

AURO-AMLODIPINE™ 5 & 10

Amlodipine (as besilate) 5 mg and 10 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions people ask about AURO-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 AURO-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 AURO-AMLODIPINE is used for

AURO-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.

AURO-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.

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

AURO-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 AURO-AMLODIPINE for another purpose.

Always ask your doctor if you need more information.

AURO-AMLODIPINE is available only with a doctor's prescription.

Use in children

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

Before you take it

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take it

Do not take AURO-AMLODIPINE 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.

You are allergic to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to AURO-AMLODIPINE may include rash, itching or hived on the skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.

Do not take AURO-AMLODIPINE after the use by (expiry) date printed on the pack has passed.

It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take AURO-AMLODIPINE if the packaging is torn or shows signs of tampering..

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

Before you start to take it

You must tell your doctor if:

- **You are pregnant or intend to become pregnant while taking AURO-AMLODIPINE.**
Medicines like AURO-AMLODIPINE may affect the developing baby if you take it during pregnancy. Your doctor will discuss the possible risks and benefits involved.
- **You are allergic to any other medicines, foods, dyes, or preservatives.**
- **You have any medical problems, including:**
 - heart disease, including heart failure; or
 - liver problems.

Do not breast-feed if you are taking this medicine.

It is not known if the active ingredient in AURO-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 them before you start taking AURO-AMLODIPINE.

Taking other medicines

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

Some medicines and AURO-AMLODIPINE 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, 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; or
- St John's Wort.

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

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How to take it

Take AURO-AMLODIPINE exactly as your doctor has prescribed.

Follow all directions given to you by your doctor.

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 AURO-AMLODIPINE is 5 mg each day. Your doctor may increase this to 10 mg each day.

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

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

How and when to take it:

Your AURO-AMLODIPINE 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.

AURO-AMLODIPINE can be taken with or without food.

How long to take it:

You must take AURO-AMLODIPINE 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 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 take too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 for Australia, 0800 POISON or 0800 764 766 for New Zealand) for advice, or go to Accident and Emergency at nearest hospital if you think you or anyone else may have taken too much AURO-AMLODIPINE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include dizziness, lightheadedness or fainting and an irregular heart-beat.

While you are taking it

Things you must do:

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking AURO-AMLODIPINE.

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

If you become pregnant while taking AURO-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.

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

Things you must not do:

Do not stop taking AURO-AMLODIPINE, or lower the dose, without checking with your doctor.

Do not use AURO-AMLODIPINE to treat any other conditions unless your doctor tells you to.

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

Things to be careful of:

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 AURO-AMLODIPINE.

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

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

AURO-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.

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

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

- Your doctor or pharmacist can give you more information about these measures.
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 AURO-AMLODIPINE.

AURO-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.

It can be difficult to tell whether side effects are the result of taking AURO-AMLODIPINE, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

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

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

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

These are the more common side effects of AURO-AMLODIPINE. All side effects should be reported to a health professional.

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

- indigestion; or
- sexual problems.

These may or may not be due to AURO-AMLODIPINE but you should tell your doctor.

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

- 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 lightheadedness 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;
- shortness of breath;
- symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark coloured urine, or
- 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.

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

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

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

If you are 65 years or older, you should be especially careful while taking AURO-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 it

Storage:

Keep AURO-AMLODIPINE 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.

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

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

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

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

Do not leave AURO-AMLODIPINE on a window sill or in the car.

Heat and dampness can destroy some medicines.

Disposal:

If your doctor tells you to stop taking AURO-AMLODIPINE, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What AURO-AMLODIPINE looks like

AURO-AMLODIPINE 5 and 10 (5 and 10 mg amlodipine (as besilate)) are presented in a blister pack, size of 30 tablets.

AURO-AMLODIPINE 5

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

AURO-AMLODIPINE 10

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 ingredient

Amlodipine (as besilate).

Other ingredients

- microcrystalline cellulose-;
- calcium hydrogen phosphate anhydrous;
- sodium starch glycolate; and
- magnesium stearate.

AURO-AMLODIPINE does not contain
gluten, sugar or lactose.

Sponsor/Marketing Authorisation Holder

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Toll free telephone (Australia): 1800 233 588

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AURO-AMLODIPINE™ 10 blister pack:

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