

**Approved Patient Information Leaflet for Medicines for Human Use:**

**AMLODIPINE 5 and 10 GDC**

**SCHEDULING STATUS:** S3

**AMLODIPINE 5 GDC tablets**

**AMLODIPINE 10 GDC tablets**

**Amlodipine besylate**

**Sugar free.**

**Read all of this leaflet carefully before you start taking AMLODIPINE GDC**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AMLODIPINE GDC 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 AMLODIPINE GDC is and what it is used for
2. What you need to know before you take AMLODIPINE GDC
3. How to take AMLODIPINE GDC
4. Possible side effects
5. How to store AMLODIPINE GDC
6. Contents of the pack and other information

## **1. What AMLODIPINE GDC is and what it is used for**

AMLODIPINE GDC contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists. AMLODIPINE GDC is used to treat high blood pressure (hypertension) and a type of chest pain called angina pectoris, a rare form of which is Prinzmetal's or variant angina. AMLODIPINE GDC is also used to reduce the risk of fatal and non-fatal heart disease or stroke.

AMLODIPINE GDC can be used alone or in combination with other medicines to treat these conditions.

## **2. What you need to know before taking AMLODIPINE GDC**

### **Do not take AMLODIPINE GDC tablets**

- if you are sensitive (allergic) or ever had a harmful reaction to amlodipine, dihydropyridine (used to lower blood pressure), or any of the other ingredients of AMLODIPINE GDC (see section 6)
- if you suffer from severe hypotension (severe low blood pressure, symptoms include light headedness or dizziness)
- if you have previously experienced shock which could include cardiogenic shock (this is the term used when blood pressure becomes so low that your heart stops working properly and medical treatment is required)
- if you recently (within the past 28 days) suffered a heart attack
- if the blood flow from the left side of your heart is obstructed (e.g. aortic valve narrowing)
- if you have unstable angina (chest pain which may occur when you are resting)
- in combination with grapefruit juice (see "Take special care with AMLODIPINE GDC")
- if you are pregnant or breastfeeding your baby
- if you are younger than 6 years of age.

## **Warnings and precautions**

Take special care with AMLODIPINE GDC

- If you have heart failure
- If you have severe increase in blood pressure (hypertensive crisis)
- If you suffer from aortic stenosis (a heart condition where the aortic valve, located between the heart's left ventricle and the aorta, narrows or thickens, restricting blood flow) with symptoms such as fatigue, feeling faint or fainting when exercising and shortness of breath
- If you are taking anti-fungal medicine or certain HIV medicines as these may increase the blood pressure lowering effects of AMLODIPINE GDC (see “Other medicines and AMLODIPINE GDC”)
- If you suffer from diabetes
- If you need to undergo blood tests, as the use of AMLODIPINE GDC may interfere with the results
- If you are an elderly patient
- If you suffer from severe kidney problems
- If you suffer from liver problems
- If you have low blood pressure or other heart conditions
- If you suffer from porphyria
- If you are about to have a procedure where you would need general anaesthesia, you must tell the doctor that you are taking AMLODIPINE GDC.

## **Children and adolescents**

AMLODIPINE GDC has not been studied in children under the age of 6 years. AMLODIPINE GDC should only be used for hypertension in children and adolescents from 6 years to 17 years of age (see “How to take AMLODIPINE GDC”).

## **Other medicines and AMLODIPINE GDC**

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

AMLODIPINE GDC can interact with the following medicines to make their effect and risk of adverse effects stronger. If you are taking any of the following, your doctor might monitor you more closely:

- Other medicines for hypertension (high blood pressure). AMLODIPINE GDC may lower your blood pressure even more if you are already taking other hypertension medicines which can lead to dizziness, blurred vision and fainting,
- Medicines used to treat diabetes, as the doses of these medicines may need to be adjusted.
- Lithium (used to treat mania (mental state characterised by an unusually elevated, unrestrained, excessive emotionally expressive or irritable mood, as well as increased energy, activity, and productivity) that is part of bipolar disorder (manic-depressive illness), as you may develop toxic blood concentrations of lithium if used in combination with AMLODIPINE GDC.
- Tacrolimus, sirolimus, temsirolimus, and everolimus (medicines used to change the way your immune system works). AMLODIPINE GDC may increase the levels of these medicines in your blood. Your doctor may monitor the blood levels of these medicines and change their dose if required.
- Ciclosporin (an immunosuppressive medicine used to treat organ rejection post-transplant). If you have had a renal transplant your doctor will monitor your ciclosporin levels and may reduce your dose if necessary.
- Simvastatin (used to lower cholesterol), as simultaneous use of AMLODIPINE GDC may result in increased levels of simvastatin in the blood. Your doctor may reduce your simvastatin dose.
- Quinidine or procainamide (used to treat and prevent abnormal heart rhythms, or dysrhythmias). AMLODIPINE GDC may increase the activities these medicines, potentially leading to or worsening of irregular heartbeats.

Some medicines can interact with AMLODIPINE GDC to make its effect and risk of adverse effects stronger. If you are taking the medicines below, your doctor might monitor you more closely:

- Medicines used to treat viral, fungal and bacterial infections (such as clarithromycin, erythromycin, ketoconazole, itraconazole or rifampicin), as these may lead to increased levels of the active ingredient amlodipine in the blood. Your doctor may want to monitor you more closely and adjust your dose of AMLODIPINE GDC if required (see section 2, “Warnings and precautions”).
- Protease inhibitors used to treat HIV (such as ritonavir, saquinavir, indinavir, nelfinavir, amprenavir, lopinavir and atazanavir). This may cause increased levels of the active ingredient amlodipine in your blood. Your doctor may want to monitor you more closely and adjust your dose of AMLODIPINE GDC if required (see section 2, “Warnings and precautions”).
- Grapefruit or grapefruit juice must not be taken AMLODIPINE GDC as the levels of the active ingredient amlodipine in the blood may be increased resulting in increased blood pressure lowering effects (see section 2, “Do not take AMLODIPINE GDC”).
- Dantrolene (a muscle relaxant and sometimes used as infusion for severe body temperature abnormalities) may affect potassium levels in the blood when taken with AMLODIPINE GDC.
- Medicines for angina (chest pains), such as nitro-glycerine tablets administered under the tongue, long acting nitrates or other medicines for hypertension (high blood pressure) such as beta-blockers or calcium channel blockers (such as verapamil, diltiazem), as this may increase the blood pressure lowering effects of AMLODIPINE GDC.
- Aldesleukin used in the treatment of kidney cancer and skin melanoma or medicines used to treat mental conditions (antipsychotics), as this may cause a strengthening of the blood pressure lowering effects.
- Sodium valproate (used for epilepsy), as this may increase blood levels of the active ingredient amlodipine with an increase the blood pressure lowering effects of AMLODIPINE GDC (Discuss with your doctor if you are unsure).

Some medicines can interact with AMLODIPINE GDC to make its effect weaker. You should avoid taking AMLODIPINE GDC together these medicines:

- St John's Wort (an herbal medicine used to treat anxiety), as this may lead to decreased levels of the active ingredient amlodipine in the blood and lead to a reduced blood pressure lowering effect of AMLODIPINE GDC.
- Certain medicines used to treat fits (carbamazepine, phenobarbital, phenytoin), as these may reduce the effect of AMLODIPINE GDC.

### **AMLODIPINE GDC with food and drink**

AMLODIPINE GDC can be taken with or without food.

Grapefruit and grapefruit juice must not be taken with AMLODIPINE GDC (see section 2, "Do not take AMLODIPINE GDC" and "Other medicines and AMLODIPINE GDC").

### **Pregnancy and breastfeeding**

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 this medicine.

If you are pregnant, or become pregnant whilst taking AMLODIPINE GDC, stop taking AMLODIPINE GDC and talk to your doctor as soon as possible (see section 2, "Do not take AMLODIPINE GDC").

You should not take AMLODIPINE GDC when breastfeeding your baby (see section 2, "Do not take AMLODIPINE GDC").

If you are a female of childbearing potential, you should ensure that you and your partner take adequate contraceptive cover to avoid pregnancy.

### **Driving and using machines**

AMLODIPINE GDC can have minor or moderate influence on the ability to drive and use machines. The use of AMLODIPINE GDC may lead to dizziness, visual disturbances, headache, fatigue or nausea and therefore your ability to react may be impaired.

It is not always possible to predict to what extent AMLODIPINE GDC 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 AMLODIPINE GDC affects you.

### **AMLODIPINE GDC contains sodium**

AMLODIPINE GDC contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take AMLODIPINE GDC**

Do not share medicines prescribed for you with others.

Always take AMLODIPINE GDC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### ***Adults***

The usual dose is initially 5 mg once daily taken at the same time every day with or without food. If no improvement is seen after 10 – 14 days, your doctor may increase the dose to the maximum of 10 mg AMLODIPINE GDC per day (taken as a single dose).

#### ***Children and adolescents***

For children and adolescents (6 – 17 years old), the recommended usual starting dose is 2,5 mg a day. The maximum recommended dose is 5 mg a day.

The effect of AMLODIPINE GDC on blood pressure in patients less than 6 years of age is not known.

Your doctor will decide on the dose depending on your condition. Your doctor will tell you how long your treatment with AMLODIPINE GDC will last. Do not stop treatment early because your condition may worsen and discontinuation is recommended to be under medical practitioner supervision.

## **Special populations**

### ***Elderly people***

If you are elderly patient and if your doctor needs to increase your dose, this should happen with care.

### ***Patients with liver disease***

If you have severe liver disease, your doctor will start your treatment at the lowest dose and slowly increase your dose.

### ***Patients with kidney disease***

If you have severe kidney disease, your dosage should be reduced.

## **Method of administration**

The tablets should be swallowed whole, with a glass of water. AMLODIPINE GDC can be administered with or without the intake of food.

You must not take AMLODIPINE GDC with grapefruit and grapefruit juice (see section 2, “Do not take AMLODIPINE GDC” and “Other medicines and AMLODIPINE GDC”).

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

### **If you take more AMLODIPINE GDC than you should**

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

Taking too many AMLODIPINE GDC tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak or have a rapid heartbeat. If your blood pressure drop is severe enough, shock can occur which may be fatal. 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. You may require ventilatory support.

### **If you forget to take AMLODIPINE GDC**

It is important to take AMLODIPINE GDC tablets regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for forgotten individual doses.

### **If you stop taking AMLODIPINE GDC**

Take AMLODIPINE GDC for as long as your doctor recommends. Don't stop unless your doctor advises you to. Your condition may return if you stop using this medicine before you are advised.

## **4. Possible side effects**

AMLODIPINE GDC can have side effects.

Not all side effects reported for AMLODIPINE GDC are included in this leaflet. Should your general health worsen while taking AMLODIPINE GDC, please consult your doctor, pharmacist or other health care professional for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or severe itching
- fainting
- severe and serious skin reactions which can include:
  - reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, forming very painful raw areas, called erosions that resemble severe hot-water burns. These intense and serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN))
  - severe and potentially life-threatening inflammation and scaling and extreme loss of skin over most of the body's skin surface (exfoliative or bullous dermatitis)
- heart failure (when the heart cannot pump adequate amounts of blood to body tissues). You may experience chest pain, shortness of breath, fatigue, swollen legs and rapid heartbeat
- severe liver problems (hepatitis) which can cause symptoms such as fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, light-coloured stools, joint pain, and jaundice (yellowing of the eyes and skin).

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

- increased vulnerability to infections as this may be a sign of lowered white blood cells (leukopenia)
- easy bruising, abnormal bleeding gums, nose bleeds and internal bleeding due to a low number of platelets in the blood involved in blood clotting (thrombocytopenia) which will be shown in blood tests
- bleeding that occurs during or after a surgical procedure which can manifest as uncontrolled bleeding, damage to blood vessels, or a life-threatening condition called haemorrhagic shock, which results from excessive blood loss
- change in the number and function of blood cells (blood dyscrasias) which can cause symptoms such as fever, chills, weakness, sore throat, sores in the mouth or throat, bleeding gums, bone pain, low blood pressure, fast heartbeat, and trouble breathing
- large, symmetrical red blotches that appear all over the skin in a circular pattern (erythema multiforme)
- high blood sugar levels (hyperglycaemia)
- involuntary movements, excessive muscle stiffness, and involuntary rhythmic shaking movement of a body part (tremors)
- changes in the way your heart beats, slow heartbeat (bradycardia) or rapid heartbeat (tachycardia), chest pains
- low blood pressure (hypotension) with symptoms such as fainting or light-headedness
- inflamed blood vessels (vasculitis) with common symptoms such as fever, fatigue, weight loss, and muscle/joint pain
- inflammation of the pancreas (pancreatitis) with symptoms such as stomach pain, nausea, vomiting, fever, increased heart rate and tenderness in the upper-abdomen

- inflammation of the stomach lining (gastritis) which may cause symptoms such as stomach pain or upset, nausea, vomiting, a feeling of fullness, loss of appetite, and potentially blood in the vomit or stool
- purple or reddish-purple spots or patches on the skin, or in the mucous membranes like the mouth, caused by bleeding under the skin (purpura)
- a swelling beneath the skin, often involving the face, lips, tongue, and throat (angioedema also known as Quincke oedema). The swelling can be severe enough to cause difficulty breathing, making it a medical emergency
- kidney problems (passing less urine than is normal for you)
- difficulty in achieving and maintaining erection in males (impotence).

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*

- dizziness, headache, sleepiness
- a sudden turning red or darker colour in the face, neck, and upper chest (flushing)
- swelling commonly affecting the extremities (arms and legs)
- stomach pain, nausea (feeling sick), discomfort or pain in the upper abdomen, often after eating or drinking (indigestion/dyspepsia), change in bowel habits (including diarrhoea and constipation)
- ankle swelling
- swelling in any part of the body
- tiredness
- physical weakness or a lack of energy.

*Less frequent side effects*

- sleeplessness, mood changes (including anxiety)
- persistent feeling of sadness and changes in how you think, sleep, eat and act (depression)
- trembling, distorted sense of taste, decrease in normal sensations or feeling of pins and needles and tingling, weakness, numbness and pain
- visual disturbances including double vision
- ringing or other noises in one or both of your ears (tinnitus)
- cough, shortness of breath, runny nose, sneezing, and stuffiness (rhinitis)
- vomiting, dry mouth, swelling of the gums
- increase in liver enzymes
- hair loss, skin discoloration
- excessive sweating
- itching and rash (red or pink spots, bumps, or blotches on the skin)
- raised red, itchy skin rash that can sting or burn (hives/urticaria)
- increased sensitivity of skin to sun (photosensitivity)
- back pain, muscle cramps and pain, joint stiffness, physical weakness
- frequent urination especially during the night
- enlargement of male breasts
- weight increase/decrease.

*Side effects occurring with frequency unknown*

- If you have a condition where the adrenal glands produce too much of the hormone aldosterone (hyperaldosteronism), laboratory tests may incorrectly diagnose this condition as high blood pressure where the underlying cause is unknown (essential hypertension).

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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AMLODIPINE GDC.

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per [info@gulfdrug.co.za](mailto:info@gulfdrug.co.za).

### **5. How to store AMLODIPINE GDC**

Store all medicines out of reach of children.

- Store at or below 25 °C in a cool, dry place.
- Protect from light and moisture.
- Keep container tightly closed.
- Do not remove tablets from container/blister until required for use.

Return all unused or expired 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 AMLODIPINE GDC contains**

- The active substance is amlodipine besylate.

AMLODIPINE 5 GDC:

Each tablet contains amlodipine besylate equivalent to amlodipine 5 mg.

AMLODIPINE 10 GDC:

Each tablet contains amlodipine besylate equivalent to amlodipine 10 mg.

- The other ingredients are:

Anhydrous dicalcium phosphate

Colloidal silicon dioxide

Magnesium stearate

Microcrystalline cellulose

Sodium starch glycollate.

### **What AMLODIPINE GDC looks like and contents of the pack**

#### **AMLODIPINE 5 GDC**

White to off white, flat, round, bevel edged tablet with a break line on one side. Diameter ( $\pm 8$  mm).

The break line is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

#### **AMLODIPINE 10 GDC**

White to off white, flat, round, bevel edged tablet with a break line on one side. Diameter ( $\pm 11$  mm).

The break line is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

AMLODIPINE GDC is packed in:

- Push-through PVC/Al blister strips of 10 tablets in packs of 30 tablets in a unit carton.
- White HDPE containers of 30, 100, 500 and 1000 tablets.

**Holder of the Certificate of Registration**

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