

APO-Amlodipine

contains the active ingredient, amlodipine (am-load-i-peen) besylate

Consumer Medicine Information

For a copy of a large print leaflet Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about amlodipine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Amlodipine. It contains the active ingredient amlodipine (as amlodipine besylate).

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

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

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

How it works

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.

Use in children

Do not give amlodipine to a child. Amlodipine is not recommended for use in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are sensitive to, or have had an allergic reaction to, amlodipine, other calcium channel blockers, or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take

any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver problems
 - heart disease, including heart failure.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with amlodipine. These include:

- 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
- cyclosporin or tacrolimus, medicines used to suppress the immune system
- St John's Wort.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with amlodipine.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how many amlodipine tablets to take each day. This will depend on your condition and whether you are taking any other medicines.

The usual dose of 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 amlodipine, depending on your condition and how you respond to this medicine.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablet with a full glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take this medicine with or without food.

How long to take it for

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

Do not stop taking it unless your doctor tells you to - even if you feel better.

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.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how amlodipine affects you.

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

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

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.

Drinking very large quantities (over 1.2 liters) of grapefruit juice each day while taking amlodipine may increase the effects of this medicine.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking amlodipine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- headache
- dizziness
- flushing
- tiredness
- drowsiness or sleepiness
- stomach pain or nausea.

Tell your doctor if you experience any of the following:

- indigestion
- sexual problems.

These may or may not be due to amlodipine but you should tell your doctor.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention.

- 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.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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
- severe upper stomach pain, often with nausea and vomiting.

If you are 65 years or older, you should be especially careful while taking 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 if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to amlodipine, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Amlodipine looks like

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

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

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

Available in blister packs and bottles of 30 tablets.

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

Ingredients

Each tablet contains 2.5 mg, 5 mg or 10 mg as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- microcrystalline cellulose
- maize starch
- magnesium stearate.

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

Australian Registration Numbers

APO-Amlodipine 2.5 mg tablets (blister): AUST R 135120.

APO-Amlodipine 5 mg tablets (blister): AUST R 135124.

APO-Amlodipine 10 mg tablets (blister): AUST R 135125.

APO-Amlodipine 2.5 mg tablets (bottle): AUST R 135144.

APO-Amlodipine 5 mg tablets (bottle): AUST R 135145.

APO-Amlodipine 10 mg tablets (bottle): AUST R 135146.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was prepared in November 2015.