

PACKAGE LEAFLET INFORMATION FOR THE USER

Norvalet 5 mg and 10 mg capsules

Amlodipine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If any of the side effect gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Norvalet is and what it is used for
2. Before you take Norvalet
3. How to take Norvalet
4. Possible side effects
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6. Further information

1. WHAT NORVALET IS AND WHAT IT IS USED FOR

Norvalet belongs to a group of medicines called calcium-channel blockers. Norvalet is used to treat:

- high blood pressure
- chest pain due to narrowing of the coronary arteries of the heart muscle (angina pectoris) or the more rare form of chest pain caused by cramping of the coronary arteries of the heart muscle (vasospastic angina).

If you suffer from high blood pressure, Norvalet works by relaxing blood vessels, so that blood passes through them more easily.

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

2. BEFORE YOU TAKE NORVALET

Do not take Norvalet

- if you have very low blood pressure
- in states of shock
- if you are hypersensitive (allergic) to the active substance or to any of the excipients
- if you have heart failure after acute myocardial infarction (within the last 28 days)
- if you have narrowing of the aorta (aortic stenosis)
- if you have unstable angina pectoris

Take special care with Norvalet

- if you have poor heart function (e.g. heart failure)
- if you have impaired liver function
- if you are undergoing dialysis
- if you are elderly and increase of the dosage is needed

As experience is insufficient, use of Norvalet in children and adolescents (below 18 years old) is not recommended.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Always tell your doctor or pharmacist if you are using or receiving any of the following medicines in addition to Norvalet:

- ketoconazole, itraconazole (against fungal infections) or ritonavir (an AIDS drug), as the amlodipine concentration may be raised.

- rifampicin, as the amlodipine concentration may be reduced.
- natural remedies that contain St. John's wort (*Hypericum perforatum*), as the amlodipine concentration may be reduced.
- other blood pressure lowering drugs and diuretics, as amlodipine may strengthen their action.

Taking Norvalet with food and drink

You can take Norvalet with food and drink.

Pregnancy and breast-feeding

Pregnancy

You must only take Norvalet on your doctor's instructions.

Breast-feeding

If you are breast-feeding you must not take Norvalet.

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

Driving and using machines

Use of Norvalet may possibly give side effects, such as dizziness, headache, fatigue or nausea, that to a greater or lesser degree may affect safety at work and in traffic.

3. HOW TO TAKE NORVALET

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

Adults:

The normal dose is 5 mg daily. If necessary the dose can be raised to 10 mg once daily after 2-4 weeks.

Elderly:

The dose must be adjusted. Follow the doctor's instructions. Any increase in dose requires caution.

Impaired liver function:

The dose must be reduced. Follow the doctor's instructions.

The capsule should be taken with a glass of water.

If you take more Norvalet than you should

If you accidentally take too many capsules, the following symptoms may be appeared: extreme dizziness and/or very light feeling in the head, difficulty in breathing, increased urine output.

Contact your nearest hospital and emergency department or tell your doctor immediately.

If you forget to take Norvalet

If you have forgotten to take a capsule, you can still take it up to 12 hours after you usually take your capsule. If it is more than 12 hours after the time that you should have taken the capsule, you should not take the missed dose and you should take the next capsule at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Norvalet

The treatment must only be changed or stopped in consultation with your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.