

APO-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 APO-AMLODIPINE?

APO-AMLODIPINE contains the active ingredient amlodipine (besilate).

APO-AMLODIPINE is used to lower high blood pressure (hypertension) and treat angina pectoris.

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

2. What should I know before I use APO-AMLODIPINE?

Do not use if you have ever had an allergic reaction to amlodipine, other calcium channel blockers, or any of the ingredients listed at the end of the CMI.

For more information, see Section [2. What should I know before I use APO-AMLODIPINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-AMLODIPINE and affect how it works. 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.

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 APO-AMLODIPINE?

- Take your tablet at about the same time each day.
- APO-AMLODIPINE can be taken with or without food.
- Take APO-AMLODIPINE exactly as your doctor has prescribed.
- More instructions can be found in Section [4. How do I use APO-AMLODIPINE?](#) in the full CMI.

5. What should I know while using APO-AMLODIPINE?

Things you should do	<ul style="list-style-type: none">• Tell any doctors, dentists and pharmacists who are treating you that you are taking APO-AMLODIPINE.• Tell your doctor if you become pregnant while taking APO-AMLODIPINE.
Things you should not do	<ul style="list-style-type: none">• Do not take APO-AMLODIPINE to treat any other conditions unless your doctor says so.• Do not give this medicine to anyone else, even if their symptoms are similar to yours.• Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice.
Driving or using machines	<ul style="list-style-type: none">• APO-AMLODIPINE may cause dizziness or drowsiness in some people and affect alertness. If affected, do not drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Keep APO-AMLODIPINE Tablets in a cool dry place where the temperature is below 30°C. Protect from light.

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

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The serious side effects are: signs of allergy; fast or irregular heart beats; chest pain; shortness of breath; severe upper stomach pain, often with nausea and vomiting. The common side effects are headache; dizziness; flushing; tiredness; drowsiness or sleepiness; stomach pain or nausea.

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.

APO-AMLODIPINE Tablets

Active ingredient(s): *Amlodipine (besilate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-AMLODIPINE tablets. 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 risks of you taking APO-AMLODIPINE against the benefits this medicine is expected to have for you.

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 APO-AMLODIPINE.

Keep this leaflet with your medicine. You may need to read it again.

Where to find information in this leaflet:

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

1. Why am I using APO-AMLODIPINE?

APO-AMLODIPINE 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.

APO-AMLODIPINE is not for the relief of a sudden attack of angina. Your doctor will give you other medication to treat this.

How it works:

APO-AMLODIPINE belongs to a group of medicines called calcium channel blockers or calcium ion antagonists. They work by widening your blood vessels, making it easier for your heart to pump blood around the body and help increase the supply of blood and oxygen to your heart. Calcium channel blockers do not change the amount of calcium in your blood or bones.

Your doctor may have prescribed APO-AMLODIPINE for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Use in Children

There is not enough information to recommend the use of this medicine in children.

2. What should I know before I use APO-AMLODIPINE?

Warnings

Do not use APO-AMLODIPINE if:

- you have ever had an allergic reaction to amlodipine (including Norvasc) or other calcium channel blockers. These medicines include felodipine (Plendil ER, Agon SR, Felodur ER), nifedipine (Adalat, Adalat Oros, Nifecard, Nifedipine-BC, Nifehexal, Nyefax, SBPA Nifedipine) or lercanidipine (Zanidip) (Not all brands are given). Check with your doctor or pharmacist if you are unsure. Some of the symptoms of an allergic reaction to APO-AMLODIPINE may include a skin rash similar to hives, itchiness, shortness of breath, Wheezing or difficulty breathing, swelling of the face, lips or tongue or other parts of the body.
- you are allergic to any of the ingredients listed at the end of this leaflet.

If you are not sure whether you should be taking APO-AMLODIPINE, talk to your doctor.

Do not use APO-AMLODIPINE if the packaging is torn or shows signs of tampering. Do not use APO-AMLODIPINE beyond the expiry date printed on the pack.

Check with your doctor or pharmacist if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
 - heart problems, including heart failure
 - liver problems.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given APO-AMLODIPINE.

Your doctor will advise you whether or not to take APO-AMLODIPINE or if you need to adjust the dose or adapt your treatment.

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

Tell your doctor if you are pregnant or plan 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.

It is not known if the active ingredient in APO-AMLODIPINE passes into breast milk or if your baby may be affected.

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

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 be affected by APO-AMLODIPINE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will advise you.

In particular, you should tell your doctor if you are taking or have recently taken medicines like:

- 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 or tacrolimus, sirolimus or everolimus, medicines used to suppress the immune system
- temsirolimus, a medicine used to treat kidney cancer
- St John's Wort.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking APO-AMLODIPINE.

4. How do I use APO-AMLODIPINE?

Take amlodipine tablets exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. 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 for help.

How much to take

The usual dose of APO-AMLODIPINE is one 5 mg tablet each day, although a 2.5 mg dose may be prescribed in some cases.

Your doctor may increase this to one 10 mg tablet each day.

Your doctor may prescribe another dose of APO-AMLODIPINE depending on your condition and how you respond to this medicine.

When to take / use APO-AMLODIPINE

Take your tablet at about the same time each day, either morning or evening.

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

You must take APO-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.

How to take APO-AMLODIPINE?

- Swallow the tablet whole with a full glass of water.
- APO-AMLODIPINE 5 mg tablets can be divided in half along the scoreline if your doctor has prescribed a 2.5 mg dose.
- APO-AMLODIPINE can be taken with or without food.
- If you accidentally take a larger dose than recommended, tell your doctor immediately.
- If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you forget to use APO-AMLODIPINE

If you miss a dose and it is less than 12 hours from when you should take it, take it straight away, then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.

Do not take a double dose to make up for the dose that 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 to take your medicine, ask your pharmacist for some hints.

If you use too much APO-AMLODIPINE

If you think that you have used too much APO-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. You may need urgent medical attention.

You may need urgent medical attention.

If you take too many tablets, you may feel dizzy, lightheaded, faint, have breathing difficulty and an irregular heartbeat.

5. What should I know while using APO-AMLODIPINE?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking APO-AMLODIPINE.

If you are about to start any new medicine, tell your doctor or pharmacist that you are taking APO-AMLODIPINE.

If you become pregnant while taking APO-AMLODIPINE tell your doctor immediately.

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.

Things you should not do

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

Driving or using machines

Be careful driving or operating machinery until you know how APO-AMLODIPINE affects you.

Amlodipine may cause dizziness or drowsiness in some people and affect alertness.

If this occurs, do not drive, operate machinery or do things that could be dangerous if you are not alert.

Effects of food

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 APO-AMLODIPINE.

Drinking very large quantities (over 1.2 litres) of grapefruit juice each day while taking APO-AMLODIPINE may increase the effects of this medicine.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

- 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 unusual 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 APO-AMLODIPINE tablets in the original pack until it is time to take them.
- Keep APO-AMLODIPINE tablets in a cool dry place where the temperature is below 30°C. Protect from light.

Do not store APO-AMLODIPINE, or any other medicine, in the bathroom or near a sink.

Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• headache• dizziness• flushing• tiredness• drowsiness or sleepiness• stomach pain or nausea.	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • indigestion • sexual problems. 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p> <p>These may or may not be due to APO-AMLODIPINE but you should tell your doctor.</p>
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	may need urgent medical attention or hospitalisation.
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If you are 65 years or older, you should be especially careful while taking APO-AMLODIPINE. Report any side effects promptly to your doctor.

Some people in this age group may be 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.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • changes in heart beat either fast or slow • swelling of the ankles, feet, face or hands • tingling or numbness of the hands or feet • dizziness or light-headedness on standing up from a sitting or lying position • unusual tiredness or weakness • muscle cramps or aches • joint pain • eye pain or change in vision • changes in mood, feeling anxious or nervous • symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark coloured urine • 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. 	<p>Call your doctor straight away if you notice any of these serious side effects.</p> <p>These may be serious side effects that may need urgent medical attention</p>
<ul style="list-style-type: none"> • fast or irregular heart beats • chest pain • chest pain 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 itching • severe upper stomach pain, often with nausea and vomiting. 	<p>Tell your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>The above list includes very serious side effects. You</p>

7. Product details

This medicine is available with a doctor's prescription.

What APO-AMLODIPINE contains

Active ingredient (main ingredient)	Amlodipine besilate
Other ingredients (inactive ingredients)	APO-AMLODIPINE tablets contain: <ul style="list-style-type: none"> • lactose • microcrystalline cellulose • maize starch • magnesium stearate
Potential allergens	Contains sugars as lactose.

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

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

What APO-AMLODIPINE looks like

2.5 mg tablets: white to off-white, round, unscored, engraved tablets "APO" on one side and "AML" over "2.5" on the other side.

(Blister): AUST R 135120.

(Bottle): AUST R 135144.

5 mg tablets: white to off-white, round, scored tablets, engraved "AML" over score "5" on one side and "APO" on the other side.

(Bottle): AUST R 135145.

10 mg tablets: white to off-white, round, unscored tablets, engraved "APO" on one side and "AML" over "10" on the other side.

(Bottle): AUST R 135146.

Available in blister packs and bottles of 30 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Who distributes APO-AMLODIPINE

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in December 2024