

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S3

**NORVASC® TABLETS 5 mg**

**NORVASC® TABLETS 10 mg**

**Amlodipine besylate**

**Sugar free**

### **Read all of this leaflet carefully before you start taking NORVASC**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NORVASC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **What is in this leaflet**

1. What NORVASC is and what it is used for
2. What you need to know before you take NORVASC
3. How to take NORVASC
4. Possible side effects
5. How to store NORVASC
6. Contents of the pack and other information

#### **1. What NORVASC is and what it is used for**

NORVASC belongs to a group of medicines called calcium antagonists.

NORVASC is used to treat high blood pressure (hypertension) and a type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina. NORVASC is also used to reduce the risk of fatal and non-fatal heart disease or stroke.

NORVASC can be used alone or with other medicines to treat these conditions.

## **2. What you need to know before you take NORVASC**

### **Do not take NORVASC:**

- If you are hypersensitive (allergic) to amlodipine or any of the other ingredients of NORVASC (listed in section 6).
- If you have had an allergic reaction to other medicines of this type.
- In combination with grapefruit juice.
- If you have severe low blood pressure (hypotension).
- If you have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you have 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).
- If you suffer from heart failure after a heart attack.

### **Warnings and precautions**

Take special care with NORVASC:

- If you are taking other medicines such as anti-fungal medicines (ketoconazole, itraconazole) or protease inhibitors used to treat HIV (ritonavir). Using these medicines together with NORVASC may decrease the blood pressure even further (see Other medicines and NORVASC).
- If you are elderly and your dose needs to be increased. This should take place with care.
- If you have kidney disease.
- If you have liver disease and your dose needs to be increased. You will be closely monitored by your doctor if you have severe liver failure.
- If you have heart failure (a condition where the heart cannot pump blood well).

### **Other medicines and NORVASC**

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

NORVASC may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure. Do not stop taking your other prescription medicines, including any other blood pressure medicines, without talking to your doctor or health care provider first.

NORVASC may affect or be affected by other medicines, such as:

- Cholesterol-lowering medicine (simvastatin)
- Heart medicines (diltiazem)
- Anti-fungal medicines (ketoconazole, itraconazole) (see Warnings and precautions)
- Antibiotics (erythromycin, clarithromycin, rifampicin)
- Protease inhibitors used to treat HIV (ritonavir) (see Warnings and precautions)
- St. John's Wort (*hypericum perforatum*)
- Immunosuppressive medicines (tacrolimus, sirolimus, temsirolimus, everolimus and ciclosporin)

#### **NORVASC with food and drink**

Do not eat grapefruit or drink grapefruit juice with NORVASC.

#### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

If you are a woman of childbearing potential, you and your partner should ensure you are both using adequate contraception.

The safety of NORVASC in human pregnancy has not been established.

NORVASC has been shown to pass into breast milk.

#### **Driving and using machines**

NORVASC may make you feel dizzy; assess how it affects you before driving or using machinery.

It is not always possible to predict to what extent NORVASC may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NORVASC affects them.

#### **NORVASC contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take NORVASC**

Do not share medicines prescribed for you with any other person.

Always take NORVASC exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of NORVASC is one 5 mg tablet once a day; however, sometimes one 10 mg tablet a day may be required. NORVASC tablets may be taken with or without food.

The usual starting dose for children aged 6 – 17 years is 2,5 mg increased to 5 mg once a day.

Your doctor will tell you how long your treatment with NORVASC will last and will determine the dose that is best suited to you. If you have the impression that the effect of NORVASC is too strong or too weak, tell your doctor or pharmacist.

Continue taking NORVASC until your doctor tells you to stop at which time it should be done gradually.

#### **If you take more NORVASC than you should**

It is important not to take more NORVASC tablets than you should. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24 – 48 hours after intake.

#### **If you forget to take NORVASC**

It is important to take your NORVASC tablets regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for forgotten individual doses.

#### **4. Possible side effects**

NORVASC can have side effects.

Not all side effects reported for NORVASC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NORVASC, please consult your healthcare provider for advice.

If any of the following happens, stop taking NORVASC and tell your doctor immediately or go to the casualty department at your nearest hospital:

Allergic reaction including:

- Pruritus (severe itching of the skin).
- Rash.

- Angioedema (swelling under the skin, often around your face and lips)
- Erythema multiforme (large, symmetrical red blotches that appear all over the skin in a circular pattern).

These are all very serious side effects. If you have them, you may have had a serious reaction to NORVASC. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Frequent side effects*

- Headache, dizziness especially when standing up, sleepiness.
- Heart palpitations (very fast heartbeat), flushing (hot or warm feeling in your face).
- Stomach pain, nausea.
- Swelling of your legs or ankles, tiredness.

*Less frequent side effects*

- Too few white blood cells, too few blood platelets, too much sugar in the blood.
- Mood changes, sleeplessness.
- Tightening of the muscles, loss of pain sensation, numbness or tingling sensation, fainting, taste abnormalities, trembling, movement disorder.
- Visual disturbances.
- Ringing in the ears.
- Low blood pressure, inflammation of the blood vessels.
- Cough, shortness of breath, sneezing/running nose.
- Change in bowel habit, dry mouth, indigestion, swelling of the gums, bleeding gums, inflammation of the pancreas, vomiting.
- Hair loss, increased sweating, itchy skin, red patches on skin.
- Joint or muscle pain, back pain, muscle cramps.
- Increased need to urinate especially at night, pain when urinating.
- Enlargement of male breasts, inability to obtain an erection.
- Feeling unwell, weakness, pain.
- Increase or decrease in weight.
- Itching, rash, swelling under the skin, red blotchy skin.
- 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.

- Heart attack, increase in heart rate, chest pain.

Should any of these symptoms occur, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of NORVASC.

## **5. How to store NORVASC**

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Keep the tablets in the original packaging and protect from light.
- Do not use this medicine after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What NORVASC contains**

The active substance is amlodipine besylate equivalent to 5 mg or 10 mg active amlodipine base.

The other ingredients are dibasic calcium phosphate anhydrous, magnesium stearate, microcrystalline cellulose and sodium starch glycollate.

### **What NORVASC looks like and contents of the pack**

NORVASC 5 mg: White, emerald shaped tablets marked PFIZER on one side and AML-5 on the other.

NORVASC 10 mg: White, emerald shaped tablets marked PFIZER on one side and AML-10 on the other.

NORVASC 5 mg and 10 mg are available strip packed in blister strips in outer cardboard cartons each containing 30, 60 and 90 tablets.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

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**Registration numbers**

NORVASC TABLETS 5 mg: Y/7.1/26

NORVASC TABLETS 10 mg: Y/7.1/27

**BOTSWANA: S2**

NORVASC TABLETS 5 mg – Reg. no.: B9316370

NORVASC TABLETS 10 mg – Reg. no.: BOT9800295

**NAMIBIA: NS2**

NORVASC TABLETS 5 mg – Reg. no.: 04/7.1/1228

NORVASC TABLETS 10 mg – Reg. no.: 04/7.1/1229

**ZAMBIA: POM**

NORVASC TABLETS 5 mg – Reg. no.: 120/013

**ZIMBABWE: PP10**

NORVASC TABLETS 5 mg – Reg. no.: 90/12.6/2422

NORVASC TABLETS 10 mg – Reg. no.: 90/12.6/2423