

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Norvasc® 5 mg
Norvasc® 10 mg
Tablets**

Each tablet contains:

Amlodipine (as besylate) 5 mg, 10 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. Consult your doctor or pharmacist if you have any further questions.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- treating hypertension
- treating chronic stable angina pectoris
- treating vasospastic angina pectoris (called Prinzmetal angina)

Therapeutic group:

calcium channel blockers (dihydropyridines).

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6) or other calcium channel blockers. This sensitivity may be experienced as itching, reddening of the skin, or difficulty in breathing.
- You have severe low blood pressure (hypotension).
- You have a narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- You have heart failure after a heart attack.

Special warnings regarding use of the medicine

Before starting treatment with Norvasc® tell your doctor if you have or have ever had any of the following conditions:

- a recent heart attack
- heart failure
- severe increase in blood pressure (hypertensive crisis)
- liver disease
- you are elderly and need a dose increase

Children and adolescents

There is no information regarding the safety and effectiveness of using this medicine in children under 6 years old. This medicine is for use in adults and in children aged 6 to 17 years old.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Norvasc® can affect other medicines and can be affected by other medicines, for example:

- ketoconazole, itraconazole (used to treat fungal infections)
- ritonavir, indinavir, nelfinavir (protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- Hypericum perforatum (St. John's wort)
- verapamil, diltiazem (heart medicines)

- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus, sirolimus, temsirolimus, and everolimus (medicines used to alter the way your immune system works)
- simvastatin (cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)

Norvasc® may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Using this medicine and food

Do not consume grapefruit or grapefruit juice while you are taking Norvasc®. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Norvasc®.

You may take this medicine with or without meals.

Pregnancy and breastfeeding

Pregnancy

The safety of amlodipine in pregnant women has not been established yet. If you think you might be pregnant, or are planning to become pregnant, you must tell your doctor before taking Norvasc®.

Breastfeeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breastfeeding or are planning to breastfeed you must tell your doctor before taking Norvasc®.

Driving and using machines

Norvasc® may affect your ability to drive and use machines. Do not drive or use machines if the medicine makes you feel nauseous, dizzy or tired, or gives you a headache, and consult your doctor immediately.

Important information about some of this medicine's ingredients

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by your doctor only.

You may take this medicine with or without meals. Take this medicine at the same time each day, with a drink of water.

Do not take Norvasc® with grapefruit juice.

Do not exceed the recommended dose.

Norvasc® 10 mg tablets: Do not crush/divide in half/chew the tablet because the effect of these methods of taking the medicine has not been tested.

Norvasc® 5 mg tablets can be divided into halves.

If you take too much Norvasc®

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may experience lightheadedness, dizziness, weakness, or fainting. If your drop in blood pressure is severe, shock can occur.

Your skin could feel cool and clammy and you will lose consciousness.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take Norvasc®

If you forget to take a tablet, skip the missed dose. Take your next dose at the usual time. Do not take a double dose to make up for the missed dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking Norvasc®

Your doctor will advise you how long to take this medicine. Your medical condition may return if you stop using this medicine before you are advised to stop.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Norvasc® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Contact your doctor immediately if you experience any of the following side effects after taking this medicine:

- sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- swelling of your eyelids, face, or lips
- swelling of the tongue and throat which causes difficulty breathing
- severe skin reactions including skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis) or any other allergic reaction
- heart attack, changes in heart rate
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling unwell

Additional side effects

Very common side effects (affect more than one in ten users): If they cause you problems or if they last for more than one week, consult your doctor.

- edema (fluid retention)

Common side effects (affect 1-10 in 100 users): If they cause you problems or if they last for more than one week, consult your doctor.

- headache, dizziness, or sleepiness (especially at the beginning of treatment)
- irregular or strong heartbeat (palpitations), flushed face
- abdominal pain, nausea
- changes in bowel habits, diarrhea, constipation, indigestion
- tiredness, weakness
- vision disturbances, double vision
- muscle cramps
- swollen ankles

Uncommon side effects (affect 1-10 in 1,000 users):

- mood changes, anxiety, depression, difficulty sleeping
- trembling, altered sense of taste, feeling faint
- numbness or tingling in the limbs, loss of pain sensation
- ringing in the ears
- low blood pressure
- sneezing or runny nose caused by inflammation of the inner lining of the nose (rhinitis)
- cough
- dry mouth, vomiting (feeling nauseous)
- hair loss, increased sweating, itchy skin, red patches on the skin, skin discoloration
- difficulty in passing urine, increased need to urinate at night, increased frequency of passing urine
- difficulty obtaining an erection, breast discomfort or enlarged breasts in men
- pain, feeling unwell
- muscle or joint pain, back pain
- weight gain or loss

Rare side effects (affect 1-10 in 10,000 users):

- confusion

Very rare side effects (affect less than one in 10,000 users):

- reduced numbers of white blood cells, reduced numbers of platelets which may result in unusual bruising or easy bleeding
- excess sugar in blood (hyperglycemia)
- a nervous system disorder which can cause muscle weakness, tingling or numbness
- swelling of the gums
- abdominal bloating (gastritis)

- abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- increased muscle tension
- inflammation of blood vessels, usually with skin rash
- sensitivity to light
- disorders combining rigidity, tremor, and/or movement disorders

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by using the link: <https://sideeffects.health.gov.il>.

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C, protect from light.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

microcrystalline cellulose, calcium hydrogen phosphate anhydrous, sodium starch glycolate (Type A), magnesium stearate.

What the medicine looks like and contents of the pack:

Norvasc® 5 mg: white to off-white octagonal tablet with a score line and 'AML-5' engraved on one side and 'Pfizer' on the other.

or

white to off-white octagonal tablet with a score line and 'AML-5' engraved on one side and plain on the other side.

Norvasc® 10 mg: white to off-white octagonal tablet with 'AML-10' engraved on one side and 'Pfizer' on the other.

or

white to off-white octagonal tablet with 'AML-10' engraved on one side and plain on the other side.

This medicine is available in packs of 20 or 30 tablets.

Not all pack sizes may be marketed.

Registration holder name and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Manufacturer's name and address:

R-Pharm Germany GmbH, Illertissen, Germany.

or

Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany.

Registration numbers of the medicine in the Ministry of Health's National Drug Registry:

Norvasc® 5 mg: 129.48.30946

Norvasc® 10 mg: 129.49.30947

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