

AMLO

Contains the active ingredient amlodipine (besilate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AMLO.

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 AMLO 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 AMLO is used for

AMLO 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.
AMLO is not for the relief of a sudden attack of angina. Your

doctor will give you other medication to treat this.

How it works

AMLO 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 Amlodipine for another purpose.

Ask your doctor if you have any questions about why AMLO 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.

Before you take AMLO

When you must not take it

Do not take AMLO 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, Nifhexal, 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 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 AMLO, talk to your doctor.

Do not take AMLO if:

- 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

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems, including heart failure
- liver problems.

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 AMLO 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 AMLO.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by AMLO 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.

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, 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 AMLO.

How to take AMLO

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 AMLO 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 AMLO depending on your condition and how you respond to this medicine.

How to take it

Swallow the tablet whole with a full glass of water.

AMLO 5 mg tablets can be divided in half along the scoreline if your doctor has prescribed a 2.5 mg dose.

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.

AMLO can be taken with or without food.

How long to take it

You must take AMLO 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.

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 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. The telephone number in Australia is 131 126 - or go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too many AMLO.

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, lightheaded or faint and have an irregular heartbeat.

While you are using it

Things you must do

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

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

If you become pregnant while taking AMLO 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 must not do

Do not take AMLO 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

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 AMLO.

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

Be careful driving or operating machinery until you know how AMLO 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.

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 AMLO.

AMLO 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 AMLO, 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.

Tell your doctor if...

Ask your doctor or pharmacist for advice if you experience any of the following and they worry you:

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

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

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

- indigestion
- sexual problems.

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

Tell your doctor as soon as possible if...

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 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.

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

Go to hospital if...

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
- 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.

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

If you are 65 years or older, you should be especially careful while taking AMLO. 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 is making you feel unwell.

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

After taking AMLO

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 in the original packaging where temperatures stay below 30°C. Protect from light.

Do not store AMLO 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 AMLO 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 AMLO, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

AMLO is available in two strengths.

5 mg tablets- White to off-white, octagonal shaped, uncoated tablets debossed with “AM 5” on one side and scoreline on the other side

10 mg tablets - White to off-white, octagonal shaped, uncoated tablets debossed with “AM 10” on one side and plain on the other side.

A carton contains 30 tablets.

Ingredients

Active ingredients

AMLO 5 tablets contain amlodipine besilate equivalent to amlodipine 5 mg.

AMLO 10 tablets contain amlodipine besilate equivalent to amlodipine 10 mg.

Other ingredients

- microcrystalline cellulose

- mannitol
- sodium starch glycollate
- colloidal anhydrous silica
- magnesium stearate

AMLO does not contain gluten, sugar or lactose.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street,
Cremorne VIC 3121
www.arrotex.com.au

Australian Registration Numbers

AMLO 5 tablets: AUST R 201371

AMLO 10 tablets: AUST R 201372

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