Shanur Healthcare (Pty) Ltd, 48/7.1/0037, AMLODIPINE DEZZO 5, Tablets, 5 mg
Shanur Healthcare (Pty) Ltd, 48/7.1/0038, AMLODIPINE DEZZO 10, Tablets, 10 mg

Approved Patient Information Leaflet for Medicines for Human Use:

AMLODIPINE DEZZO 5

AMLODIPINE DEZZO 10

SCHEDULING STATUS: S3

AMLODIPINE DEZZO 5 (5 mg) tablets

AMLODIPINE DEZZO 10 (10 mg) tablets

Amlodipine besilate

Contains sugar: mannitol

AMLODIPINE DEZZO 5 (5 mg) tablets

Each tablet contains 63 mg mannitol.

AMLODIPINE DEZZO 10 (10 mg) tablets

Each tablet contains 126 mg mannitol.

Read all of this leaflet carefully before you start taking AMLODIPINE DEZZO 5 (5 mg) tablets or AMLODIPINE DEZZO 10 (10 mg) tablets

- 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.
- AMLODIPINE DEZZO 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.

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

AMLODIPINE DEZZO contains the active substance called amlodipine besilate which belongs to the group of medicines called calcium channel blockers.

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AMLODIPINE DEZZO works by relaxing the blood vessels, so that the blood passes through the blood vessels more easily.

AMLODIPINE DEZZO 5 & AMLODIPINE DEZZO 10 is used to treat high blood pressure and angina pectoris or chest pain.

AMLODIPINE DEZZO 5 & AMLODIPINE DEZZO 10 may be used with other medicines which also lower your blood pressure.

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

Do not take AMLODIPINE DEZZO 5 (5 mg) or AMLODIPINE DEZZO 10 (10 mg) tablets:

- if you are hypersensitive (allergic) to amlodipine or any of the other ingredients of AMLODIPINE DEZZO (listed in section 6), or to any other calcium antagonists.
- 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 suffer from heart failure after a heart attack
- if you are pregnant or breast-feeding.
- AMLODIPINE DEZZO may not be given to children.

Warnings and precautions

Take special care with AMLODIPINE DEZZO 5 or AMLODIPINE DEZZO 10:

- if you are elderly
- if you have severe kidney function disease
- if you have liver function disease
- if you have heart failure, severe low blood pressure, shock, hypertensive crisis (very high blood pressure)

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- if you have obstruction to blood flow in the heart (aortic stenosis)
- if you have porphyria.

Children

Safety and efficacy in children have not been established.

Other medicines and AMLODIPINE DEZZO

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

AMLODIPINE DEZZO may be taken with:

- Thiazide diuretics (medicines used to decrease blood pressure)
- Beta blockers (medicines used to decrease blood pressure)
- ACE inhibitors (medicines used to decrease blood pressure)
- Long-acting nitrates (medicines used to treat chest pain)
- Sublingual nitroglycerine (medicine used to treat chest pain)
- Non-steroidal anti-inflammatory drugs (medicines used to treat inflammation)
- Antibiotics (medicines used to treat infection)
- Oral hypoglycaemic medicines (medicines used to decrease blood sugar)
- Cimetidine (medicines used as an antacid)
- Warfarin (medicines used to thin blood)
- Indomethacin (medicines used to treat inflammation).

The effects of AMLODIPINE DEZZO may be increased by the simultaneous intake of the following medicines:

- Digoxin (medicine used to treat irregular heartbeat)

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- Ritonavir, indinavir, nefinavir (medicines used to treat HIV)
- Ketoconazole, itraconazole, fluconazole (medicines used to treat fungal infections)
- Erythromycin, clarithromycin (antibiotics)
- Verapamil, diltiazem (heart medicines).

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

- Dantrolene (infusion for severe body temperature abnormalities)
- Tacrolimus, sirolimus, temsirolimus, everolimus (immunosuppressant medicines used to prevent organ rejection after a transplant)
- Cyclosporin (immunosuppressant medicine used to prevent organ rejection after a transplant).

Taking AMLODIPINE DEZZO with simvastatin (cholesterol lowering medicine) can increase the effects of simvastatin.

AMLODIPINE DEZZO may change the response to insulin and glucose in your body. If you are a diabetic, your dose may need to be adjusted.

The effects of AMLODIPINE DEZZO may be lessened by the simultaneous intake of the following medicines:

- Rifampicin (medicine used to treat TB)
- Carbamazepine, phenytoin, phenobarbitone (medicines used to treat epilepsy).

AMLODIPINE DEZZO with food and drink:

Do not consume grapefruit or grapefruit juice while taking AMLODIPINE DEZZO. If you do, it could lead to an increase in the effects of AMLODIPINE DEZZO**.**

Pregnancy and Breastfeeding:

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Do not take AMLODIPINE DEZZO 5 or AMLODIPINE DEZZO 10 if you are pregnant or breast-feeding. 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 AMLODIPINE DEZZO.

Driving and using machines:

- AMLODIPINE DEZZO may make you feel dizzy or tired or may give you a headache.
- Do not drive because AMLODIPINE DEZZO could interfere with your ability to drive safely.
- Do not operate any tools or machines.

It is not always possible to predict to what extent AMLODIPINE DEZZO 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 DEZZO affects them.

AMLODIPINE DEZZO contains mannitol which may have a laxative effect or cause diarrhoea.

3. How to take AMLODIPINE DEZZO

Do not share medicines prescribed for you with any other person.
Always take AMLODIPINE DEZZO 5 or AMLODIPINE DEZZO 10 exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.
The usual dose is 5 – 10 mg daily. AMLODIPINE DEZZO 5 (5 mg) tablets should not be broken.

Duration of administration

- Your doctor will determine your dose according to your condition.
- Your doctor will tell you how long your treatment with AMLODIPINE DEZZO will last.
- Do not stop treatment early because your blood pressure may increase again.

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

Method of administration

- Take the tablet/s with a sufficient quantity of liquid (e.g. one glass of water).
- Take AMLODIPINE DEZZO once a day, every day, at about the same time each day.
- Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you to remember when to take the tablets.

If you take more AMLODIPINE DEZZO than you should:

You may experience flushing, (reddening of the face), a drop in blood pressure, feel dizzy or light headed.

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

If you forget to take AMLODIPINE DEZZO

If you forget to take a dose, you should take it as soon as you realise it. If you were closer to taking the next dose, then skip the forgotten dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

AMLODIPINE DEZZO can have side effects.

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

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

Less frequent:

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

Frequency unknown:

- yellowing of the skin and eyes (jaundice).

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

Frequent:

- chest pain
- changes in the way your heart beats, for example, if you notice it beating faster.

Less frequent:

- difficulty breathing.

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

Tell your doctor if you notice any of the following:

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Frequent side effects:

- headache, sleepiness, dizziness
- palpitations
- reddening of face (flushing)
- visual disturbances, e.g. double vision or blurred vision
- abdominal pain, altered bowel habits (diarrhoea or constipation), indigestion
- feeling sick (nausea)
- muscle cramps
- tiredness, weakness
- Ankle swelling.

Less frequent side effects:

- inflammation of blood vessels, often with skin rash
- taste abnormalities
- fainting
- a disorder of the nerves, which can cause weakness, tingling or numbness
- shaking
- tinnitus (ringing in the ears)
- slower or faster heartbeat
- low blood pressure
- dry mouth, increased sweating
- mood changes, depression
- vomiting
- abdominal bloating
- swelling of the gums
- inflammation of the pancreas, which causes severe pain in the abdomen and back
- joint or muscle pain, back pain

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- decreased number of white blood cells which increases risk of infection
- decrease in blood platelets which increases risk of bleeding or bruising
- increased need to urinate
- inability to obtain erection, discomfort or enlargement of the breasts in men
- weight increase or decrease
- high blood sugar (hyperglycaemia)
- hair loss, itchy skin, red patches on skin
- sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- cough
- inflammation of the liver (hepatitis), liver enzyme increase which may have an effect on some medical tests
- heart attack.

Side effects with frequency unknown:

- involuntary movements
- increased pain, discoloration, blistering and sloughing of your skin (skin necrosis).

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: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AMLODIPINE DEZZO.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

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5. How to store AMLODIPINE DEZZO

- Store all medicines out of reach of children.
- Store in a cool, dry place at or below 30 °C.
- Protect from light and moisture.
- Do not remove the blister from the carton until required for use.
- Store in the original package.
- Do not use after the expiry date stated on the carton.
- Return all unused 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 DEZZO contains

The active substance is amlodipine besilate.

The other ingredients are colloidal silica anhydrous, magnesium stearate, mannitol, microcrystalline cellulose and sodium starch glycolate.

AMLODIPINE DEZZO 5 (5 mg) tablets

Each tablet contains amlodipine besilate equivalent to 5 mg amlodipine base.

AMLODIPINE DEZZO 10 (10 mg) tablets

Each tablet contains amlodipine besilate equivalent to 10 mg amlodipine base.

What AMLODIPINE DEZZO looks like and contents of the pack

AMLODIPINE DEZZO 5 (5 mg) tablets

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White to off white, octagonal shaped, uncoated tablets, debossed with “AM 5” on one side and breakline on the other side. This breakline is non-functional. AMLODIPINE DEZZO 5 (5 mg) tablets should therefore not be broken.

AMLODIPINE DEZZO 10 (10 mg) tablets
White to off white, octagonal shaped, uncoated tablets, debossed with “AM 10” on one side and plain on the other side.

AMLODIPINE DEZZO 5 (5 mg) tablets and AMLODIPINE DEZZO 10 (10 mg) tablets are both packed in white, opaque PVC/PVDC-Aluminium foil blister strips [with VMCH (copolymer of vinyl chloride and vinyl acetate) heat seal coating] containing 10 tablets or 14 tablets in each pack size of 30 tablets or 28 tablets packed in an outer carton.

Holder of Certificate of Registration

Shanur Healthcare (Pty) Ltd.
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AMLODIPINE DEZZO 5 (5 mg) tablets: 48/7.1/0037
AMLODIPINE DEZZO 10 (10 mg) tablets: 48/7.1/0038