

Applicant: Oethmaan Biosims (Pty) Ltd	SAHPRA approval date: 22 December 2023
Product: AMLODIPINE 5 OETHMAAN AMLODIPINE 10 OETHMAAN	Dosage form and strength: Each tablet contains amlodipine maleate equivalent to 5 mg or 10 mg amlodipine

PROPOSED PATIENT INFORMATION LEAFLET -CLEAN

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

AMLODIPINE 5 OETHMAAN (Tablets)

AMLODIPINE 10 OETHMAAN (Tablets)

Amlodipine


Sugar free

Read all of this leaflet carefully before you are given AMLODIPINE OETHMAAN.

- 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 OETHMAAN 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 OETHMAAN is and what it is used for
2. What you need to know before you take AMLODIPINE OETHMAAN
3. How to take AMLODIPINE OETHMAAN

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	22/12/2023

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4. Possible side effects
5. How to store AMLODIPINE OETHMAAN
6. Contents of the pack and other information

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

AMLODIPINE OETHMAAN contains the active substance amlodipine maleate which belongs to a group of medicines called calcium antagonist.


AMLODIPINE OETHMAAN is used to treat a certain type of chest pain called angina, and to treat high blood pressure.

For the treatment of high blood pressure, this medicine can be used alone or together with other medicines used for the treatment of high blood pressure. AMLODIPINE OETHMAAN is also used to reduce the risk of fatal and non-fatal heart disease or stroke.

2. What you need to know before you are given AMLODIPINE OETHMAAN

Do not take AMLODIPINE OETHMAAN:

- If you had an allergic reaction to similar tablets (amlodipine or other calcium-antagonists), or any of the other ingredients of AMLODIPINE OETHMAAN tablets. (see “What AMLODIPINE OETHMAAN contains”).
- 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

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- 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)
- If you are pregnant or breastfeeding your baby
- In children younger than 6 years of age.
- In combination with grapefruit juice.

Warnings and precautions

Take special care with AMLODIPINE OETHMAAN if:

- your doctor diagnosed you with severe high blood pressure
- you suffer from aortic stenosis with symptoms such as fatigue, feeling faint or fainting when exercising and shortness of breath
- you experience chest pain when taking AMLODIPINE OETHMAAN
- you suffer from diabetes
- if you need to undergo blood tests, as the use of AMLODIPINE OETHMAAN may interfere with the results
- you have liver or kidney problems
- you have any heart problem
- you are under 6 years of age
- you are elderly, your doctor may monitor you closely
- you are pregnant or there is a possibility that you may become pregnant
- you are breastfeeding
- you are taking other medicines such as anti-fungal medicines (ketoconazole, itraconazole) or protease inhibitors used to treat HIV (ritonavir). Using these medicines together with

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AMLODIPINE OETHMAAN may decrease the blood pressure even further (see Other medicines an AMLODIPINE OETHMAAN)

- you are about to have a procedure where you would need general anaesthesia.

Other medicines and AMLODIPINE OETHMAAN

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


The following medicines may have an added antihypertensive and antianginal effect if used with AMLODIPINE OETHMAAN:

- Sublingual nitroglycerine (used to treat chest pains that increase in frequency and/or severity, or occurring at rest).
- Beta-blockers, ACE-inhibitors and diuretics (used to treat high blood pressure).

AMLODIPINE OETHMAAN may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure. Do not stop taking your other prescription medicines, including any other blood pressure medicines, without talking to your doctor or health care provider first.

AMLODIPINE OETHMAAN 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 (erythromycin, clarithromycin, rifampicin)
- Protease inhibitors used to treat HIV (ritonavir) (see Warnings and precautions)
- St. John's Wort (*hypericum perforatum*)

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- Immunosuppressive medicines (tacrolimus, sirolimus, temsirolimus, everolimus and ciclosporin)
- Aldesleukin used in the treatment of kidney cancer and skin melanoma or medicines used to treat mental conditions (antipsychotics), as this may increase the levels of AMLODIPINE OETHMAAN in the blood
- Grapefruit or grapefruit juice may increase the blood pressure lowering effects of AMLODIPINE OETHMAAN
- Medicines used to treat diabetes, as the doses of these medicines may need to be adjusted
- Medicines that alter the heart rate, such as quinidine or procainamide
- Certain medicines used to treat fits (carbamazepine, phenobarbital, phenytoin), as these may reduce the effect of AMLODIPINE OETHMAAN
- Sodium valproate (used for epilepsy), as this may increase AMLODIPINE OETHMAAN blood levels. (Discuss with your doctor if you are unsure)
- Dantrolene (a muscle relaxant) may affect potassium levels in the blood
- Lithium, as this may result in toxic blood concentrations if used in combination with AMLODIPINE OETHMAAN

AMLODIPINE OETHMAAN with food and drink and alcohol

Do not eat grapefruit or drink grapefruit juice with AMLODIPINE OETHMAAN.

Pregnancy and breastfeeding and fertility

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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 provider for advice before taking AMLODIPINE OETHMAAN.

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

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

AMLODIPINE OETHMAAN has been shown to pass into breast milk.

Driving and using machines

AMLODIPINE OETHMAAN tablets can affect your ability to perform any tasks that requires alertness and concentration such as operating machinery or driving.

3. How to take AMLODIPINE OETHMAAN

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

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


The usual dose is:

Adults:

The initial daily dose is 5 mg. Your doctor may need to increase the dose to 10 mg once a day after 10 to 14 days of treatment, if there is no improvement.

No dose adjustment is required in case of concomitant treatment with diuretics, beta-blockers or angiotensin-converting enzyme inhibitors.

Children aged 6 - 17 years

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

Elderly:

Your doctor may need to start you a lower dose.

Patients with liver problems:

Your doctor may need to give you on a lower dose.

Patients with kidney problems:

Your doctor may need to lower your dose depending on the severity of your problem.

Duration of treatment:

Your doctor will tell you how long your treatment with AMLODIPINE OETHMAAN will last. Do not stop treatment early because your condition may worsen.


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

Do not chew the tablets. Swallow the tablets whole with half a glass of water. It is best to take your tablets at the same time each day.

If you take more AMLODIPINE OETHMAAN than you should

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

Symptoms of overdose may include:

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- decreased blood pressure resulting in severe dizziness and fainting
- difficulty breathing, extreme shortness of breath, feeling of suffocating or drowning, cough that produces frothy sputum that may have blood in it, rapid, irregular heartbeat, anxiety, restlessness, cold and clammy skin, wheezing.

If you forget to take AMLODIPINE OETHMAAN

If you miss a dose do not worry, take it as soon as you remember. Do not take two doses together. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for the one you missed.

If you stop taking AMLODIPINE OETHMAAN

Do not stop taking your medication abruptly, as your doctor will prescribe the gradual lowering of the dose.


When it is time to stop taking your AMLODIPINE OETHMAAN tablets, your doctor will reduce the dose gradually over time until you are at a suitable dose to stop completely. It is important that you do not stop taking these tablets unless your doctor tells you to.

4. Possible side effects

AMLODIPINE OETHMAAN can have side effects.

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

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

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- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing.

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

- Erythema multiforme (large, symmetrical red blotches that appear all over the skin in a circular pattern).
- Rapid and irregular heartbeat sensations, heart attack (severe chest pain).
- Inflammation of the liver (hepatitis causing tiredness, pain in abdomen, joints or muscles), yellowing of the skin or whites of the eyes (jaundice).
- Tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes (symptoms of abnormal liver function or hepatitis).
- Itching, a rash, circular, irregular red patches on the skin of the hands and arms (erythema exsudativum multiforme).
- Skin that is red, flaky and peeling (exfoliative dermatitis).
- Severe form of a skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome).

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


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- Hot flushing in the face or headache (especially at the start of treatment)
- Tiredness, dizziness, weakness
- Palpitations (a quick or irregular heartbeat)
- Nosebleeds (in children)
- Feeling sick, indigestion, stomach pain, changes in bowel habits
- Swollen hands, ankles, feet and legs, swollen face

Less frequent side effects

- A decrease in white blood cells resulting in infections
- A decrease in blood platelets, which increases risk of bleeding or bruising
- Bleeding complications in patients undergoing surgery
- High levels of sugar in the blood
- Sleeplessness, irritability, depression, confusion, mood changes, anxiety
- A feeling of general discomfort and illness, dry mouth, tremor, “pins and needles”, increased sweating, reduced sense of touch, taste disorders, weakness, numbness and pain from nerve damage, usually in the hands and feet.
- Visual disturbances
- Ringing in the ears
- Fainting, slow heartbeat, rapid and irregular heartbeat sensations, chest pain
- Low blood pressure (lightheadedness or dizziness), inflammation of the blood vessels, swelling of your lower legs or hands
- Breathing difficulties, runny nose, cough
- Vomiting, constipation, diarrhoea, swollen gums, stomach pain, inflammation of the pancreas

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- Skin rash accompanying a disease or fever (exanthema), pale or red irregular raised patches with severe itching (hives), hair loss, skin discolouration, increased sensitivity to sunlight
- Muscle cramps, muscle, back or joint pain
- Passing more urine than is normal for you, especially at night
- Reduced sexual performance, enlarged breasts in men
- Swollen ankles, feet and legs
- Weight loss or gain
- Laboratory test may show the following:
 - raised liver enzymes (detected in a blood test)

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. This includes any possible side effects not listed in this leaflet. 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 OETHMAAN.

5. How to store AMLODIPINE OETHMAAN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store below 25 °C. Protect from light and moisture.

Keep the tablets in the pack they came in. Do not put them into another container. Do not use after the expiry date stated on the label. Return out of date or unused tablets to your pharmacist

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or nearest hospital. Do not dispose of unused medicine in drains or sewerage systems (eg. toilets).

6. Contents of the pack and other information

What AMLODIPINE OETHMAAN contains

Each AMLODIPINE 5 OETHMAAN Tablet contains: amlodipine maleate equivalent to 5 mg amlodipine base.

Each AMLODIPINE 10 OETHMAAN Tablet contains: amlodipine maleate equivalent to 10 mg amlodipine base.

Both AMLODIPINE 5 OETHMAAN and AMLODIPINE 10 OETHMAAN are sugar free.

The other ingredients are: Microcrystalline cellulose, calcium hydrogen phosphate anhydrous, magnesium stearate, sodium starch glycollate.

What AMLODIPINE OETHMAAN looks like and contents of the pack

AMLODIPINE 5 OETHMAAN: White to off-white, uncoated, oblong tablet.

AMLODIPINE 10 OETHMAAN: White to off-white, uncoated, oblong tablet, scored on one side.

AMLODIPINE OETHMAAN are packed in:

White opaque blisters and white opaque plastic securitainers of 30 and 100 tablets.


Holder of Certificate of Registration

Oethmaan Biosims (Pty) Ltd

207A Sherwood House

Greenacres Office Park

c/o Victory and Rustenburg Roads

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Victory Park

Johannesburg

2195


This leaflet was last revised in

22 December 2023

Registration number

AMLODIPINE 5 OETHMAAN: 37/7.1/0376

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