

1.3.2 Current Approved Clean Patient Information Leaflet

SCHEDULING STATUS S3

CALBLOC 5 (Tablets)

CALBLOC 10 (Tablets)

Amlodipine besylate

Sugar free

Read all of this leaflet carefully before you start taking CALBLOC.

- 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.
- CALBLOC 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 CALBLOC is and what it is used for
2. What you need to know before you take CALBLOC
3. How to take CALBLOC
4. Possible side effects
5. How to store CALBLOC
6. Contents of the pack and other information

1. What CALBLOC is and what it is used for

CALBLOC belongs to a group of medicines called calcium antagonists.

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

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

2. What you need to know before you take CALBLOC

Do not take CALBLOC:

- if you are hypersensitive (allergic) to amlodipine or any of the other ingredients of CALBLOC (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 CALBLOC:

- 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 CALBLOC may decrease the blood pressure even further (see Other medicines and CALBLOC).
- 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).

Benzyl alcohol content in CALBLOC 10:

This medicine contains 0,214 mg of benzyl alcohol in each 10 mg tablet.

Benzyl alcohol may cause allergic reactions

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called 'gasping syndrome') in young children.

Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding. This is because large amount of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amount of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Benzyl alcohol may cause mild irritation.

Other medicines and CALBLOC

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

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

Tell your doctor if you are already taking or planing to take any of the followng as they may interact with CALBLOC:

- 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 medicine (tacrolimus, ciclosporin)

CALBLOC with food and drink

Do not eat grapefruit or drink grapefruit juice with CALBLOC.

Pregnancy, breast-feeding 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 healthcare provider for advice before being taking this medicine. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”)

The safety of CALBLOC in pregnancy or lactation has not been established.

Driving and using machines

CALBLOC may make you feel dizzy therefore assess how it affects you before driving or using machinery.

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

3. How to take CALBLOC

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

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

Adults:

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

If you are elderly CALBLOC therapy should be started at a lower dose.

Therapy should be started at the lowest dose and increased slowly if you suffer from severe liver or kidney disease.

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 your treatment with CALBLOC will last. Do not stop treatment early without consulting your doctor. If you have the impression that the effect of CALBLOC is too strong or too weak, tell your doctor or pharmacist.

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

If you take more CALBLOC than you should

It is important not to take more CALBLOC 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.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake. Seek immediate medical attention if you take too many Amlodipine tablets.

If you forget to take CALBLOC

It is important to take your CALBLOC 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.

If you stop taking CALBLOC

Take CALBLOC for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

CALBLOC can have side effects.

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

If any of the following happens, stop taking CALBLOC 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 a very serious side effects. If you have them, you may have had a serious allergic reaction to CALBLOC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately 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/runny 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 or nurse. 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 CALBLOC.

5. How to store CALBLOC

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Store in the original package.

Do not store in a bathroom.

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

Return all unused medicine 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 CALBLOC contains

The active substance is amlodipine besylate equivalent to 5 mg or 10 mg active amlodipine base.

CALBLOC 5:

Each tablet contains amlodipine besylate equivalent to 5 mg active amlodipine base.

CALBLOC 10:

Each tablet contains amlodipine besylate equivalent to 10 mg active amlodipine base.

CALBLOC 10 contains 0,214 mg of benzyl alcohol. See Section 4.4 and 4.6.

The other ingredients are benzyl alcohol, calcium hydrogen phosphate, colour tabcoat brown, croscarmellose sodium, hydroxy propyl methyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, purified talc, purified water, red iron oxide, titanium dioxide.

What CALBLOC looks like and contents of the pack

What CALBLOC looks like:

CALBLOC 5: Brown, smooth, round, biconvex, film coated

Tablets plain on both sides.

CALBOC 10: White to off-white, round biconvex, film coated

tablets plain on one side and a break line on the other side.

Holder of Certificate of Registration

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