PROPOSED CLEAN COPY PATIENT INFORMATION LEAFLET

Scheduling status

S3

VASLOC 5 mg Tablets

VASLOC 10 mg Tablets

Amlodipine (as besilate)

Sugar free

Read all of this leaflet carefully before you start taking VASLOC

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

1. What VASLOC is and what it is used for

VASLOC contains the active substance amlodipine which belongs to a group of medicines called selective calcium channel blockers.

VASLOC is used to treat high blood pressure (hypertension) and to treat chest pain or discomfort called angina pectoris.

Your doctor may prescribe you VASLOC together with other medicines used to lower your blood pressure.

2. What you need to know before you take VASLOC

Do not take VASLOC:

- if you are hypersensitive (allergic) to amlodipine, other calcium-channel blockers or any of the other ingredients of VASLOC (see section 6).
- if you have severe low blood pressure.
- if you have had shock or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- if you have aortic stenosis (narrowing of the heart valve of the aorta).
- if you recently suffered a heart attack (within the past 28 days).
- if you have been diagnosed with unstable angina (chest pain occuring while resting).
- if you are pregnant or breastfeeding.

Warnings and precautions

Tell your doctor before taking VASLOC:

- if you suffer from heart failure.
- if you have been diagnosed with aortic stenosis (narrowing of the aortic heart valve).
- if you have severe liver problems. Your doctor may need to monitor your liver function and adjust your dose of VASLOC accordingly.
- if you are 65 years or older.
- if you suffer from severe kidney problems.
- if you suffer from diabetes.

- if you have porphyria (a group of disorders that result in a build-up of natural chemicals called porphyrins in your body).
- if you experience chest pain while taking VASLOC.
- if you have low blood pressure.

Children and adolescents

Do not give VASLOC to children and adolescents as safety and efficacy have not been established.

Other medicines and VASLOC

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

Tell your doctor or pharmacist before you take VASLOC if you are taking:

- Protease inhibitors (used to treat human immunodeficiency virus (HIV)).
- Azole antifungals, such as itraconazole or ketoconazole (used to treat fungal infections).
- Macrolide antibacterials, such as erythromycin or clarithromycin (used to treat bacterial
- infections).
- Verapamil (used to treat high blood pressure and heart pain) or any medicine that may lower your blood pressure.
- Diltiazem (used to treat chest pain).
- Rifampicin (used to treat tuberculosis (TB) or certain other bacterial infections).
- St. John's Wort (herbal medicine).
- Carbamazepine, phenobarbitone, phenytoin or valproate (used to treat seizures (fits)).
- Dantrolene (used to treat severe body temperature abnormalities).
- Medicines for treating angina (chest pains), such as nitro-glycerine or beta-blockers.
- Tacrolimus (used to treat eczema or during organ transplants).

- Mammalian target of rapamycin (mTOR) inhibitors, such as temsirolimus, everolimus and
- sirolimus (used to treat cancer).
- Simvastatin (used to lower fat in your blood).
- Quinidine or procainamide (used to treat heart rhythm disorders).
- Lithium (used to treat some types of depression).

Tell your doctor or pharmacist before you take VASLOC if you have had a kidney transplant and are taking ciclosporin (used to treat cancer, rheumatoid arthritis or organ transplants). Your doctor may need to monitor your blood and adjust your dose of ciclosporin according to the test results.

VASLOC with food and drink

While taking VASLOC you should avoid consuming grapefruit juice or grapefruits as it may increase the risk of your blood pressure lowering more than expected.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking VASLOC**.**

You should not take VASLOC if you are pregnant or breastfeeding.

Driving and using machines

VASLOC may cause dizziness, tiredness, nausea (feeling sick) or headaches, which may affect your ability to drive or use machines. You may experience these effects more at the start of your treatment with VASLOC. Do not drive or operate machinery until you know how VASLOC affects you.

3. How to take VASLOC

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

Always take VASLOC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one tablet of VASLOC 5 mg or one tablet of VASLOC 10 mg once a day taken orally.

Your doctor will determine your dose based on your age, liver function or your response to VASLOC.

VASLOC can be taken with or without food.

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

If you have the impression that the effect of VASLOC is too strong or too weak, tell your doctor or pharmacist.

Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets.

If you take more VASLOC 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, including the carton, so that the hospital staff can easily tell what you have taken.

If you forget to take VASLOC

If you forgot to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

VASLOC can have side effects.

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

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

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

These are all very serious side effects. If you have them, you may have had a serious reaction to VASLOC. 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:

- changes in the way your heart beats (irregular heartbeats, beating slower or faster than usual) or heart attack
- painful, blistering or peeling skin rash
- bleeding or bruising more easily than normal or abnormal blood test results
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of your skin and eyes, also called jaundice or hepatitis
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back)
- erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea)
- difficulty breathing or chest pain.

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

Tell your doctor if you notice any of the following*:*

Frequent side effects

- water retention (causing swelling of your ankles, hands and feet)
- visual disturbances (seeing double)
- sleepiness, dizziness or headaches (especially when you first start taking VASLOC)
- pain in your stomach area, nausea (feeling sick), feeling bloated (caused by excessive gas) and indigestion
- changes in bowel movements, such as constipation or diarrhoea
- muscle cramps, physical weakness and lack of energy
- flushing of your skin (blushing).

Less frequent side effects

- bleeding or small pin-sized purple spots on the skin
- increased blood sugar levels
- changes in test results when your doctor monitors your liver function
- a decrease in blood pressure (causing light-headedness, clammy skin, nausea and dizziness)
- vasculitis (fever, headache, fatigue, weight loss, general aches and pains, night sweats, nerve problems such as numbness or weakness)
- changes in the frequency or control of urination, urinating more at night
- feeling depressed or confused, changes in your mood, anxiousness and insomnia
- shaking (tremor)
- ringing in the ears
- numbness, a loss of sensation, tingling or numbness in your hands or feet, feeling of weakness or heaviness in your arms and legs

- stiffness of your muscles and joint, muscle or back pain, pain in a joint and feeling unwell
- vomiting (being sick), a dry mouth or gastritis (causing pain, nausea, vomiting, vomiting blood, blood in the stool)
- overgrowth of the gums (causing pain, swelling and bad breath)
- distortion of the sense of taste
- coughing or a runny nose
- breast enlargement in men
- problems with sexual performance
- hair loss or excessive sweating
- discolouration of the skin or sensitivity to the sun
- gaining or losing weight.

Side effects with an unknown frequency

- muscle spasms, slow movement and irregular, jerky movements.

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: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VASLOC**.**

5. How to store VASLOC

Store all medicines out of reach of children.

Store at or below 30°C, in the original package. Keep blisters in the carton until required for use.

Do not use VASLOC after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

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 VASLOC contains

The active substance in VASLOC is amlodipine.

VASLOC 5 mg: Each tablet contains 5 mg amlodipine (as amlodipine besilate).

VASLOC 10 mg: Each tablet contains 10 mg amlodipine (as amlodipine besilate).

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

What VASLOC looks like and contents of the pack

VASLOC 5 mg: White to off white, octagonal shaped, uncoated tablets, debossed with “AM 5” on one side and plain on the other side.

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

The tablets are packed in PVC/PVDC/Aluminium foil blisters strips. The blister strips are packed in cartons containing 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein, Cape Town

7570

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