

## **PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS**

**S3**

**ASCIVASC 5 mg Tablets**

**ASCIVASC 10 mg Tablets**

**Amlodipine (as besilate)**

**Sugar free**

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

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



## 1. What ASCIVASC is and what it is used for

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

ASCIVASC is used:

- To treat high blood pressure (hypertension)
- To treat angina pectoris, which is characterised by chest pain and discomfort.

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

## 2. What you need to know before you take ASCIVASC

### Do not take ASCIVASC:

- If you are hypersensitive (allergic) to amlodipine, other calcium channel blockers or any of the other ingredients of ASCIVASC (listed in 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 (within the past 28 days) suffered a heart attack.
- If you have unstable angina (chest pain which may occur when you are resting).
- If you are pregnant or breastfeeding.

### Warnings and precautions

*Tell your doctor before taking ASCIVASC:*



- If you have severe liver problems. Your doctor may need to monitor your liver function and adjust your dose of ASCIVASC accordingly.
- If you suffer from heart failure.
- 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 buildup of natural chemicals called porphyrins in your body)
- If you experience chest pain while taking ASCIVASC.
- If you have low blood pressure.

### **Children and adolescents**

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

### **Other medicines and ASCIVASC**

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

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

- Azole antifungals, such as ketoconazole or itraconazole (used to treat fungal infections).
- Protease inhibitors (used to treat human immunodeficiency virus (HIV)).
- Macrolide antibacterials, such as erythromycin or clarithromycin (used to treat bacterial infections).



- St. John's Wort (herbal medicine).
- 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).
- Dantrolene (used to treat severe body temperature abnormalities).
- Carbamazepine, phenobarbitone, phenytoin or valproate (used to treat seizures (fits)).
- Medicines for treating angina (chest pains), such as nitro-glycerine or beta-blockers.
- Mammalian target of rapamycin (mTOR) inhibitors, such as temsirolimus, everolimus and sirolimus (used to treat cancer).
- Tacrolimus (used to treat eczema or during organ transplants).
- Medicines for treating angina (chest pains), such as nitro-glycerine or beta-blockers.
- 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 ASCIVASC 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.

### **ASCIVASC with food and drink**

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Grapefruit juice and grapefruit should not be consumed by people who are taking ASCIVASC as it may cause an unpredictable increase in the blood pressure lowering effect of ASCIVASC.

### **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 ASCIVASC.

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

### **Driving and using machines**

ASCIVASC may cause dizziness, headaches, tiredness or nausea (feeling sick), which may affect your ability to drive or use machines.

You may experience these effects more at the start of your treatment with ASCIVASC. Do not drive or operate machinery until you know how ASCIVASC affects you.

### **3. How to take ASCIVASC**

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

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

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

ASCIVASC can be taken with or without food.



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

Your doctor will tell you how long your treatment with ASCIVASC will last. If you have the impression that the effect of ASCIVASC 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 ASCIVASC than you should**

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 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 ASCIVASC**

If you forget to take a dose of ASCIVASC, take one as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double dose to make up for the forgotten individual doses.

## **4. Possible side effects**



ASCIVASC can have side effects.

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

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

- swelling of the hands, feet, ankles, lips, 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 ASCIVASC. 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:

- 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;
- heart attack (severe chest pain) abnormal heartbeat;
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back);
- changes in the way your heart beats (irregular heart beats, beating slower or faster than usual) or heart attack;



- 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);
- yellow discolouration of the skin and eyes; also called jaundice or hepatitis;
- 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);
- headache, dizziness, sleepiness (especially at the beginning of treatment);
- pain in your stomach area, feeling sick (nausea), feeling bloated (caused by excessive gas);
- changes in bowel movements, such as constipation or diarrhoea;
- visual disturbances, double vision;
- 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
- feeling depressed or confused, mood changes, anxiousness, and insomnia;
- shaking (tremor);
- distortion of the sense of taste;



- numbness, a loss of sensation, tingling or numbness in your hands or feet, feeling of weakness or heaviness in your arms and legs;
- ringing in the ears (tinnitus);
- a decrease in blood pressure (causing light-headedness, clammy skin, nausea and dizziness);
- coughing or a runny nose;
- dry mouth, vomiting (being sick) or gastritis (causing pain, nausea, vomiting, vomiting blood, blood in the stool);
- hair loss or increased sweating;
- discolouration of the skin or sensitivity to the sun;
- disorder in passing urine, increased need to urinate at night, increased number of times of passing urine;
- enlargement of the breasts in men;
- problems with sexual performance;
- stiffness of your muscles and joint, feeling unwell, joint or muscle pain, back pain;
- weight increase or decrease;
- increased blood sugar levels;
- overgrowth of the gums (causing pain, swelling and bad breath);
- changes in test results when your doctor monitors your liver function;
- vasculitis (fever, headache, fatigue, weight loss, general aches and pains; night sweats, nerve problems such as numbness or weakness);

*Side effects with an unknown frequency*

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

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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>. By reporting side effects, you can help provide more information on the safety of ASCIVASC.

### **5. How to store ASCIVASC**

Store all medicines out of reach of children.

- Store in a cool, dry place at or below 25 °C.
- Store in the original container.
- Do not remove the blister from the carton until required for use.
- Do not use after the expiry date stated on the label / carton / bottle.

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 ASCIVASC contains**

- The active substance is amlodipine.

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



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

Sugar free.

- The other ingredients are colloidal silicon dioxide, dibasic calcium phosphate (anhydrous), magnesium stearate, microcrystalline cellulose (Grade 102), sodium starch glycolate.

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

ASCIVASC 5 mg: White to off white round flat faced beveled edge tablets '210' debossed on one side and plain on other side.

ASCIVASC 10 mg: White to off white round flat faced beveled edge tablets '209' debossed on one side and plain on other side.

ASCIVASC 5 and 10 mg tablets are packed as follows:

- Alu-Alu blister packs of 10 tablets per blister. Three blisters of 10 tablets each are packed in an outer cardboard carton.
- White opaque, round HDPE container with child resistant cap containing 90 tablets.
- White opaque, round HDPE container with nonchild resistant cap containing 500 tablets.

Not all pack sizes may be marketed.



Applicant: Ascendis Pharma (Pty) Ltd  
Product name: ASCIVASC 5 & 10  
Registration numbers: 50/7.1/0557 & 50/7.1/0558

Date: 06 August 2023  
Module 1  
Module 1.3.2

**Holder of Certificate of Registration**

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