

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

AMLODIPINE 5 KIARA tablets

AMLODIPINE 10 KIARA tablets

Amlodipine (as besilate)

Sugar free

Read all of this leaflet carefully before you start taking AMLODIPINE KIARA:

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

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

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

AMLODIPINE KIARA is used to treat high blood pressure (hypertension) and to treat chest pain or

discomfort, called angina, a rare form of which is Prinzmetal's or variant angina.

AMLODIPINE KIARA is also used to reduce the risk of fatal and non-fatal heart disease or stroke.

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

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

Do not take AMLODIPINE KIARA

- If you are hypersensitive (allergic) to amlodipine, other calcium channel blockers or any of the other ingredients of AMLODIPINE KIARA listed in section 6 of this leaflet.
- 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 suffer from heart failure after a recent heart attack (within the past 28 days).
- If you have been diagnosed with unstable angina (chest pain occurring while resting).
- For rapid or immediate reduction of blood pressure.
- If you are pregnant or breastfeeding.
- In combination with grapefruit juice.

Warnings and precautions

Tell your doctor before taking AMLODIPINE KIARA:

- If you suffer from heart failure (a condition where the heart cannot pump blood well).
- If you have been diagnosed with aortic stenosis (narrowing of the aortic heart valve).
- If you have liver problems. Your doctor may need to monitor your liver function and adjust your dose of AMLODIPINE KIARA accordingly.
- If you are 65 years or older.
- If you suffer from severe kidney problems.
- If you suffer from diabetes.

- If you need to go for laboratory tests, such as plasma aldosterone and renin ratios.
- 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 AMLODIPINE KIARA.
- If you have low blood pressure.

Children and adolescents

The effect of AMLODIPINE KIARA on blood pressure in children younger than 6 years is not known.

AMLODIPINE KIARA should only be used for high blood pressure in children and adolescents from 6 years to 17 years of age (see section 3).

For more information, talk to your doctor.

Other medicines and AMLODIPINE KIARA

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 AMLODIPINE KIARA if you are taking:

- Protease inhibitors, such as ritonavir (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 (*Hypericum perforatum*) (herbal medicine used to treat mild depression).
- Anti-epileptic medicines, such as carbamazepine, phenobarbital, phenytoin or valproate (used

to treat seizures [fits]).

- Dantrolene (used to treat severe body temperature abnormalities).
- Medicines for treating angina (chest pains), such as nitroglycerine, long-acting nitrates or beta-blockers.
- Tacrolimus (used to treat eczema or during organ transplants).
- Immunosuppressive medicines, such as tacrolimus (used to treat eczema or to prevent organ rejection during organ transplants), temsirolimus, everolimus, sirolimus (used to treat cancer) and ciclosporin (used to treat cancer, rheumatoid arthritis or prevent organ rejection after an organ transplant). Tell your doctor or pharmacist before you take AMLODIPINE KIARA if you have had a kidney transplant and are taking ciclosporin. Your doctor may need to monitor your blood and adjust your dose of ciclosporin according to the test results.
- Simvastatin (used to control high cholesterol levels).
- Quinidine or procainamide (used to treat heart rhythm disorders).
- Lithium (used to treat some types of depression).

AMLODIPINE KIARA with food and drink

Do not eat grapefruit or drink grapefruit juice while taking AMLODIPINE KIARA as it may increase the risk of your blood pressure lowering more than expected (see **Do not take AMLODIPINE KIARA**).

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 AMLODIPINE KIARA.

You should not take AMLODIPINE KIARA if you are pregnant or breastfeeding.

If you are a woman of childbearing potential, you and your partner should ensure that you are both using adequate contraception. Consult your doctor immediately if you become pregnant while taking AMLODIPINE KIARA.

Driving and using machines

AMLODIPINE KIARA 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 AMLODIPINE KIARA. Do not drive or operate machinery until you know how AMLODIPINE KIARA affects you.

AMLODIPINE KIARA contains sodium

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

3. How to take AMLODIPINE KIARA

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

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

The usual starting dose is one tablet of AMLODIPINE 5 KIARA once a day, which may be increased to a maximum of one tablet of AMLODIPINE 10 KIARA once a day, depending on your response. AMLODIPINE KIARA should be taken orally.

If you suffer from high blood pressure, AMLODIPINE KIARA may be used either alone or in combination with other medicines used to treat high blood pressure.

If you suffer from liver problems, your doctor will determine the most suitable dose for you.

Children and adolescents

The usual starting dose for children aged 6 to 17 years is 2,5 mg, which can be increased to 5 mg

once a day.

AMLODIPINE KIARA can be taken with or without food.

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

Continue taking AMLODIPINE KIARA until your doctor tells you to stop at which time it should be done gradually.

If you have the impression that the effect of AMLODIPINE KIARA 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 AMLODIPINE KIARA than you should

If you have taken an overdose of AMLODIPINE KIARA, you may appear flushed (your skin will look red) and your heart may beat faster than usual. Your blood pressure may be lower than usual for a long time which can make you feel dizzy, lightheaded, faint or weak. If your blood pressure drop is severe enough, shock can occur (pale, cold, clammy skin with difficulty breathing) and you could lose consciousness.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may only develop later (24 – 48 hours after intake). You may stop breathing and need to be ventilated.

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 AMLODIPINE KIARA

If you forget 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.

If you stop taking AMLODIPINE KIARA

Abruptly stopping your treatment with AMLODIPINE KIARA may cause worsening of your chest pain (angina). Your doctor will advise you how long to take AMLODIPINE KIARA and will gradually reduce your dose before you can finally stop taking AMLODIPINE KIARA.

4. Possible side effects

AMLODIPINE KIARA can have side effects.

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

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

- swelling of your 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 AMLODIPINE KIARA. 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 start 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 disturbance (seeing double);
- sleepiness, dizziness or headaches (especially when you first start taking AMLODIPINE KIARA);
- 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 (characterised by increased thirst, dry mouth, frequent urination, blurred vision and feeling weak or unusually tired);
- 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 joints, muscle or back pain, pain in a joint and feeling unwell;
- muscle spasms, slow movement and irregular, jerky movements;
- 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

- nosebleeds in children and adolescents (aged 6 – 17 years).

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: www.sahpra.org.za

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

5. How to store AMLODIPINE KIARA

- Store at or below 25 °C.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AMLODIPINE KIARA contains

The active substance in AMLODIPINE KIARA is amlodipine.

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

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

The other ingredients in AMLODIPINE KIARA are calcium phosphate anhydrous (dibasic), magnesium stearate (E572), microcrystalline cellulose (E460[i]) and sodium starch glycolate.

What AMLODIPINE KIARA looks like and contents of the pack

AMLODIPINE 5 KIARA: White to off-white, round, flat faced, bevelled edged tablet, debossed with 'U' and 'L' on either side of the break line on one side and break line on the other side.

AMLODIPINE 10 KIARA: White to off-white, round, flat faced, bevelled edged tablet, with 'UH' debossed on one side and plain on the other side.

AMLODIPINE KIARA is packed into clear PVC/PVdC and aluminium blister strips and placed in an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

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