

Approved Patient Information Leaflet for AMLOBLOC 5 and AMLOBLOC 10

SCHEDULING STATUS: S3

AMLOBLOC 5 and AMLOBLOC 10 (Tablet)

Amlodipine besylate

Sugar free

Read all of this leaflet carefully before you start using AMLOBLOC

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

1. What AMBLOBLOC is and what it is used for

AMBLOBLOC belongs to a group of medicines called calcium antagonists.

AMLOBLOC is used to treat high blood pressure (hypertension) and a type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina. AMLOBLOC is also

used to reduce the risk of fatal and non-fatal heart disease or stroke. AMLOBLOC can be used alone or with other medicines to treat these conditions.

2. What you need to know before you take AMLOBLOC

Do not take AMLOBLOC:

- If you are hypersensitive (allergic) to amlodipine or any of the ingredients of AMLOBLOC (listed in section 6).
- If you have had an allergic reaction to other medicines of this type.
- In combination with grapefruit juice.

Warnings and precautions

Take special care with AMLOBLOC:

- If 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 AMLOBLOC may decrease the blood pressure even further (see Other medicines and AMLOBLOC).
- If you are elderly.
- If you have severe kidney disease.
- If you have liver disease.
- If you have heart failure (a condition where the heart cannot pump blood well).

Other medicines and AMLOBLOC

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

AMLOBLOC 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.

AMLOBLOC 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*)
- Immunosuppressive medicines (tacrolimus, sirolimus, temsirolimus, everolimus and ciclosporin)

AMLOBLOC with food and drink

Do not eat grapefruit or drink grapefruit juice with AMLOBLOC.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, 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 this medicine.

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

The safety of AMLOBLOC in human pregnancy has not been established.

AMLOBLOC has been shown to pass into breast milk.

Driving and using machines:

AMLOBLOC may make you feel dizzy; assess how it affects you before driving or using machinery. It is not always possible to predict to what extent AMLOBLOC may interfere with 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 AMLOBLOC affects them.

3. How to take AMLOBLOC

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

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

The usual dose of AMLOBLOC is one 5 mg tablet once a day; however, sometimes one 10 mg tablet a day may be required. AMLOBLOC tablets may be taken with or without food.

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

Your doctor will tell you how long treatment with AMLOBLOC will last and will determine the dose that is best suited to you. If you have the impression that the effect of AMLOBLOC is too strong or too weak, tell your doctor or pharmacist.

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

If you take more AMLOBLOC than you should

It is important not to take more AMLOBLOC tablets than you should. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

If you forget to take AMLOBLOC

It is important to take your AMLOBLOC 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.

4. Possible side effects

AMLOBLOC can have side effects.

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

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

Allergic reaction including:

- Pruritus (severe itching of the skin)
- Rash
- 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).
- These are all very serious side effects. If you have them, you may have had a serious reaction to AMLOBLOC. You may need urgent medical attention or hospitalisation.
- Tell your doctor if you notice any of the following:

Frequent side effects

- Headache, dizziness especially when standing up, sleepiness.

- Heart palpitations (very fast heartbeat), flushing (hot or warm feeling in your face).
- Stomach pain, nausea.
- Swelling of your legs or ankles, tiredness.

Less frequent side effects

- Too few white blood cells, too few blood platelets, too much sugar in the blood.
- Mood changes, sleeplessness
- Tightening of the muscles, loss of pain sensation, numbness or tingling sensation, fainting, taste abnormalities, trembling, movement disorder.
- Visual disturbances
- Ringing in the ears
- Low blood pressure, inflammation of the blood vessels
- Cough, shortness of breath, sneezing/running nose.
- Change in bowel habit, dry mouth, indigestion, swelling of the gums, inflammation of the pancreas, vomiting.
- Hair loss, increased sweating, itchy skin, red patches on skin.
- Joint or muscle pain, back pain, muscle cramps
- Increased need to urinate especially at night, pain when urinating.
- Enlargement of male breasts, inability to obtain an erection
- Feeling unwell, weakness, pain.
- Increase or decrease in weight.
- Itching, rash, swelling under the skin, red blotchy skin.
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increases which may have an effect on some medical tests.
- Heart attack, increase in heart rate, chest pain

Should any of these symptoms occur, or 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 report side effects to SAHPRA via the "6.04 Adverse Drug Reactions 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 AMLOBLOC

5. How to store AMLOBLOC

Store at or below 25 °C, in original packaging.

Do not use this medicine after the expiry date stated on the label and carton. Return out of date or unused tablets to your pharmacist or nearest hospital. Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets)

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What AMLOBLOC contains

The active substance is amlodipine besylate.

The other ingredients are calcium hydrogen phosphate anhydrous, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

What AMLOBLOC looks like and contents of the pack

Amlobloc 5:

A white or almost white, oblong, bevelled tablet, scored on one side and coded 5 on the other.

Tablet size: Approximately 8.6 mm x 5.8 mm

Average mass: Approximately 160 mg

Amlobloc 10:

A white or almost white, oblong, bevelled tablet, scored on one side and coded 10 on the other.

Tablet size: Approximately 10.8 mm x 7.5 mm

Average mass: Approximately 320 mg

AMLOBLOC 5 mg and 10 mg tablets are available in packs of 30's and/or 100's in Al/PVC blisters or Al/OPA/al/PVC or polyethylene containers.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹

Magwa Crescent West

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Jukskei View

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2090

This leaflet was last revised in

28 March 2023

Applicant/PHCR: Sandoz SA (Pty) Ltd

Submission date: November 2022

Proprietary name: AMLOBLOC 5 and AMLOBLOC 10

Dosage form and strength: Tablet. Each tablet contains amlodipine besylate equivalent to amlodipine 5 mg and 10 mg, respectively.

Registration number

AMLOBLOC 5: A40/7.1/0435

AMLOBLOC 10: A40/7.1/0436

¹Company Reg. No.: 1990/001979/07