

NORVASC® TABLETS

Amlodipine besilate (5 mg and 10 mg)

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What Norvasc is used for

Norvasc is under the group of medicines called calcium antagonists.

Norvasc is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina (Prinzmetal's or variant angina).

How Norvasc works

In patients with high blood pressure Norvasc works by relaxing blood vessels, so that blood passes through them more easily.

In patients with angina, Norvasc works by improving blood supply to the heart muscle which then receives more oxygen and as a result, chest pain is prevented. Norvasc does not provide immediate relief of chest pain from angina.

Before you use Norvasc

- When you must not use it

Do not use Norvasc if you are allergic to dihydropyridines (the active ingredient in amlodipine), or to the inactive ingredients. Your doctor or pharmacist can give you a list of these ingredients.

Pregnancy and lactation

The safety of amlodipine in human pregnancy has not been established. If you are pregnant, trying to get pregnant or think you may be pregnant, ask your doctor or pharmacist for advice before taking any medicine.

Amlodipine has been shown to pass into breast milk in small amounts.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor if you:

- ever had heart disease
- ever had liver problems

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, including natural or herbal remedies like:

- Simvastatin
- CYP3A4 Inhibitors such as ketoconazole, itraconazole, ritonavir and diltiazem
- Clarithromycin
- CYP3A4 Inducers such as rifampicin, *Hypericum perforatum*
- Tacrolimus
- mTOR inhibitors such as sirolimus, temsirolimus, and everolimus

- Taking with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking Norvasc. This is because grapefruit and grapefruit juice can increase the levels of active ingredient amlodipine in the blood, which can cause an unpredictable increase in the blood pressure lowering effect of Norvasc.

How to use Norvasc

- How much to use

The usual dose of Norvasc is one tablet of 5 mg daily which may be increased to 10 mg.

The recommended dose in children aged 6 to 17 years is 2.5 mg to 5 mg once daily. Norvasc is not recommended for children below 6 years of age.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

It is best to take your medicine at the same time each day with a drink of water.

Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are still not sure.

- How long to use it

Continue taking Norvasc for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think 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.

Taking too many tablets may cause excessive relaxation of blood vessels and an increased heart rate. If blood pressure drop is severe enough, shock can occur.

While you are using it

- Things you must do

Keep this leaflet. You may need to read it again.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Norvasc.

Tell your doctor immediately if you become pregnant while taking this medication.

If you have any further questions, ask your doctor or pharmacist.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

- Things to be careful of

Driving and using machines

Norvasc is unlikely to affect your ability to drive or use machines.

Side effects

Norvasc may cause the following side effects. Most side effects are mild or moderate:

- headache, dizziness, extreme sleepiness (somnolence)
- heart palpitations (very fast heartbeat)
- flushing (hot or warm feeling in your face)
- stomach pain, nausea
- swelling of your legs or ankles, tiredness (fatigue)

The most frequent side effects in children are:

- headaches, dizziness
- widening of blood vessels which cause low blood pressure (vasodilation)
- bleeding from the nose (epistaxis)
- stomach pain
- physical weakness and lack of energy (asthenia)

Tell your doctor if you are concerned about any side effects, you experience. These are not all the possible side effects of Norvasc. For a complete list, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Norvasc

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Do not use your medicine after the expiry date which is stamped on the pack.

Medicines should not be disposed of via wastewater of household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Norvasc 5 mg: White to off-white, emerald-shaped tablets engraved “AML 5” and breaker score on one side, and “VLE” logo on the other side. The 5 mg tablet can be divided into equal halves.

Norvasc 10 mg: White, to off-white emerald-shaped engraved “AML-10” on one side and “VLE” logo on the other side.

- Ingredients

- Active ingredient

Amlodipine besilate

The tablets contain amlodipine besilate equivalent to 5 mg amlodipine.

The tablets contain amlodipine besilate equivalent to 10 mg amlodipine.

- Inactive ingredients

Microcrystalline cellulose, dibasic calcium phosphate anhydrous, sodium starch glycolate, magnesium stearate.

- MAL numbers:

<u>Product Name</u>	<u>Registration Number</u>
Norvasc 5 mg	MAL1997026 9ARZ
Norvasc 10 mg	MAL1997026 8ARZ

Manufacturer

Viatrix Pharmaceuticals LLC,
Km 1.9, Road 689, Vega Baja,
P.R. 00693,
United States

NORVASC[®] TABLETS

Amlodipine besilate (5 mg and 10 mg)

Product Registration Holder

Viatrix Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.

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