

Apo-Amlodipine

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

For a copy of a large print leaflet, ph: 1800 195 055

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about about Apo-Amlodipine.

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 they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Apo-Amlodipine is used for

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

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.

How Apo-Amlodipine 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.

Apo-Amlodipine is also used to 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 have given you other medication to treat this.

Your doctor may have prescribed Apo-Amlodipine for another purpose.

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

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

Before you take Apo-Amlodipine

When you must not take it

Do not take Apo-Amlodipine if:

- * **you have ever had an allergic reaction to the active ingredient, amlodipine, or other calcium channel blockers.**

These medicines include:

- Felodipine (Plendil ER, Agon SR, Felodur ER)
- Nifedipine (Adalat, Adalat Oros, Nifecard, Nifedipine-BC, Nifehexal, Nyefax, SBP A Nifedipine)
- Lercanidipine (Zanidip).(Not all brands are given).

Some of the symptoms of an allergic reaction to Apo-Amlodipine may include a skin rash similar to hives, itchiness, shortness of breath, swelling of the face, lips or tongue.

- * **you are allergic to any of the ingredients (including lactose) listed at the end of this leaflet.**

Apo-Amlodipine is not recommended for use in children as there have been no studies of its effects in children.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if:

- * **you are pregnant or intend to become pregnant while taking Apo-Amlodipine.**

Medicines like Apo-Amlodipine may affect the developing baby if you take it during pregnancy. Your doctor will discuss the possible risks and benefits of taking Apo-Amlodipine during pregnancy.

- * **you are breast-feeding or wish to breast-feed.**
Your doctor will discuss the risks and benefits of taking Apo-Amlodipine when breast-feeding.
- * **you are allergic to any foods, dyes, preservatives or any other medicines.**
- * **you have any health problems, including heart disease such as heart failure, liver problems, any other allergies.**

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Apo-Amlodipine may interfere with each other.

Your doctor or pharmacist has a complete list of medicines to be careful with or avoid while taking Apo-Amlodipine.

If you have not told your doctor or pharmacist about these things, tell them before you start taking Apo-Amlodipine.

How to take Apo-Amlodipine

Take Apo-Amlodipine exactly as your doctor as 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 for help.

How much to take

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

How to take it

Swallow the tablet with a full glass of water.

Apo-Amlodipine 5 mg Tablets can be divided in half along the scoreline, if your doctor has prescribed half a tablet.

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

You must take Apo-Amlodipine every day. Continue taking your medicine for as long as your doctor tells you.

When to take it

Take your medicine at about the same time each day.

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

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

If you forget to take it

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Apo-Amlodipine.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many tablets, you may feel dizzy, light-headed or faint and have an irregular heart beat.

While you are taking Apo-Amlodipine

Things you must do

Tell any other doctors, dentists, or pharmacists who treat you that you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Apo-Amlodipine.

If you become pregnant while taking Apo-Amlodipine tell your doctor immediately.

Things you must not do

Do not take Apo-Amlodipine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Apo-Amlodipine affects you.

Apo-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.

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

Some self-help measures suggested below may assist your condition.

Talk to your doctor about these for more information:

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Apo-Amlodipine.

Apo-Amlodipine helps most people but it may have some unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor if you experience any of the following and they worry you:

- * swelling of the ankles, feet, face or hands
- * headache
- * dizziness
- * flushing
- * palpitations
- * tiredness
- * drowsiness or sleepiness
- * stomach pain or nausea
- * indigestion
- * unusual tiredness or weakness.

These are the more common side effects of Apo-Amlodipine.

Tell your doctor if you experience any of the following:

- * muscle cramps or aches
- * sexual problems
- * swollen gums
- * constipation
- * weight gain
- * sleeplessness
- * feeling nervous, depressed or moody
- * changes in vision or sight
- * loss or thinning of hair

- * ringing in the ears.

These may or may not be due to Apo-Amlodipine but you should tell your doctor if they worry you.

Tell your doctor immediately if you notice any of the following:

- * changes in heart beat either fast or slow
- * chest pain
- * dizziness or light-headedness on standing up from a sitting or lying position
- * shortness of breath
- * symptoms of allergy such as skin rash and/or itching
- * symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark coloured urine.

These may be serious side effects that may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you notice any other symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you don't understand anything in this list.

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.

After taking Apo-Amlodipine

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Apo-Amlodipine looks like

Apo-Amlodipine tablets are uncoated tablets and are available in 2 strengths:

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

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

A pack contains 30 tablets.

Ingredients

Active ingredient:

Amlodipine 5 mg or 10 mg respectively (as amlodipine besylate), as active ingredient.

Other 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 5 mg tablets (blister): AUST R 135124.

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

Sponsor

Apotex Pty Ltd
ABN 52 096 916 418
66 Waterloo Road
North Ryde NSW 2113
Australia

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