PATIENT INFORMATION LEAFLET
BESYLOC

SCHEDULING STATUS:

S3

BESYLOC 5 mg tablets.

BESYLOC 10 mg tablets.

Amlodipine besylate

BESYLOC is sugar free.

Read all of this leaflet carefully before you start taking BESYLOC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- BESYLOC 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 BESYLOC is and what it is used for

BESYLOC contains amlodipine, which belongs to a group of medicines called calcium channel blocking medicines (dihydropyridine calcium antagonists).

BESYLOC may be used alone or in combination with other medicines used to treat high blood pressure and angina, a rare form of which is Prinzmetal's or variant angina.

In patients with high blood pressure this medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina, BESYLOC work by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina.

2. What you need to know before you take BESYLOC

Do not take BESYLOC:

- if you are hypersensitive (allergic) to amlodipine, dihydropyridine (used to lower blood pressure), or any of the other ingredients of BESYLOC (see section 6)
- 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
- 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)
- when taken with grapefruit juice (see take special care with BESYLOC)
- if you are pregnant or breastfeeding your baby
- if you are younger than 18 years of age.

Warnings and precautions

Special care should be taken with BESYLOC:

- if your doctor diagnosed you with severe high blood pressure
- if you suffer from aortic stenosis with symptoms such as fatigue, feeling faint or fainting when exercising and shortness of breath

- if you experience chest pain when taking BESYLOC
- if you suffer from diabetes
- if you need to undergo blood tests, as the use of BESYLOC may interfere with the results
- if you are an elderly patient
- if you suffer from severe kidney problems
- if you suffer from liver problems
- if you have low blood pressure or other heart conditions
- if you are taking anti-fungal medicine or certain HIV medicines as these may increase the blood pressure lowering effects of BESYLOC (see Other medicines and BESYLOC)
- if you are younger than 18 years of age
- if you are about to have a procedure where you would need general anaesthesia.

Children

The safety and efficacy of BESYLOC in children under the age of 6 years has not been established.

Other medicines and BESYLOC

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

Medicine that may influence BESYLOC:

- other medicines for hypertension (high blood pressure) or angina (chest pains), such as nitro glycerine tablets under the tongue, long acting nitrates, beta blockers or calcium channel blockers (such as verapamil, diltiazem), as this may increase the levels of BESYLOC in the blood
- 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

BESYLOC in the blood

- grapefruit or grapefruit juice may increase the blood pressure lowering effects of BESYLOC
- 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 BESYLOC
- sodium valproate (used for epilepsy), as this may increase BESYLOC blood levels. (Discuss with your doctor if you are unsure)
- medicines used to treat viral, fungal and bacterial infections (such as clarithromycin, erythromycin, ketoconazole, itraconazole or rifampicin), or St John's Wort (a herbal medicine used to treat anxiety), as these may lead to either increased or decreased levels of BESYLOC in the blood
- ritonavir used in the treatment of HIV infections, as this may lead to increased levels of BESYLOC in the blood
- 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 BESYLOC
- simvastatin (used to lower cholesterol), as this may result in increased levels of simvastatin in the blood. The simvastatin dose may need to be reduced
- tacrolimus, sirolimus, temsirolimus, and everolimus (medicine used to alter the way your immune system works) as BESYLOC may affect how these medicines work.

Tell your doctor before you receive anaesthesia that you are taking BESYLOC.

BESYLOC with food and drink

BESYLOC can be taken with or without food.

Grapefruit and grapefruit juice should be avoided (see Other medicines and BESYLOC).

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before using BESYLOC.

If you are pregnant, or become pregnant whilst taking BESYLOC, stop taking BESYLOC and talk to your doctor as soon as possible (see Do not take Besyloc).
You should not take BESYLOC when breastfeeding your baby (see Do not take Besyloc).

Driving and using machines

Amlodipine can have minor or moderate influence on the ability to drive and use machines. BESYLOC can cause dizziness, headache, fatigue or nausea therefore the ability to react may be impaired.

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

3. How to take BESYLOC

Do not share medicines prescribed for you with any other person.
Always take BESYLOC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

A usual starting dose of 5 mg BESYLOC once a day, taken at the same time every day with or

without food. Grapefruit and grapefruit juice should be avoided.

The tablets should be swallowed whole, with a glass of water.

If no improvement is seen after 10 - 14 days, your doctor may increase the dose to the maximum of 10 mg BESYLOC per day (taken as a single dose).

Your doctor will decide on the dose depending on your condition.

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

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

Use in children and adolescents

For children and adolescents (6 - 17 year old), the recommended usual starting dose is 2,5 mg a day. The maximum recommended dose is 5 mg a day.

The effect of BESYLOC on blood pressure in patients less than 6 years of age is not known.

If you take more BESYLOC than you should

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

Symptoms of overdose may include:

- 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 BESYLOC

If you forget to take BESYLOC, take it as soon as you remember. If it is almost time for your

next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking BESYLOC

It is important that you continue the course of treatment even if you begin to feel better after a few days. If your treatment with BESYLOC is stopped suddenly, your chest pain may worsen.

4. Possible side effects

BESYLOC can have side effects.

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

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

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

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

- slow heartbeat (bradycardia) or rapid heartbeat (tachycardia), palpitations, heart attack
- low blood pressure (hypotension) with symptoms such as fainting or light-headedness

- high blood sugar levels (hyperglycaemia)
- hepatitis, a liver condition, with symptoms such as stomach pain, fever, nausea, vomiting or loss of appetite
- weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis)
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnsons Syndrome, toxic epidermal necrolysis)
- kidney problems (passing less urine than is normal for you)
- pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever).

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:

- headache, dizziness and fatigue
- flushing
- nausea, stomach pain, change in bowel habits
- ankle swelling, swelling in any part of the body.

Less frequent side effects:

- joint pain, back pain, muscle cramps or weakness
- mood and/or sleep disorders, depression, anxiety
- reduced sense of touch or sensation (numbness)
- tingling sensation in hands, feet or lips (feeling of “pins and needles”)
- involuntary trembling (tremors), increased sweating
- muscle rigidity, slowness of movement, tremor, and irregular, jerky movements
- blurred vision, worsening eyesight

- ringing in the ears (tinnitus)
- cough
- inflammation of the mucous membrane in the nose (rhinitis)
- constipation, vomiting, diarrhoea, indigestion
- dry mouth, swelling of the gums
- passing more urine than is normal for you, especially at night
- skin conditions such as rash, excessive skin pigmentation, hives, itchy skin, hair loss
- change taste perception (including loss of taste)
- abnormal physical weakness or lack of energy, general feeling of discomfort, illness, or unease, general pain
- problems with sexual performance, enlarged breasts in men
- weight loss or weight gain.

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, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the following links: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of BESYLOC. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store BESYLOC

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original packaging (keep blisters in carton until required for use, protect from light).

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

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 BESYLOC contains:

The active substance is amlodipine besylate.

Each BESYLOC 5 mg contains amlodipine besylate equivalent to 5 mg amlodipine.

Each BESYLOC 10 mg contains amlodipine besylate equivalent to 10 mg amlodipine.

The other ingredients are

Tablet cores:

Colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate.

What BESYLOC looks like and contents of the pack

BESYLOC 5 mg: White, round (diameter 8,0 mm), slightly biconvex tablets, with bevelled edges, scored on one side.

BESYLOC 10 mg: White, round (diameter 10,5 mm), slightly biconvex tablets, with bevelled edges.

BESYLOC 5 mg: Opaque PVC / Aluminium foil blisters of 30 tablets, contained in a printed outer carton.

BESYLOC 10 mg: Opaque PVC / Aluminium foil blisters of 30 tablets, contained in a printed outer carton.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

This leaflet was last revised in

29 January 2024

Registration number(s)

BESYLOC 5 mg: A41/7.1/0560

BESYLOC 10 mg: A41/7.1/0561

NAMIBIA:

BESYLOC 5 mg: NS2 08/7.1/0155

BESYLOC 10 mg: NS2 08/7.1/0156