

Norvasc[®]

Amlodipine <am-load-i-peen> Besylate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Norvasc.

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 Norvasc 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 Norvasc is used for

Norvasc 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.

Norvasc 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.

Norvasc is not for the relief of a sudden attack of angina. Your doctor will give you other medication to treat this.

Norvasc 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.

Ask your doctor if you have any questions about why Norvasc has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine 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 Norvasc

When you must not take it

Do not take Norvasc if you have an allergy to:

- Norvasc, or any other medicine containing amlodipine (for example Perivasc)
- other calcium channel blockers such as those listed below:

felodipine (Plendil ER, Felodil XR, Felodur ER), nifedipine (Adalat, Adalat Oros, Addos XR, Adefine, GenRx)

Nifedipine, Nifehexal, Nyefax) or lercanidipine (Zanidip).

Not all brands are given. Check with your doctor or pharmacist if you are unsure.

- 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 or other parts of the body
- rash, itching or hives on the skin

Do not breast-feed if you are taking this medicine. It is not known if the active ingredient in Norvasc passes into breast milk or if your baby may be affected.

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:

- heart disease such as 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.

If you have not told your doctor about any of the above, tell him/her before you start taking Norvasc.

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 Norvasc 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 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 and pharmacist have more information on medicines to be careful with or avoid while taking Norvasc.

How to take Norvasc

Take Norvasc exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist carefully. 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 Norvasc is 5 mg each day. Your doctor may increase this to 10 mg each day.

Your doctor may prescribe another dose of Norvasc 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.

When to take it

Take your medicine at about the same time each day, either morning or evening.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Norvasc can be taken with or without food.

How long to take it

You must take Norvasc 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 it is less than 12 hours before your next dose, skip the dose you

missed and take your next dose when you are meant to.

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 the dose that you missed.

This may increase the chance of you 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 and in New Zealand is 0800 POISON or 0800 764 766 – for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Norvasc.

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 heart beat.

While you are taking Norvasc

Things you must do

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

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

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

Things you must not do

Do not take Norvasc to treat any other conditions unless your doctor tells you 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 Norvasc affects you.

Norvasc may cause dizziness or drowsiness in some people.

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 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 Norvasc.

Norvasc 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 attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking Norvasc, 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 or pharmacist 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

These are the more common side effects of Norvasc.

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

- indigestion
- unusual tiredness or weakness
- muscle cramps or aches
- sexual problems

These may or may not be due to Norvasc 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, tell your doctor or pharmacist.

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 Norvasc. 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 Norvasc

Storage

Keep your tablets in the pack until it is time to take them. If you take your tablets out of the pack they may not keep as well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

Product description

What it looks like

Norvasc tablets are available in two strengths:

- Norvasc 5 mg tablets - white, scored and marked NVC/5 on one side and Pfizer on the other.
- Norvasc 10 mg tablets - white, scored and marked NVC/10 on one side and Pfizer on the other.

The 5 mg tablets come in packs of 10 and 30. The 10 mg tablets come in packs of 30.

Ingredients

Active ingredients

- Norvasc 5 mg tablets contain amlodipine besylate equivalent to amlodipine 5 mg.
- Norvasc 10 mg tablets contain amlodipine besylate equivalent to amlodipine 10 mg.

Other ingredients

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

Norvasc does not contain gluten, sugar or lactose.

Supplier

Norvasc is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 5000 8422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia
Toll Free Number: 1800 675 229

Norvasc is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand
Toll Free Number: 0800 736 363

Australian Registration Numbers:

Norvasc 5 mg - AUST R 42902.

Norvasc 10 mg - AUST R 42903.

This leaflet was prepared on 11 January 2010

NORVASC® is a registered trademark of Pfizer Products Inc

© Pfizer Australia Pty Ltd

All rights reserved