

NOUMED AMLODIPINE

amlodipine (as besilate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOUMED 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 this medicine 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 Noumed Amlodipine is used for

NOUMED AMLODIPINE tablets contain amlodipine besilate, which forms into the active ingredient amlodipine after you have taken it.

Amlodipine belongs to a group of medicines called calcium channel blockers or calcium ion antagonists. They work by relaxing the blood vessels in your body, making it easier for your heart to pump blood around the body. It also widens the blood vessels leading to your heart and so helps to increase the supply of oxygen-rich blood to the heart.

Calcium channel blockers do not change the amount of calcium in your blood or bones.

NOUMED AMLODIPINE is used to treat high blood pressure.

Everyone has blood pressure. This pressure helps circulate the blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are.

You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

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. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure. Amlodipine helps lower your blood pressure.

NOUMED AMLODIPINE is also used to treat chronic stable angina. Angina is caused by a shortage of the supply of oxygen to the heart and is characterised by a painful and uncomfortable feeling in the chest. This feeling often spreads to the arms or neck, and sometimes also to the shoulders and back.

NOUMED AMLODIPINE is not for the relief of a sudden attack of angina. If such an attack occurs, you should take other medication that your doctor will have given to you.

Your doctor may have prescribed NOUMED AMLODIPINE for another reason.

Ask your doctor if you have any questions about why NOUMED AMLODIPINE was prescribed for you.

Noumed Amlodipine is available only with a doctor's prescription.

There is no evidence that NOUMED AMLODIPINE is addictive.

Before you take it

When you must not take it

Do not take NOUMED AMLODIPINE if:

- you are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description.
- you have ever had an allergic reaction to other medicines of this drug class. Examples of these medicines are felodipine, nifedipine, or lercanidipine.

If you are not sure whether you have ever taken any of these medicines, check with your doctor or pharmacist.

Some of the symptoms of an allergic reaction may include: 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.

- you are pregnant or breastfeeding, unless permitted by your doctor.
- it is past the expiry date printed on the pack, or the packaging is torn or appears to have been tampered with.

If you take it after the expiry date has passed, it may not work as well.

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

NOUMED AMLODIPINE is not recommended for the use in children as the safety and efficacy in this age group have not been established.

Before you start to take it

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

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.

Tell your doctor if you are breast-feeding or intend to breast-feed.

Amlodipine passes into breast milk and may affect your baby, therefore breastfeeding is not recommended while taking NOUMED AMLODIPINE.

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

- heart problems, including heart failure
- liver disease.

Taking other medicines

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

Some medicines may be affected by NOUMED AMLODIPINE, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines.

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start to take NOUMED AMLODIPINE.

How to take Noumed Amlodipine

Take NOUMED AMLODIPINE 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, ask your doctor or pharmacist for help.

How much to take

The usual dose of NOUMED AMLODIPINE is one 5mg tablet each day. Your doctor may increase this to one 10mg tablet each day.

Your doctor may prescribe another dose of NOUMED 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. If you need to break NOUMED AMLODIPINE, hold tablet with both hands and snap along break line.



When to take it

Take your tablets about the same time each day, either morning or evening. This will help you to get the best effect and also makes it easier to remember when to take it.

NOUMED AMLODIPINE can be taken with or without food.

How long to take it

Keep taking NOUMED AMLODIPINE for as long as your doctor recommends.

If you forget to take it

If less than 12 hours have passed since the time when you should have taken your dose, then take your dose as soon as you remember, and continue to take it as you would normally.

Otherwise, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

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 the Poisons Information Centre (13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else

has taken too much NOUMED AMLODIPINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much NOUMED AMLODIPINE, you may feel dizzy, light-headed or faint or have an irregular heart beat.

While you are taking it

Things you must do

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

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking NOUMED AMLODIPINE.

Tell your doctor immediately if you become pregnant while taking NOUMED AMLODIPINE.

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 stop taking NOUMED AMLODIPINE unless your doctor has told you to.

Do not use NOUMED AMLODIPINE to treat any other complaint unless your doctor says so.

Do not give this medicine to anyone else, even if their symptoms are similar to yours.

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 amlodipine.

Drinking more than 1.2 litres of grapefruit juice each day while taking NOUMED AMLODIPINE may increase the effects of this medicine.

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

This medicine may cause dizziness or light-headedness in some people, especially after taking the first dose or after the dose has been increased.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Managing your high blood pressure or angina

This medicine helps to control your condition, but does not cure it. Your doctor or pharmacist can give you more information on other measures to help manage your condition, such as:

- Losing weight: a dietician can help you plan a suitable diet for sustainable weight loss.
- Regular exercise helps lower blood pressure and strengthen the heart, but it is important not to overdo it. Before starting, you should ask your doctor about the most suitable exercises for you. If you experience discomfort, chest pain or breathlessness when exercising, see your doctor.
- Limiting your alcohol intake.
- Reducing salt in your diet.
- Stop or cut down on smoking.

Side effects

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not.

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

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

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

These are the more common side effects of NOUMED AMLODIPINE. Mostly, these are mild and short-lived.

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

- indigestion
- sexual problems
- swollen gums
- constipation
- weight gain
- hair loss
- ringing in the ears.

These may or may not be due to NOUMED AMLODIPINE.

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

- changes in heart beat (fast or slow)
- swelling of the ankles, feet, face or hands
- tingling or numbness of the hands or feet
- dizziness or light-headedness when standing up.
- unusual tiredness or weakness
- muscle pain or cramps
- joint pain
- eye pain, changes in vision or sight
- changes in mood, feeling anxious or nervous
- symptoms of liver disease such as itching, yellowing of the eyes or

skin (jaundice) 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 are rare, but serious side effects of NOUMED AMLODIPINE. You may need urgent attention.

If any of the following happen, stop taking NOUMED AMLODIPINE and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fast or irregular heart beat
- chest pain, including 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, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- severe upper stomach pain, often with nausea and vomiting

These are very rare, but very serious side effects. You may need urgent medical attention or hospitalisation.

If you are 65 years or older, you should be especially careful when you are taking NOUMED AMLODIPINE.

People in this age group are more likely to experience side effects such as swelling of the feet and ankles, muscle cramps and dizziness. Make sure to tell your doctor if you experience any side effects.

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

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

After taking Noumed Amlodipine

Storage

Keep your medicine in the original packaging until it is time to take it.

If you take the tablets out of its original container, they may not keep well.

Keep your medicine in a cool, dry place, protected from light, where the temperature stays below 25°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 especially on hot days.

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 its expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

NOUMED AMLODIPINE tablets are available in 2 strengths.

NOUMED AMLODIPINE 5 mg: white or almost white, round, convex tablets scored on one side and embossed with '5' on the other side.

NOUMED AMLODIPINE 10 mg: white or almost white, round, convex tablets scored on one side and embossed with '10' on the other side.

Available in blister packs of 30 tablets each.

Ingredients

Active ingredient

NOUMED AMLODIPINE tablets contain 5 mg or 10 mg of amlodipine (as amlodipine besilate).

Inactive ingredients

- calcium hydrogen phosphate
- microcrystalline cellulose
- sodium starch glycollate
- magnesium stearate

NOUMED AMLODIPINE tablets do not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Sponsor

Avallon Pharmaceuticals Pty Ltd
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Macquarie Park NSW 2113
Telephone 1800 930 999

Australian Registration numbers

5 mg: AUST R 308448
10 mg: AUST R 308450

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