

AMLODIPINE AN

amlodipine (as besilate)

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start AMLODIPINE AN.

This leaflet answers some common questions about AMLODIPINE AN. 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 AMLODIPINE AN against the benefits it is expected to 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 AMLODIPINE AN is used for

AMLODIPINE AN 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.

AMLODIPINE AN 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.

AMLODIPINE AN 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.

AMLODIPINE AN is not for the relief of a sudden attack of angina. Your doctor may have given you other medication to treat this.

Your doctor may have prescribed AMLODIPINE AN for another purpose. Ask your doctor if you have any questions about why AMLODIPINE AN has been prescribed for you.

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

AMLODIPINE AN is not recommended for use in children as there have been no studies of its effects in children.

Before you take AMLODIPINE AN

When you must not take it

Do not take AMLODIPINE AN if:

- **You have ever had an allergic reaction to amlodipine or other calcium channel blockers.** These medicines include felodipine, nifedipine or lercanidipine. Check with your doctor or pharmacist if you are unsure. Some of the symptoms of an allergic reaction to AMLODIPINE AN may include a skin rash similar to hives, itchiness, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips or tongue.
- **You are allergic to any of the ingredients listed at the end of this leaflet.**
- **The packaging shows signs of tampering or does not look quite right.**
- **The expiry date marked on the packaging has passed, even though the tablets may look alright.** If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if:

- **You are pregnant or intend to become pregnant while taking AMLODIPINE AN.** Medicines like AMLODIPINE AN may affect the developing baby if you take it during pregnancy. Your doctor will discuss the possible risks and benefits of taking AMLODIPINE AN during pregnancy.

- **You are breastfeeding or wish to breastfeed.**
Your doctor will discuss the risks and benefits of taking AMLODIPINE AN when breastfeeding.
- **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 if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines and AMLODIPINE AN may interfere with each other.

Tell your doctor or pharmacist if you are taking any of the following:

- other medicines used to treat angina, such as diltiazem
- some antibiotics, such as erythromycin or rifampicin
- some antifungals, such as ketoconazole or itraconazole
- anti-proteases, medicines used to treat HIV infection, such as Ritonavir
- St John's Wort
- grapefruit or grapefruit juice

Your doctor or pharmacist has a complete list of medicines to be careful with or avoid while taking AMLODIPINE AN.

If you have not told your doctor or pharmacist about these things, tell them before you start taking AMLODIPINE AN.

How to take AMLODIPINE AN

Take AMLODIPINE AN exactly as your doctor has prescribed.

Follow all directions given to you by your doctor.

Your doctor will tell you how many doses to take each day. This depends on your condition and whether you are taking other medicines.

How much to take

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

As the 5 mg AMLODIPINE AN tablets do not have a breakline, alternative amlodipine besilate products should be used if a 2.5 mg dose is required. The 5 mg AMLODIPINE AN tablets must not be broken in half to give a 2.5 mg dose.

How to take it

Your AMLODIPINE AN should be swallowed with a drink of water.

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.

AMLODIPINE AN can be taken with or without food.

How long to take it

You must take AMLODIPINE AN every day. Continue taking your medicine for as long as your doctor tells you.

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, and 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 Poisons Information Centre - the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766 or go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much AMLODIPINE AN. 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, lightheadedness or faint and have an irregular heart beat.

While you are taking AMLODIPINE AN

Things you must do

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

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

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

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

Things you must not do

Do not take AMLODIPINE AN to treat any other conditions unless your doctor says to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

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

AMLODIPINE AN 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 strengthens 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 AMLODIPINE AN.

AMLODIPINE AN 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 AMLODIPINE AN.

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 AMLODIPINE AN 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 lightheadedness 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 AMLODIPINE AN. 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 AMLODIPINE AN

Storage

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

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

Keep your tablets in a cool dry place where temperatures stay below 30°C.

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

Do not leave your medicines on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep AMLODIPINE AN 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 AMLODIPINE AN, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Cellulose-microcrystalline, Calcium hydrogen phosphate anhydrous, Sodium starch glycolate and Magnesium stearate.

AMLODIPINE AN does not contain gluten, sugar or lactose.

Name and Address of the Sponsor

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra, VIC 3141
Australia

Date of Preparation:

January 2015

Product description

What it looks like

AMLODIPINE AN tablets come in 5 mg & 10 mg:

AMLODIPINE AN comes in Pack sizes of 30.

AMLODIPINE AN (AUST R 186306):

- are white to off-white, flat, bevel edged barrel shaped uncoated tablets, debossed with 'C' on one side and '58' on the other side.

AMLODIPINE AN (AUST R 186307):

- are white to off-white, flat, bevel edged round shaped uncoated tablets, debossed with 'C' on one side and '59' on the other side.

Ingredients

Active ingredients

- AMLODIPINE AN contains 5 mg or 10 mg amlodipine (as besilate) per tablet.

Inactive ingredients