PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

AMLODIPINE 5 BIOTECH tablets

AMLODIPINE 10 BIOTECH tablets

Amlodipine maleate

Sugar free

Read all of this leaflet carefully before you start taking AMLODIPINE BIOTECH

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

What is in this leaflet

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

1. What AMLODIPINE BIOTECH is and what it is used for

Amlodipine maleate, the active ingredient in AMLODIPINE 5 BIOTECH and AMLODIPINE 10 BIOTECH, is a selective calcium channel blocker that have an effect on the blood vessels.

AMLODIPINE BIOTECH is used to treat angina pectoris and mild- to moderate hypertension, alone or in combination with other antihypertensive medicines.

2. What you need to know before you take AMLODIPINE BIOTECH

Do not take AMLODIPINE BIOTECH:

- if you are hypersensitive (allergic) to amlodipine maleate or any of the other ingredients of AMLODIPINE BIOTECH (listed in section 6).
- if you are hypersensitive to dihydropyridines.

Warnings and precautions

Special care should be taken with AMLODIPINE BIOTECH:

- if you are elderly and your dose needs to be increased
- if you have liver disease
- if you have heart failure
- if you had a recent heart attack

Children

Safety and efficacy have not been established.

Other medicines and AMLODIPINE BIOTECH

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

AMLODIPINE BIOTECH may be affected by other medicines, such as:

- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- ketoconazole, itraconazole (anti-fungal medicines)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- verapamil, diltiazem (heart medicines)
- hypericum perforatum (St. John's Wort)
- dantrolene (infusion for severe body temperature abnormalities)

AMLODIPINE BIOTECH may affect other medicines, such as:

- tacrolimus, sirolimus, temsirolimus, and everolimus (medicine used to alter the way your immune system works)
- ciclosporin (an immunosuppressant)
- simvastatin (a cholesterol lowering medicine)

AMLODIPINE BIOTECH with food and alcohol

Grapefruit juice and grapefruit should not be consumed by people who are taking AMLODIPINE BIOTECH. This is 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 amlodipine.

Pregnancy, breastfeeding and fertility

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

Pregnancy

The safety of AMLODIPINE BIOTECH in human pregnancy has not been established.

Breastfeeding

Amlodipine has been shown to pass into breast milk in small amounts.

Driving and using machines

If you may feel nauseous, dizzy, tired or have a headache do not drive or operate machinery, especially at the beginning of taking AMLODIPINE BIOTECH.

It is not always possible to predict to what extent AMLODIPINE BIOTECH may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which AMLODIPINE BIOTECH affects you.

3. How to take AMLODIPINE BIOTECH

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

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

Your doctor will tell you how long your treatment with AMLODIPINE BIOTECH will last. Do not stop treatment early. If you have the impression that the effect of AMLODIPINE BIOTECH is too strong or too weak, tell your doctor or pharmacist.

Take the tablets with a sufficient quantity of liquid (e.g., one glass of water)

The recommended dose of 5 mg AMLODIPINE BIOTECH once daily.

If there is no improvement after 10 to 14 days of therapy, AMLODIPINE BIOTECH doses can be increased to 10 mg once daily.

If your take more AMLODIPINE BIOTECH than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

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 an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take AMLODIPINE BIOTECH

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

AMLODIPINE BIOTECH can have side effects.

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

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

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

- fainting.

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

- deficiency of the platelets in the blood, causing bleeding into the tissues, bruising and slow blood clotting after injury (thrombocytopenia)
- reduction in the number of white cells in the blood (leukocytopenia)
- excess of glucose in the bloodstream (hyperglycaemia)
- temporary loss of consciousness caused by a fall in blood pressure
- rapid, strong, or irregular heartbeat
- heart attack
- heartbeat is irregular (slow, rapid) or have an abnormal rhythm (heart's two upper chambers (the atria) beat chaotically and irregularly (atrial fibrillation))
- difficulty in breathing
- inflammation of the pancreas
- inflammation of the liver
- elevated liver enzymes and liver disease

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>

- dizziness
- headache (especially at the beginning of the treatment)
- drowsy
- visual disturbance and double vision
- flushing, become red and hot
- nausea
- abdominal pain
- indigestion (dyspepsia)
- diarrhoea
- constipation
- swelling of the ankles
- muscle cramps
- extreme tiredness
- physical weakness or lack of energy
- excess of watery fluid collecting in the cavities or tissues of the body (oedema)

Less frequent side effects:

- Depression
- Mood changes, including feeling of worry and nervousness
- Sleepiness
- confusion
- high levels of muscle tone or tension (hypertonia)
- loss of sensation in the body (hypoesthesia)
- pins and needles feeling (paraesthesia)

- weakness, numbness and pain, usually in your hands and feet (peripheral neuropathy)
- involuntary movement (tremor)
- disfunction in the sense of taste (dysgeusia)
- ringing or buzzing in the ears
- low blood pressure
- inflammation of the blood vessels
- coughing
- rhinitis
- vomiting
- dry mouth
- overgrowth of gum tissue around the teeth
- inflammation of the lining of the stomach
- yellowing of the skin or whites of the eyes
- complete absence of hair from areas of the body where it normally grows, baldness (alopecia)
- a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura)
- skin discolouration
- abnormally excessive sweating that is not necessarily related to heat or exercise (hyperhidrosis)
- itching of the skin (pruritus)
- rash
- red, raised, itchy rash
- swelling around the eyes and lips (angioedema)
- skin immune reaction (erythema multiforme)
- redness and peeling of the skin (exfoliative dermatitis)

- is a rare, serious disorder of the skin and mucous membranes. It's usually a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters. Then the top layer of affected skin dies, sheds and begins to heal after several days (Steven-Johnson syndrome).
- joint pain
- back pain
- muscle pain
- need to urinate more often than usual
- abnormalities in the process of urine voiding, including bladder control, frequency of urination, as well as the volume and composition of urine.
- wake up during the night to urinate (nocturia)
- enlargement of a man's breasts (gynaecomastia)
- inability for a man to achieve an erection or orgasm (impotence)
- pain
- chest pain
- general feeling of discomfort, illness, or unease (malaise)
- weight increase
- weight decrease

Side effects with unknown frequency:

- life-threatening skin disorder characterised by a blistering and peeling of the skin (toxic epidermal necrolysis).

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 "**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 AMLODIPINE BIOTECH.

5. How to store AMLODIPINE BIOTECH

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from moisture.

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 AMLODIPINE BIOTECH contains

The active substance is amlodipine maleate equivalent to amlodipine. AMLODIPINE BIOTECH is available in two strengths, containing either 5 mg or 10 mg amlodipine.

The other ingredients are microcrystalline cellulose (Avicel PH 112), calcium hydrogen phosphate anhydrous, magnesium stearate and sodium starch glycollate (Type A) (sodium carboxymethyl starch).

What AMLODIPINE BIOTECH looks like and contents of the pack

AMLODIPINE 5 BIOTECH tablets are white to off-white, uncoated, oblong tablets.

AMLODIPINE 10 BIOTECH tablets are white to off-white, uncoated, oblong tablet, scored on one side.

AMLODIPINE BIOTECH is packed in white opaque blisters and white opaque plastic securitainers of 28, 30 and 100 tablets.

Holder of Certificate of registration

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