full glass of water.

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

5. What should I know while using Blooms Amlodipine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Blooms Amlodipine.• Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice.
Things you should not do	<ul style="list-style-type: none">• Do not give Blooms Amlodipine to anyone else, even if they have the same condition as you.• Do not take Blooms Amlodipine to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how this medicine affects you.• Blooms Amlodipine 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.
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">• Store tablets below 25°C.

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

6. Are there any side effects?

Common side effects: headache, dizziness, flushing, tiredness, drowsiness or sleepiness, stomach pain or nausea

Serious side effects: changes in heart beat (fast or slow), swelling of the ankles, feet, face of hands, tingling or numbness of the hands or feet, muscle cramps or aches, changes in mood, feeling anxious or nervous.

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.

Blooms Amlodipine

Active ingredient(s): *amlodipine besilate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Blooms Amlodipine?

Blooms Amlodipine contains the active ingredient amlodipine besilate. Blooms Amlodipine 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.

Blooms Amlodipine is used to treat high blood pressure and angina pectoris. Blooms Amlodipine 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 Blooms Amlodipine has been prescribed for you.

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

Warnings

Do not use Blooms Amlodipine if:

- you are allergic to amlodipine, other medicines of this drug class (Felodipine, nifedipine or lercandipine) or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Before you start to take it

Check with your doctor if you:

- are pregnant or intend to become pregnant
- are breastfeeding
- 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.

If you have not told your doctor about any of the above, tell them before you take any Blooms Amlodipine.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in Children

- Blooms Amlodipine 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 Blooms Amlodipine and affect how it works. This includes:

- 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.

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

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

4. How do I use Blooms Amlodipine?

How much to take

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

When to take Blooms Amlodipine

- **Blooms Amlodipine may be taken at any time of the day.**
- **However, take your tablet about the same time each day, either morning or evening.** This will help you to get the best effect and also makes it easier to remember when to take it.

How to take Blooms Amlodipine

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



- Blooms Amlodipine can be taken with or without food.

How to long to take Blooms Amlodipine

- You must take Blooms Amlodipine 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 Blooms Amlodipine

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(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.

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

If you use too much Blooms Amlodipine

If you take too much Blooms Amlodipine, you may feel dizzy, light-headed or faint or have an irregular heart beat.

If you think that you have used too much Blooms Amlodipine, 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 Blooms Amlodipine?

Things you should do

- **If you become pregnant while taking Blooms Amlodipine, tell your doctor immediately.**
- **If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Blooms Amlodipine.**
- **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 Blooms Amlodipine.

Things you should not do

- Do not give Blooms Amlodipine to anyone else, even if they have the same condition as you.
- Do not take Blooms Amlodipine to treat any other complaints unless your doctor tells you to.
- 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 Blooms Amlodipine. Drinking very large quantities (over 1.2 litres) of grapefruit juice each day while taking Blooms Amlodipine 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 Blooms Amlodipine affects you.

Blooms Amlodipine 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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. Blooms Amlodipine helps most people with high blood pressure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. 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
General Disorders: <ul style="list-style-type: none"> • headache • dizziness • tiredness • drowsiness or sleepiness • dizziness or light-headedness on standing up from a sitting or lying position 	Speak to your doctor if you have any of these less serious side effects and they worry you. They are generally mild and do not cause patients to stop taking Blooms Amlodipine.
Gut or Gastrointestinal related: <ul style="list-style-type: none"> • stomach pain or nausea • indigestion 	
Others:	

- sexual problems
- flushing

Serious side effects

Serious side effects	What to do
Muscle-joint related: <ul style="list-style-type: none"> • swelling of the ankles, feet, face or hands • tingling or numbness of the hands or feet • muscle cramps or aches • joint pain 	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.
Brain related: <ul style="list-style-type: none"> • changes in mood, feeling anxious or nervous 	
Liver related: <ul style="list-style-type: none"> • itching, yellowing of the skin and eyes, and dark coloured urine 	
Gut or Gastrointestinal related: <ul style="list-style-type: none"> • severe upper stomach pain, often with nausea and vomiting 	
Allergy related: <ul style="list-style-type: none"> • swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing. • shortness of breath • symptoms of allergy such as skin rash and/or itching 	
Heart related: <ul style="list-style-type: none"> • changes in heart beat (fast or slow) • fast or irregular heart beats • chest pain • chest pain associated with exertion (angina) that lasts longer, is more severe or occurs more often. 	
Others: <ul style="list-style-type: none"> • unusual tiredness or weakness • eye pain or change in vision • unusual movements, including trembling and shaking of the hands, and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs 	

If you are 65 years or older, you should be especially careful when you are taking Blooms Amlodipine.

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 Blooms Amlodipine contains

Active ingredient (main ingredient)	amlodipine besilate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium starch glycollate• calcium hydrogen phosphate• microcrystalline cellulose• magnesium stearate

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

What Blooms Amlodipine looks like

Blooms Amlodipine 5mg – white or almost white, oblong tablet, scored on one side and coded "5" on the other. Available in blisters of 30 tablets (Aust R 395290).

Blooms Amlodipine 10mg – white or almost white, oblong tablet, scored on one side and coded "10" on the other. Available in blisters of 30 tablets (Aust R 395291).

Who distributes Blooms Amlodipine

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Tel: 1800 726 369

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