

Amlodipine APOTEX

Amlodipine besilate

Consumer Medicine Information

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

What is in this leaflet

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.

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.

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

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Amlodipine is used to lower high blood pressure (hypertension) or treat angina. It belongs to a group of medicines called calcium channel blockers.

How it works

Amlodipine works 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.

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.

There is not enough information to recommend using amlodipine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- amlodipine
- other calcium channel blockers
- or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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

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.

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

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:

- liver problems
- heart disease or heart failure

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines may interact with amlodipine. These include:

- other medicines used to treat angina (e.g. diltiazem)
- some medicines used to treat infections (e.g. erythromycin, clarithromycin, rifampicin, ketoconazole, itraconazole)

- anti-proteases used to treat HIV infection (e.g. ritonavir)
- simvastatin, used to lower cholesterol
- cyclosporin or tacrolimus, used to suppress the immune system
- St John's Wort

These medicines may be affected by this medicine 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets to take each day, depending on your condition and whether you are taking other medicines.

The usual dose is one tablet each day.

How to take it

Swallow the tablet with a full glass of water.

When to take it

Take this 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.

How long to take it for

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.

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 dose you missed 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.

If you take too much (overdose)

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

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

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

If you become pregnant while taking amlodipine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

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

Things you must not do

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

Do not take your medicine to treat any other complaint unless your doctor or pharmacist tells you to.

Do not 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 can alter the metabolism of amlodipine. Drinking very large quantities (over 1.2 litres) of grapefruit juice each day while taking amlodipine may increase the effects of this medicine.

Side effects

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

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

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.

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

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

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

The above list includes the more common side effects. Mostly, these are mild.

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:

- changes in heartbeat, 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, vision changes
- mood changes, feeling anxious or nervous
- itching, yellowing of the skin and eyes, dark-coloured urine (signs of liver disease)
- 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

The above list includes serious side effects and you may need medical attention.

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

- 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 (symptoms of an allergic reaction)
- fast or irregular heart beats
- chest pain, alone or associated with exertion that lasts longer, is more severe or occurs more often
- shortness of breath
- severe upper stomach pain, often with nausea and vomiting

The above list includes very serious side effects and 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 occur in some patients.

Storage and disposal

Storage

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

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

Keep your medicine in a cool dry place where the temperature stays 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

5 mg tablets: white to off white, round, biconvex, uncoated tablets with 'E21' embossing on one side and break line on other side.

AUST R 307471

10 mg tablets: white to off white, round, biconvex, uncoated tablets with '10' embossing on one side.

AUST R 307472

Blister packs of 10, 14, 28, 30, 50, 56 or 84 tablets. Not all pack sizes available.

Ingredients

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

It also contains the following:

- microcrystalline cellulose
- calcium hydrogen phosphate dihydrate
- sodium starch glycollate type A
- colloidal anhydrous silica
- magnesium stearate

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

Sponsor

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