

Approved Patient Information Leaflet for Medicines for Human Use:

VASCOLOK 5 and VASCOLOK 10 (tablets)

SCHEDULING STATUS: S3

VASCOLOK 5 5 mg tablets

VASCOLOK 10 10 mg tablets

Amlodipine besilate

Contains sugar: mannitol

VASCOLOK 5 5 mg tablets

Each tablet contains 63 mg mannitol.

VASCOLOK 10 10 mg tablets

Each tablet contains 126 mg mannitol

Read all of this leaflet carefully before you start taking VASCOLOK 5 or VASCOLOK 10.

- 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.

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

1. What VASCOLOK is and what it is used for

VASCOLOK contains the active substance called amlodipine besilate which belongs to the group of medicines called calcium channel blockers.

VASCOLOK works by relaxing the blood vessels, so that the blood passes through the blood vessels more easily.

VASCOLOK 5 & VASCOLOK 10 is used to treat high blood pressure and angina pectoris or chest pain.

VASCOLOK 5 & VASCOLOK 10 may be used with other medicines which also lower your blood pressure.

2. What you need to know before you take VASCOLOK

Do not take VASCOLOK 5 or VASCOLOK 10:

- If you are hypersensitive (allergic) to amlodipine, or any of the other ingredients of VASCOLOK (listed in section 6)
- If you are pregnant or breast-feeding
- VASCOLOK may not be given to children.

Warnings and precautions

Take special care with VASCOLOK 5 or VASCOLOK 10:

- if you are elderly
- if you have severe kidney function disease
- if you have liver function disease
- if you have heart failure, severe low blood pressure, shock, hypertensive crisis (very high blood pressure)
- if you have obstruction to blood flow in the heart (aortic stenosis)

- if you have porphyria.

Children

Safety and efficacy in children have not been established.

Other medicines and VASCOLOK

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

VASCOLOK may be taken with:

- Thiazide diuretics (medicines used to decrease blood pressure)
- Beta blockers (medicines used to decrease blood pressure)
- ACE inhibitors (medicines used to decrease blood pressure)
- Long-acting nitrates (medicines used to treat chest pain)
- Sublingual nitroglycerine (medicine used to treat chest pain)
- Non-steroidal anti-inflammatory drugs (medicines used to treat inflammation)
- Antibiotics (medicines used to treat infection)
- Oral hypoglycaemic medicines (medicines used to decrease blood sugar)
- Cimetidine (medicines used as an antacid)
- Warfarin (medicines used to thin blood)
- Indomethacin (medicines used to treat inflammation).

The effects of VASCOLOK may be increased by the simultaneous intake of the following medicines:

- Digoxin (medicine used to treat irregular heartbeat)
- Ritonavir, indinavir, nefinavir (medicines used to treat HIV)
- Ketoconazole, itraconazole, fluconazole (medicines used to treat fungal infections)

- Erythromycin, clarithromycin (antibiotics)
- Verapamil, diltiazem (heart medicines).

VASCOLOK may affect other medicines, such as:

- Dantrolene (infusion for severe body temperature abnormalities)
- Tacrolimus, sirolimus, temsirolimus, everolimus (immunosuppressant medicines used to prevent organ rejection after a transplant)
- Cyclosporin (immunosuppressant medicine used to prevent organ rejection after a transplant).

Taking VASCOLOK with simvastatin (cholesterol lowering medicine) can increase the effects of simvastatin.

VASCOLOK may change the response to insulin and glucose in your body. If you are a diabetic, your dose may need to be adjusted.

The effects of VASCOLOK may be lessened by the simultaneous intake of the following medicines:

- Rifampicin (medicine used to treat TB)
- Carbamazepine, phenytoin, phenobarbitone (medicines used to treat epilepsy).

VASCOLOK with food and drink

Do not consume grapefruit or grapefruit juice while taking VASCOLOK. If you do, it could lead to an increase in the effects of VASCOLOK.

Pregnancy and breastfeeding

Do not take VASCOLOK 5 or VASCOLOK 10 if you are pregnant or breast-feeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking VASCOLOK.

Driving and using machines:

- VASCOLOK may make you feel dizzy or tired or may give you a headache.
- Do not drive because VASCOLOK could interfere with your ability to drive safely.
- Do not operate any tools or machines.

It is not always possible to predict to what extent VASCOLOK 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 VASCOLOK affects them.

VASCOLOK contains mannitol which may have a laxative effect or cause diarrhoea.

3. How to take VASCOLOK

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

Always take VASCOLOK 5 or VASCOLOK 10 exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 5 – 10 mg daily. VASCOLOK 5 tablets should not be broken.

Duration of administration

Your doctor will determine your dose according to your condition.

Your doctor will tell you how long your treatment with VASCOLOK will last.

Do not stop treatment early because your blood pressure may increase again. If you have the impression that the effect of VASCOLOK is too strong or too weak, tell your doctor or pharmacist.

VASCOLOK may not be used in children.

Method of administration

- Take the tablet/s with a sufficient quantity of liquid (e.g. one glass of water).
- Take VASCOLOK once a day, every day, at about the same time each day.
- Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you to remember when to take the tablets.

If you take more VASCOLOK 5 or VASCOLOK 10 than you should

You may experience flushing, (reddening of the face), a drop in blood pressure, feel dizzy or light headed.

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VASCOLOK 5 or VASCOLOK 10

If you forget to take a dose, you should take it as soon as you realise it. If you were closer to taking the next dose, then skip the forgotten dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

VASCOLOK can have side effects.

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

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

Less frequent:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in breathing or swallowing
- swelling of the eyes and lips
- rash or itching
- fainting.

Frequency unknown:

yellowing of the skin and eyes (jaundice).

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- chest pain
- changes in the way your heart beats, for example, if you notice it beating faster.

Less frequent:

- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice the following:

Frequent side effects:

- headache, sleepiness, dizziness
- reddening of face (flushing)
- visual disturbances, e.g. double vision or blurred vision
- vomiting, abdominal pain, altered bowel habits (diarrhoea or constipation)
- feeling sick (nausea)
- Ankle swelling

Less frequent side effects:

- inflammation of blood vessels, often with skin rash
- taste abnormalities
- a disorder of the nerves, which can cause weakness, tingling or numbness
- shaking
- tinnitus (ringing in the ears)
- slower or faster heart beat
- dry mouth, increased sweating
- mood changes, depression
- indigestion
- swelling of the gums
- inflammation of the pancreas, which causes severe pain in the abdomen and back
- joint or muscle pain, back pain, muscle cramps
- decreased number of white blood cells which increases risk of infection; decrease in blood platelets which increases risk of bleeding or bruising
- increased need to urinate
- inability to obtain erection, discomfort or enlargement of the breasts in men
- weight increase or decrease
- high blood sugar (hyperglycaemia)
- hair loss, itchy skin, red patches on skin, increased sweating
- sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis)
- inflammation of the liver (hepatitis), liver enzyme increase which may have an effect on some medical tests
- heart attack.

Side effects with frequency unknown:

- involuntary movements
- increased pain, discoloration, blistering and sloughing of your skin (skin necrosis).

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 Reaction 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 VASCOLOK.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store VASCOLOK 5 or VASCOLOK 10

- Store all medicines out of reach of children.
- Store in a cool, dry place at or below 30 °C.
- Protect from light and moisture.
- Do not remove the blister from the carton until required for use.
- Store in the original package.
- Do not use after the expiry date stated on the carton.
- Return all unused medicines 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 VASCOLOK contains

The active substance is amlodipine besilate.

The other ingredients are colloidal silica anhydrous, magnesium stearate, mannitol, microcrystalline cellulose and sodium starch glycolate.

VASCOLOK 5 mg tablets

Each tablet contains amlodipine besilate equivalent to 5 mg amlodipine base.

VASCOLOK 10 mg tablets

Each tablet contains amlodipine besilate equivalent to 10 mg amlodipine base.

What VASCOLOK looks like and contents of the pack

VASCOLOK 5 tablets: White to off white, octagonal shaped, uncoated tablets, debossed with “AM 5” on one side and breakline on the other side. This breakline is non-functional. VASCOLOK 5 tablets should therefore not be broken.

VASCOLOK 10 tablets: White to off white, octagonal shaped, uncoated tablets, debossed with “AM 10” on one side and plain on the other side.

VASCOLOK 5 and VASCOLOK 10 Tablets are both packed in white, opaque PVC/PVDC-Aluminium foil blister strips [with VMCH (copolymer of vinyl chloride and vinyl acetate) heat seal coating] containing 10 tablets each in a pack size of 30 tablets packed in an outer carton.

Holder of Certificate of Registration

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