Approved Patient Information Leaflet (PIL)

for Medicines for Human Use

AMLODIPINE 5 UNIMED (Tablets)

AMLODIPINE 10 UNIMED (Tablets)

SCHEDULING STATUS:

S3

AMLODIPINE 5 UNIMED

AMLODIPINE 10 UNIMED

Amlodipine besilate

Sugar free

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

- 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 UNIMED** 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 UNIMED** is and what it is used for

2. What you need to know before you take **AMLODIPINE UNIMED**

3. How to take **AMLODIPINE UNIMED**

4. Possible side effects

5. How to store **AMLODIPINE UNIMED**

6. Contents of the pack and other information

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

AMLODIPINE UNIMED tablets belong to a group of medicines called dihydropyridine derivatives (calcium channel blockers) and are used to treat high blood pressure (hypertension) and chest pain (angina).

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

AMLODIPINE UNIMED can be used alone or with other medicines to treat these conditions.

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

Do not take AMLODIPINE UNIMED tablets:

- if you are hypersensitive (allergic) to **AMLODIPINE UNIMED** or any of the other ingredients of **AMLODIPINE UNIMED** tablets
- if you are allergic to certain other types of hypertensive medicines, called dihydropyridines
- if you have very low blood pressure
- if you are suffering from shock (a very severe lowering of blood pressure by which you become unconscious)
- if you have heart failure after an acute heart attack
- if the blood flow from the left side of your heart is obstructed
- if you suffer from unstable angina pectoris
- if you are pregnant or breastfeeding

- in combination with grapefruit juice.

If you are not sure whether any of the above applies to you, ask your pharmacist of your doctor.

Warnings and precautions

Take special care with AMLODIPINE UNIMED:

- if you are taking other medicines such anti-fungal medicines (ketoconazole, itraconazole) or protease inhibitors used to treat HIV (ritonavir). Using these medicines together with **AMLODIPINE UNIMED** may decrease the blood pressure even further (see Other medicines and **AMLODIPINE UNIMED).**
- if you are elderly – treatment with **AMLODIPINE UNIMED** will be started at a lower dose
- if you have severe kidney problems – your dosage of **AMLODIPINE UNIMED** may be reduced
- if you have liver problems – treatment with **AMLODIPINE UNIMED** will be at a lower dose
- **AMLODIPINE UNIMED** should not be given to children less than 6 years of age because the safety and efficacy has not been established
- if you have heart failure
- **AMLODIPINE UNIMED** must be used carefully if you are a patient with a low cardiac reserve
- **AMLODIPINE UNIMED** should not be used if you are a patient with hypertensive (blood pressure) crisis because the safety and efficacy has not been established.

Other medicines and AMLODIPINE UNIMED:

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

AMLODIPINE UNIMED may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

AMLODIPINE UNIMED may affect or be affected by other medicines, such as:

- Cholesterol-lowering medicine (simvastatin)
- Heart medicines (diltiazem)
- Anti-fungal medicines (ketoconazole, itraconazole) (see **Warnings and precautions)**
- Antibiotics (clarithromycin, rifampicin)
- Protease inhibitors used to treat HIV (ritonavir) (see **Warnings and precautions)**
- St. John's Wort (*hypericum perforatum)*
- Immunosuppressive medicines (tacrolimus, sirolimus, temsirolimus, everolimus and ciclosporin)

AMLODIPINE UNIMED with food and drink:

AMLODIPINE UNIMED tablets can be taken before or after food.

Do not eat grapefruit or drink grapefruit juice with **AMLODIPINE UNIMED.**

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Safety of **AMLODIPINE UNIMED** in human pregnancy has not been established.

AMLODIPINE UNIMED has been shown to pass into breast milk.

If you are a woman of childbearing potential, you and your partner should ensure you are both using adequate contraception.

Driving and using machines:

AMLODIPINE UNIMED may cause dizziness, 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 **AMLODIPINE UNIMED** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **AMLODIPINE UNIMED** affects them.

3. HOW TO TAKE AMLODIPINE UNIMED:

Always take **AMLODIPINE UNIMED** tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The dose is decided by your doctor.

Take the **AMLODIPINE UNIMED** tablets by mouth with plenty of water.

The tablets may be taken before or after a meal.

Try to take your medicine at the same time each day.

Your doctor will tell you how long you need to keep taking your **AMLODIPINE UNIMED** tablets.

Do not suddenly stop taking the **AMLODIPINE UNIMED** tablets without

consulting your doctor first.

If you have the impression that the effect of **AMLODPINE UNIMED** is too strong or too weak, tell your doctor or pharmacist.

Adults:

The usual dose is 5 mg per day. This may be increased after 10 – 14 days to 10 mg per day if your doctor feels you will benefit from this dose.

Children:

The usual starting dose for children aged 6 – 17 years is 2,5 mg increased to 5 mg once a day.

Do not share medicines prescribed for you with others.

If you take more AMLODIPINE UNIMED tablets than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

If you forget to take AMLODIPINE UNIMED tablets:

If you miss a dose take it as soon as you remember unless it is nearly time for your next dose. In the latter case, do not take the missed dose, simply carry on as normal.

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

If you stop taking AMLODIPINE UNIMED tablets:

Your doctor has told you for how long you should take **AMLODIPINE**

UNIMED. If you stop the treatment suddenly, your symptoms may come back. Do not stop treatment earlier than agreed without discussing this with your doctor, pharmacist of healthcare professional.

4. POSSIBLE SIDE EFFECTS:

AMLODIPINE UNIMED tablets can have side effects.

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

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

Allergic reaction including:

- Pruritis (severe itching of the skin).
- Rash (suddenly appearing redness of the skin).
- Angioedema (swelling under the skin, often around your face and lips).
- Erythema multiforme (large, symmetrical red blotches that appear all over the skin in a circular pattern).
- Angioedema (sudden swelling of skin or mucous membranes e.g. throat or tongue, with difficulty breathing and/or itching and rash).
- Anaphylaxis (immediate hypersensitivity reaction resulting in life-threatening respiratory distress usually followed by vascular collapse and shock).

These are all very serious side effects. If you have them, you may have

had a serious reaction to **AMLODIPINE UNIMED.** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side-effects:

- Headache; dizziness; sleepiness.
- Palpitations (awareness of your heartbeat); flushing (redness of the neck and face).
- Dyspnoea (shortness of breath).
- Stomach pain; nausea.
- Ankle swelling; muscle cramps.
- Peripheral oedema (presence of abnormally large amounts of fluid in the tissue spaces of the body); tiredness.

Less frequent side effects:

- Leukopenia (low numbers of white blood cells giving a high risk of infections); thrombocytopenia (low numbers of platelets with the risk of bruising).
- Hyperglycaemia (increase in blood sugar).
- Mood changes including anxiety; depression; insomnia (sleeplessness); feeling confused.
- Peripheral neuropathy (numbness, tingling, a burning sensation or weakness of hands and feet); increased sweating; irritability; hypertonia (increased resistance of muscle to passive stretching); hypoesthesia (abnormally increased sensitivity to stimulation); paraesthesia (unpleasant tingling feeling in arms or legs); tremor (uncontrolled shaking); taste problems; syncope (fainting)
- Problems with sight.

- Ringing in the ears.
- Aggravation of angina pectoris (increased chest pain); heart attack and disturbance of heart rhythm (including increased heart rate, decreased heart rate); chest pain; in patients with heart problems involving the coronary artery, irregular heart beat (including missed heart beats).
- Hypotension (decreased blood pressure); vasculitis (inflamed blood vessel).
- Rhinitis (inflammation inside the nose with a runny nose); coughing.
- Vomiting; altered bowel habits; dyspepsia (indigestion); swelling of the gums; pancreatitis (inflammation of the pancreas, together with extreme pain in the upper abdomen (below the ribs) that spreads to the back); gastritis (inflammation of the stomach lining); dry mouth.
- Hepatitis; jaundice; increase of liver enzymes in the blood indicating abnormal liver function.
- Alopecia (hair loss); photosensitivity (abnormal response to sunlight or filtered or artificial light); discolouration of the skin, skin rash resulting from bleeding into the skin; itchy skin; urticaria (smooth, slightly elevated area on the skin, which is redder and paler than the surrounding skin).
- Exfolliative dermatitis (extreme redness and scaling of the skin); Stevens Johnson syndrome (serious allergic reaction with fever, red patches, joint pain and/or eye problems).
- Arthralgia (pain in a joint); myalgia (pain in a muscle or muscles); back pain.

- Increased need to urinate especially at night; pain when urinating.
- Impotence; erectile dysfunction; enlargement of male breasts.
- Malaise (feeling of bodily discomfort); asthenia (loss of strength and energy); pain.
- Increase or decrease in weight.

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 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 **AMOLIDIPINE UNIMED.**

5. How to store AMLODIPINE UNIMED

Store in the original container at or below 25 °C. Protect from light.

Keep the tablets in their original container and keep blister strips in cartons until tablets are required.

Do not use after the expiry date stated on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information

What AMLODIPINE UNIMED contains

AMLODIPINE 5 UNIMED contains 5 mg amlodipine (as amlodipine besilate).

AMLODIPINE 10 UNIMED contains 10 mg amlodipine (as amlodipine

besilate).

The other ingredients are pregelatinised starch, microcrystalline cellulose, sodium starch glycollate and magnesium stearate.

What AMLODIPINE UNIMED looks like and contents of the pack

AMLODIPINE 5 UNIMED tablets are white to off-white, round tablets with a score line over one side and “5” on the other side.

AMLODIPINE 10 UNIMED tablets are white to off-white, round tablets with “AB” over score line over “10” on one side and “G” on the other side.

AMLODIPINE 5 UNIMED tablets are packed in:

- Aluminium/aluminium foil blisters containing 28 tablets per pack

  or
- Aclar/aluminium foil blisters containing 14, 28 or 30 tablets per pack or
- white plastic bottles containing 60 tablets per bottle. Not all pack sizes may be marketed.

AMLODIPINE 10 UNIMED tablets are packed in Aclar/aluminium foil blisters containing 14, 28 or 30 tablets per pack or white plastic bottles containing 60 tablets per bottle. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To access the professional information please visit:

https://unimedhealthcare.co.za/professional-information/ or scan the

QR code.