APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

[PRODUCT NAME] 5 (Tablets)

[PRODUCT NAME] 10 (Tablets)

Amlodipine

Sugar free

Read all of this leaflet carefully before you start taking [PRODUCT NAME]

- 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.
- [PRODUCT NAME] 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 [PRODUCT NAME] IS AND WHAT IT IS USED FOR

[PRODUCT NAME] belongs to a group of medicines known as calcium-channel blockers (calcium antagonists). Calcium-channel blockers lower blood pressure by relaxing the blood vessel walls. [PRODUCT NAME] is used to treat mild to moderate high blood pressure (hypertension). [PRODUCT NAME] is also used to treat a certain type of chest pain called angina and to reduce the risk of heart disease and stroke.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE [PRODUCT NAME]:

Do not take [PRODUCT NAME]:

- If you are hypersensitive (allergic) to amlodipine, calcium-channel blockers (dihydropyridine derivatives), or to any of the other ingredients of [PRODUCT NAME] (listed in section 6).
- If you are pregnant or breastfeeding.
- If you have severe low blood pressure (hypotension).
- 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 have suffered from heart failure after a heart attack.
- If you are having grapefruit juice
- In cases of shock (where the body is not getting enough blood flow.

Take special care with [PRODUCT NAME]:

- If you are elderly, your doctor may start you on a lower dose of **[**PRODUCT NAME].
- If you have kidney or liver problems, your doctor may start you on a lower dose of [PRODUCT NAME].
- If you have heart problems such as heart failure, please inform your doctor.
- If you have porphyria (an inherited disease of certain enzymes), please inform your doctor.

Children and adolescents

If you are under 18 years of age, since the safety and effectiveness of [PRODUCT NAME] has not been established in children.

Other medicines and [PRODUCT NAME]

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

[PRODUCT NAME] may affect or be affected by other medicines, such as:

- Medicines used to treat high blood pressure and angina (chest pain) known as sublingual nitroglycerine, long acting nitrates or beta blockers, which may lower your blood pressure even further.

- Ciclosporin (an immune suppressant used after organ transplant) when used for kidney transplants; a decrease in ciclosporin dose might be required.
- The following medicines may lead to an increase in blood concentrations of amlodipine resulting in an increase in blood pressure lowering effect:
    - Protease inhibitors used to treat HIV infection (such as ritonavir, indinavir, nelfinavir).
    - Anti-fungal medicines such as ketoconazole or itraconazole.
    - Antibiotics such as erythromycin or clarithromycin.
    - Verapamil or diltiazem (heart medicines).
- Rifampicin (used to treat tuberculosis) – may reduce the effect of [PRODUCT NAME].
- Hypericum perforatum (St. John's Wort – a herbal antidepressant) -may reduce the effect of [PRODUCT NAME].
- Dantrolene (infusion for severe body temperature abnormalities) – may cause an increase in blood potassium levels.
- Tacrolimus, everolimus, sirolimus (~~an~~ immune suppressant used after organ transplant) – a dose adjustment might be required as [PRODUCT NAME] can cause tacrolimus levels to increase.
- Simvastatin (cholesterol lowering medicine); doses of simvastatin should be limited to 20 mg daily

[PRODUCT NAME] may further lower your blood pressure if you are already taking other medicines to treat your high blood pressure.

[PRODUCT NAME] with food and drink:

You should not consume grapefruit or grapefruit juice if you are taking [PRODUCT NAME], 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 [PRODUCT NAME].

Pregnancy and Breastfeeding:

The safety of [PRODUCT NAME] in pregnancy has not been established.

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 provider for advice before taking this medicine.

Driving and using machines:

[PRODUCT NAME] may cause dizziness, headache, tiredness, or make you feel sick. If you have any of these side-effects, you should keep in mind that this can affect your ability to drive and/or use machinery.

It is not always possible to predict to what extent [PRODUCT NAME] may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which [PRODUCT NAME] affects you.

3. HOW TO TAKE [PRODUCT NAME]:

Always take [PRODUCT NAME] exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is [PRODUCT NAME] 5mg once daily, which may be increased by your doctor to a maximum dose of 10 mg depending on your response after 10-14 days of treatment. [PRODUCT NAME] can be taken before or after a meal. You should take [PRODUCT NAME] at the same time each day with a glass of water.

Your doctor will tell you how long your treatment with [PRODUCT NAME] will last. If you have the impression that [PRODUCT NAME] is too strong or too weak, tell your doctor or pharmacist.
Do not share medicines prescribed for you with any other person.

If you take more [PRODUCT NAME] than you should:

Overdosage may cause your blood pressure to become very low. You may experience extreme dizziness, feel light-headed, faint or weakness. Your skin could feel cool and clammy and you could lose consciousness.
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 [PRODUCT NAME]:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time.
Do not take a double dose to make up for the forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

[PRODUCT NAME] can have side effects.

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

- swelling of the tongue or throat, which may cause difficulty in swallowing or breathing
- sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- swelling of the eyelids, face or lips
- severe skin reactions including intense 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) or other allergic reactions

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to [PRODUCT NAME]. 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:

- heart attack (severe chest pain), irregular heartbeat
- pancreatitis (upper abdominal pain that radiates into the back which may be aggravated by eating foods high in fat, accompanied with feeling unwell, nausea and vomiting)
- unexplained bleeding or bruising

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- drowsiness, dizziness, headache
- palpitations (feeling like your heart is pounding, racing or fluttering)
- flushing
- stomach pain, nausea (feeling sick) and vomiting
- ankle swelling, tiredness

Less frequent side effects:

- increased thirst, dry mouth, tiredness, blurred vision – may indicate high blood sugar levels
- mood changes, depression, difficulty sleeping, confusion
- trembling, taste abnormalities, a sensation of tingling, tickling, pricking, or burning of your skin, feeling tired, pain in the hands and feet, fainting
- visual disturbances
- ringing in the ears
- low blood pressure
- shortness of breath, cough, runny or congested nose
- change in bowel habits (diarrhoea or constipation), heartburn, dry mouth, mouth ulcers, stomach pain and indigestion
- yellowing of the skin and eyes, also called jaundice
- hair loss, purple bruises on the skin, discolouration of the skin, increased sweating, itchy skin rash, skin sensitivity to light exposure
- muscle or joint pain, back pain, muscle cramps
- increased urinary frequency, increased need to urinate at night
- inability to develop or maintain an erection, enlargement of the breasts in men
- weakness or feeling unwell
- weight increase or decrease

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

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, pharmacist or nurse. You can also report side effects to SAHPRA via the “Adverse drug reaction and quality problem reporting form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem reporting-form/.

By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME].

5. HOW TO STORE [PRODUCT NAME]

Store at or below 25 ˚C. Protect from light. Keep blister in outer carton until before use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the 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 [PRODUCT NAME] contains:

- The active substance is amlodipine.
- The other ingredients are dibasic calcium phosphate, microcrystalline cellulose, povidone, aluminium magnesium silicate, sodium starch glycolate, talc and magnesium stearate.

What [PRODUCT NAME] looks like and contents of the pack:

[PRODUCT NAME] 5: White to off-white, round, flat, uncoated tablets with bevelled edges having a break-line on one side and debossed with ‘A5’ on the other side.

[PRODUCT NAME] 10: White to off-white, round, flat, uncoated tablets with bevelled edges having a break-line on one side and debossed with ‘A10’ on the other side.

[PRODUCT NAME] 5 is packed in carton boxes containing 3 Clear PVC/Aluminium foil blister strips of 10 tablets each.

[PRODUCT NAME] 10 is packed in carton boxes containing 3 Clear PVC/Aluminium foil blister strips of 10 tablets each.

HOLDER OF CERTIFICATE OF REGISTRATION

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REGISTRATION NUMBER:

[PRODUCT NAME] 5: 41/7.1/0659 or 41/7.1/0661

[PRODUCT NAME] 10: 41/7.1/0660 or 41/7.1/0662