BESYLOC

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE
BESYLOC 5 mg tablets.
BESYLOC 10 mg tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each BESYLOC 5 mg tablet contains amlodipine besylate equivalent to 5 mg amlodipine.
Each BESYLOC 10 mg tablet contains amlodipine besylate equivalent to 10 mg amlodipine.
BESYLOC tablets are sugar free.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablets.
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.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
- treatment of angina pectoris
- treatment of mild to moderate hypertension, alone or in combination with other antihypertensives
- treatment of chronic stable angina – first line treatment of myocardial ischaemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. BESYLOC may be used alone, as monotherapy, or in combination with other antianginal medicines
- treatment of coronary artery disease – BESYLOC is indicated to reduce the risk of coronary revascularisation and the need for hospitalisation due to angina in patients with coronary artery disease
- BESYLOC is also indicated to reduce the risk of fatal coronary heart disease and non-fatal myocardial infarction, and to reduce the risk of stroke.

4.2 Posology and method of administration
Posology
BESYLOC can be administered with or without the intake of food. Grapefruit and grapefruit juice should be avoided (see section 4.5)

Coronary artery disease:
The recommended dosage range is 5 - 10 mg once daily. In clinical studies, themajority of patients required 10 mg.

Hypertension and Angina pectoris:
Adults:
An initial dose of 5 mg BESYLOC once daily is recommended, which may be increased to 10 mg once a day after 10 - 14 days of therapy, if there is no improvement.

In hypertension, no dose reduction is required when adding BESYLOC to thiazide diuretics, beta blockers, or angiotensin-converting enzyme inhibitors.

Coronary artery disease:
The recommended dosage range is 5 - 10 mg once daily. In clinical studies, the majority of patients required 10 mg.

Special populations
In the elderly:
The usual dosage regimens are recommended, but increase of the dosage should take place with care (see section 4.4).

In patients with hepatic impairment:
Dosage recommendations have not been established in patients with mild to moderate hepatic impairment; therefore, dose selection should be cautious and should start at the lower end of the dosing range. The pharmacokinetics of amlodipine have not been studied in severe hepatic impairment. BESYLOC should be initiated at the lowest dose and titrated slowly in patients with severe hepatic impairment.

In patients with renal impairment:
Changes in amlodipine plasma concentrations are not correlated with the degree of renal impairment, therefore the normal dosage is recommended.

Paediatric population
The recommended antihypertensive oral dose in paediatric patients ages 6 - 17 years is 2,5 mg to 5 mg once daily. Doses in excess of 5 mg daily have not been studied in paediatric patients.

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

Method of administration
Tablet for oral administration.

Missed dose:
If a dose is missed, the tablet should be taken as soon as the missed dose is remembered. Two tablets should not be taken to make up for the missed dose.

4.3 Contraindications
- hypersensitivity to amlodipine, dihydropyridines or to any of the ingredients of BESYLOC (see section 6.1)
- severe hypotension
- shock, including cardiogenic shock
- haemodynamically unstable heart failure after acute myocardial infarction (during the first 28 days)
- obstruction of the outflow tract of the left ventricle (e.g. high grade aortic stenosis)
- unstable angina pectoris
- concomitant use with grapefruit juice (see section 4.5)
- safety in children less than 6 years of age is not known
- pregnancy and lactation.

4.4 Special warnings and precautions for use
The safety and efficacy of BESYLOC in hypertensive crisis has not been established.

BESYLOC should not be used to treat an angina attack in chronic stable angina, nor should it be used for the acute reduction of blood pressure in adults.

In patients with severe aortic stenosis, BESYLOC may increase the risk of developing heart failure.

Sudden withdrawal of BESYLOC might be associated with an exacerbation of angina. A gradual decrease of dosage with medical practitioner supervision is recommended.

BESYLOC should be stopped in patients who have ischaemic pain after use.

Concomitant use with potent cytochrome CYP3A4 medicines:
The blood pressure lowering effect may be enhanced when potent CYP3A4 inhibitors such as ketoconazole, itraconazole or ritonavir are co-administered (see section 4.5).

Diabetes mellitus:
BESYLOC's effect on insulin and glucose responses may require antidiabetic therapy to be adjusted.

Interference with diagnostic tests:
Calcium channel blockers, such as BESYLOC, reduce the plasma aldosterone:renin ratio by increasing renin production and reducing plasma aldosterone concentrations, consequently, primary hyperaldosteronism has been misdiagnosed as essential hypertension.

Use in the elderly:
Amlodipine clearance is decreased (40 - 60 %) in the elderly, which results in increases of amlodipine concentration in the area under the concentration-time curve (AUC) and elimination half-life. Therefore, elderly patients should start BESYLOC therapy at a lower dose.

Use in renal failure:
Although BESYLOC is excreted primarily via the kidneys, mild renal impairment does not appear to have an effect on the plasma concentrations. Severe renal impairment may however require a dosage reduction. Amlodipine is not dialysable.

Use in impaired hepatic function:
The half-life of BESYLOC is significantly prolonged in patients with impaired hepatic function, dosage recommendations have not been established. BESYLOC should therefore be initiated at the lower end of the dosing range and caution should be used, both on initial treatment and when increasing the dose. Slow dose titration and careful monitoring may be required in patients with severe hepatic impairment.

Use in cardiac failure:
Calcium channel blockers, including amlodipine, should be used with caution in patients with hypotension, patients whose cardiac reserve is poor and those with congestive heart failure, as they may increase the risk of future cardiovascular events and mortality.
BESYLOC should not be used in cardiogenic shock or in patients who have suffered myocardial infarction in the previous 2 - 4 weeks, or in acute unstable angina (see section 4.3).

Porphyria:
Safety has not been established.

Paediatric population
Safety and efficacy have been established.

Patients who are taking BESYLOC should inform the anaesthetist accordingly, before receiving anaesthesia.

4.5 Interaction with other medicines and other forms of interaction
Concurrent administration of sublingual nitroglycerine, long acting nitrates, or other antianginal agents with BESYLOC may produce additive antihypertensive and antianginal effects. Sublingual nitroglycerine may be used as needed to abort acute angina attacks during BESYLOC therapy. Nitrate medication may be used during BESYLOC therapy for angina prophylaxis.

BESYLOC may enhance the antihypertensive effects of other antihypertensive medicines such as beta blockers. BESYLOC will not protect against the consequences of abrupt beta blocker withdrawal; gradual beta blocker dose reduction is recommended. Although no "rebound effect" has been reported upon discontinuation of BESYLOC, a gradual decrease of dosage with medical practitioner supervision is recommended.

Enhanced antihypertensive effects may be seen in concomitant use with medicines such as aldesleukin and antipsychotics that cause hypotension.

Administration of BESYLOC with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients resulting in increased blood pressure lowering effects (see section 4.3).

BESYLOC may modify insulin and glucose responses and therefore diabetic patients may need to adjust their antidiabetic treatment when receiving BESYLOC (see section 4.4).

BESYLOC is extensively metabolised in the liver by the cytochrome P450 isoenzyme CYP3A4 and interactions may occur with other medicines, such as quinidine or procainamide, sharing the same metabolic pathway, since both groups possess negative inotropic properties.

The effects of BESYLOC may be reduced in combination with enzyme-inducing anti-epileptics such as carbamazepine, phenobarbitone and phenytoin.
In contrast, sodium valproate has been reported to increase plasma concentrations.

Concomitant use with strong or moderate CYP3A4 inhibitors, protease inhibitors, azole antifungals, macrolide antibacterials (such as clarithromycin, erythromycin, verapamil or diltiazem, ketoconazole, itraconazole and ritonavir) may give rise to significant increase in amlodipine exposure. The clinical translation of these pharmacokinetic variations may be more pronounced in the elderly. Clinical monitoring and dose adjustment may thus be required (see section 4.4).

There is no data available regarding the effect of CYP3A4 inducers on amlodipine. The concomitant use of CYP3A4 inducers (i.e. rifampicin, *hypericum perforatum* (St. John's Wort)) may give a lower plasma concentration of amlodipine. BESYLOC should be used with caution together with CYP3A4 inducers.

Dantrolene may cause hyperkalaemia when used concomitantly with calcium channel blockers such as BESYLOC. Due to risk of hyperkalaemia, it is recommended that the co-administration of BESYLOC be avoided in patients susceptible to malignant hyperthermia and in the management of malignant hyperthermia.

The use of lithium with BESYLOC may cause lithium induced neurotoxicity in the form of nausea, vomiting, diarrhoea, ataxia, tremors and/or tinnitus, caution is therefore recommended.

Tacrolimus: There is a risk of increased tacrolimus blood levels when co-administered with BESYLOC. In order to avoid toxicity of tacrolimus, administration of BESYLOC in a patient treated with tacrolimus requires monitoring of tacrolimus blood levels and dose adjustment of tacrolimus when appropriate.

Co-administration of multiple doses of 10 mg of BESYLOC with 80 mg simvastatin resulted in a 77 % increase in exposure to simvastatin compared to simvastatin alone. Limit the dose of simvastatin in patients on BESYLOC to 20 mg daily (see simvastatin professional information).

Clarithromycin is an inhibitor of CYP3A4. There is an increased risk of hypotension in patients receiving clarithromycin with amlodipine. Close observation of patients is recommended when BESYLOC is coadministered with clarithromycin.

No medicine interaction studies have been conducted with ciclosporin and amlodipine in healthy volunteers or other populations, with the exception of renal transplant patients. Various studies in renal transplant patients report that co-administration of amlodipine with ciclosporin increased the trough concentrations of ciclosporin and increased ciclosporin toxicity, from no change up to an average increase of 40 %.

Consideration should be given for monitoring ciclosporin levels in renal transplant patients on BESYLOC.

Mechanistic target of rapamycin (mTOR) inhibitors: mTOR inhibitors such as sirolimus, temsirolimus and everolimus are CYP3A substrates. BESYLOC is a weak CYP3A inhibitor. With concomitant use of mTOR inhibitors, BESYLOC may increase exposure of mTOR inhibitors.

Medicine/laboratory test interactions: None known.

Cimetidine, aluminium/magnesium (antacid) and sildenafil do not affect the pharmacokinetics of amlodipine.

BESYLOC does not affect the pharmacokinetics of atorvastatin, digoxin, warfarin or ethanol. Amlodipine has been administered with thiazide diuretics, alpha blockers, beta blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerine, non-steroidal anti-inflammatory drugs (NSAIDs), antibiotics, and oral hypoglycaemic medicines.

In vitro data from studies with human plasma indicate that BESYLOC has no effect on protein binding of the medicines tested (digoxin, phenytoin, warfarin, or indometacin).

4.6 Fertility, pregnancy and lactation
Women of childbearing potential/contraception in males and females
Women of childbearing potential and their partners should be advised to ensure adequate contraceptive cover.

Pregnancy
BESYLOC in pregnancy and lactation is contraindicated (see section 4.3). Since teratogenic effects were noted in animals, amlodipine should not be administered to pregnant women.

Breastfeeding
BESYLOC is excreted in human milk and therefore should not be administered in lactating women (see section 4.3).

Fertility
Reversible biochemical changes in the head of spermatozoa have been reported in some patients treated by calcium channel blockers. Clinical data are insufficient regarding the potential effect of BESYLOC on fertility. In one rat study adverse effects were found on male fertility (see section 5.3).

4.7 Effects on ability to drive and use machines
Amlodipine can have minor or moderate influence on the ability to drive and use machines.

BESYLOC can cause side effects such as dizziness, headache, fatigue or nausea therefore the ability to react may be impaired.

During BESYLOC administration, patients should be cautioned about re-engaging in activities requiring rapid and precise responses such as driving a vehicle or operating machinery.

4.8 Undesirable effects
a) Summary of the safety profile
The most commonly reported adverse reactions during treatment are somnolence, dizziness, headache, palpitations, flushing, abdominal pain, nausea, ankle swelling, oedema and fatigue.

b) Tabulated list of adverse effects

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	*Less frequent*	Purpura, thrombocytopenia, leukocytopenia, haemorrhagic complications in surgical patients, blood dyscrasias
Immune system disorders	*Less frequent*	Hypersensitivity reactions: pruritus, rash, angioedema and erythema multiforme
Metabolism and nutrition disorders	*Less frequent*	Hyperglycaemia
Psychiatric disorders	*Less frequent*	Insomnia, mood changes (including anxiety), depression
Nervous system disorders	*Frequent*	Headache, somnolence, dizziness
	Less frequent	Hypertonia, hypoaesthesia/paraesthesia, peripheral neuropathy, tremor, increased sweating, dysgeusia, extrapyramidal disorder
Eye disorders	*Less frequent*	Visual disturbances
Ear and lebyrinth disorders	*Less frequent*	Tinnitus
Cardiac disorders	*Frequent*	Palpitations
	Less frequent	Myocardial infarction, dysrhythmia (including ventricular tachycardia and atrial fibrillation), chest pain, bradycardia
Vascular disorders	*Frequent*	Flushing, peripheral oedema
	Less frequent	Hypotension (including orthostatic hypotension), syncope, vasculitis
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Coughing, dyspnoea, rhinitis
Gastrointestinal disorders	*Frequent*	Nausea, abdominal pain, altered bowel habits
	Less frequent	Vomiting, dyspepsia, pancreatitis, constipation, diarrhoea, dry mouth, gingival hyperplasia
Hepato-biliary disorders	*Less frequent*	Hepatitis, jaundice, raised liver enzymes (mostly consistent with cholestasis)
Skin and subcutaneous tissue disorders	*Less frequent*	Alopecia exanthema, pruritus, purpura, skin discolouration, hyperhidrosis, rash, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, photosensitivity, urticaria, Quincke oedema
Musculoskeletal, connective tissue and bone disorders	*Frequent*	Ankle swelling
	Less frequent	Arthralgia, asthenia, back pain, muscle cramps, myalgia
Renal and urinary disorders	*Less frequent*	Increased urinary frequency, micturition disorder, nocturia
Reproductive system and breast disorders	*Less frequent*	Sexual dysfunction, gynaecomastia
General disorders and administrative site conditions	*Frequent*	Facial oedema, upper extremity oedema, fatigue
	Less frequent	Taste perversion, asthenia, malaise, pain
Investigations	*Less frequent*	Weight increase/decrease

Paediatric population
Paediatric patients (ages 6 - 17 years)
Adverse events were similar to those seen in adults. In a study of 268 children, the most frequently reported adverse events were:

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	*Frequent*	Headache, dizziness
Vascular disorders	*Frequent*	Vasodilation
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Epistaxis
Gastrointestinal disorders	*Frequent*	Abdominal pain
General disorders and administrative site conditions	*Frequent*	Asthenia

Severe adverse events (predominantly headache) were experienced by 7,2 % with amlodipine 2,5 mg, 4,5 % with amlodipine 5 mg, and 4,6 % with placebo. The most common cause of discontinuation from the study was uncontrolled hypertension. There were no discontinuations due to laboratory abnormalities. There was no significant change in heart rate

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine.
Healthcare professionals are asked to report any suspected adverse reactions 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/.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

4.9 Overdose
Signs and symptoms:
Overdosage could result in excessive peripheral vasodilatation, resulting in marked and probably prolonged systemic hypotension.

Available data for amlodipine suggest that gross overdosage could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension up to and including shock with fatal outcome have been reported. Non-cardiogenic pulmonary oedema has rarely been reported as a consequence of amlodipine overdose that may manifest with a delayed onset (24 - 48 hours post-ingestion) and require ventilatory support. Early resuscitative measures (including fluid overload) to maintain perfusion and cardiac output may be precipitating factors.

Management of overdose:
Clinically significant hypotension due to BESYLOC overdosage requires active cardiovascular support including frequent monitoring of cardiac and respiratory function, elevating of extremities and attention to circulating fluid volume and urine output. A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided there is no contraindication to its use. Intravenous calcium gluconate may be of benefit in reversing the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Calcium channel blockers, selective calcium channel blockers with mainly vascular effects.
ATC CODE: C08CA01
Pharmacological classification: A 7.1 Vasodilators, hypotensive medicine.

Amlodipine is a dihydropyridine calcium channel blocker. It inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle without affecting serum calcium concentrations. Direct relaxation of vascular smooth muscle forms the basis of the antihypertensive action.
In angina pectoris, amlodipine acts as a peripheral arteriolar vasodilator resulting in a reduction in total peripheral resistance (afterload). Dilatation of the main coronary arteries and the coronary arterioles also probably plays a role in its action. Myocardial energy and oxygen requirements are reduced. Amlodipine exerts its activity by binding to the dihydropyridine binding sites. It exerts minimal action on cardiac conduction, contraction and heart rate.

Patients with hypertension:
Once-daily dosing provides clinically significant reductions of blood pressure (in both supine and standing positions) that persist for 24 hours. Due to the slow onset of action, acute hypotension is not a feature of amlodipine administration.

Patients with angina:
Once-daily administration of amlodipine increases total exercise time, the delay of occurrence of anginal attack and the delay of the occurrence of a 1-mm ST interval. Amlodipine decreases both attack frequency and glyceryl trinitrate tablet consumption. Amlodipine has not been associated with any adverse metabolic effects or changes in plasma lipids and is suitable for use in patients with asthma, diabetes, and gout.

Use in patients with coronary artery disease (CAD):
Amlodipine treatment was associated with fewer hospitalisations for angina and revascularisation procedures in patients with CAD.

Use in patients with cardiac failure:
Haemodynamic studies and exercise based controlled clinical trials in NYHA class II-IV heart failure patients have shown that amlodipine did not lead to clinical deterioration as measured by exercise tolerance, left ventricular ejection fraction and clinical symptomatology.

A study designed to evaluate patients with NYHA class III-IV heart failure receiving digoxin, diuretics and angiotensin-converting enzyme (ACE) inhibitors has shown that amlodipine did not lead to an increase in the risk of mortality or combined mortality and morbidity in patients with heart failure.

5.2 Pharmacokinetic properties
Absorption:
Complete absorption of amlodipine is slow following oral administration with peak plasma levels being attained after 6 - 12 hours.
The absorption of amlodipine is unaffected by the concomitant intake of food.

Distribution:
The absolute bioavailability of the unchanged compound is estimated as 64 - 80 %. Peak plasma levels are attained 6 to 12 hours after administration. The volume of distribution is about 21 L/kg. Plasma protein binding *in vitro* is approximately 97,5 %.

Biotransformation:
The plasma elimination half-life of 35 - 50 hours, allowing for once-daily oral dosing. Steady state plasma concentrations are achieved after 7 - 8 days of consecutive dosing. Amlodipine is predominantly metabolised by the liver to inactive metabolites.

Elimination:
Metabolism is via the liver and is extensive with less than 10 % of amlodipine appearing unchanged in the urine. Metabolites are inactive and primarily (up to 60 %) excreted via the kidney.

Pharmacokinetics in special patient groups
Hepatic impairment:
Patients with hepatic insufficiency have decreased clearance of amlodipine resulting in a longer half-life and an increased AUC, and a lower initial dose may be required.

Renal impairment:
The pharmacokinetics of amlodipine are not significantly influenced by renal impairment.

Elderly:
The time to reach peak plasma concentrations of amlodipine is similar in elderly and younger subjects. Amlodipine clearance tends to be decreased with resulting increases in AUC and elimination half-life in elderly patients, and a lower initial dose may be required. A similar increase in AUC may be observed in patients with moderate to severe heart failure.

5.3 Preclinical safety data
Reproductive toxicology
Reproductive studies in rats and mice have shown delayed date of delivery, prolonged duration of labour and decreased pup survival at dosages approximately 50 times greater than the maximum recommended dosage for humans based on mg/kg.

Impairment of fertility
There was no effect on the fertility of rats treated with amlodipine (males for 64 days and females for 14 days prior to mating) at doses up to 10 mg/kg/day (8 times* the maximum recommended human dose of 10 mg on a mg/m² basis).
In another rat study in which male rats were treated with amlodipine besylate for 30 days at a dose comparable with the human dose based on mg/kg, decreased plasma follicle-stimulating hormone and testosterone were found as well as decreases in sperm density and in the number of mature spermatids and Sertoli cells.

Carcinogenesis, mutagenesis
Rats and mice treated with amlodipine in the diet for two years, at concentrations calculated to provide daily dosage levels of 0,5, 1,25, and 2,5 mg/kg/day showed no evidence of carcinogenicity. The highest dose (for mice, similar to, and for rats twice* the maximum recommended clinical dose of 10 mg on a mg/m² basis) was close to the maximum tolerated dose for mice but not for rats.
Mutagenicity studies revealed no medicinal product related effects at either the gene or chromosome levels.
*Based on patient weight of 50 kg

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Colloidal anhydrous silica
Magnesium stearate
Microcrystalline cellulose
Pregelatinised starch
Sodium starch glycolate

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
5 years.

6.4 Special precautions for storage
Store at or below 30 °C.
Protect from light. Keep the blisters in the outer carton until required for use.

6.5 Nature and contents of container
BESYLOC 5 mg: OPA/AL/PVC film and heat sealing aluminium foil blisters of 30 tablets, contained in a printed outer carton.
BESYLOC 10 mg: OPA/AL/PVC film and heat sealing aluminium foil blisters of 30 tablets, contained in a printed outer carton.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa

8. REGISTRATION NUMBERS
BESYLOC 5 mg: A41/7.1/0560
BESYLOC 10 mg: A41/7.1/0561

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
30 November 2007

10. DATE OF REVISION OF THE TEXT
29 January 2024

NAMIBIA
BESYLOC 5 mg: NS2 08/7.1/0155
BESYLOC 10 mg: NS2 08/7.1/0156

PATIENT INFORMATION LEAFLET

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, 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
2. What you need to know before you take BESYLOC
3. How to take BESYLOC
4. Possible side effects
5. How to store BESYLOC
6. Contents of the pack and other information

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 to any of the 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 16 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 nitroglycerine 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 taking this medicine.

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 instructed. You should check with your doctor or pharmacist if you are unsure.

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 healthcare provider 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
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Silverwood Close
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BESYLOC 5 mg: A41/7.1/0560
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NAMIBIA
BESYLOC 5 mg: NS2 08/7.1/0155
BESYLOC 10 mg: NS2 08/7.1/0156

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S3

BESYLOC 5 mg tablette.
BESYLOC 10 mg tablette.
Amlodipienbesilaat
BESYLOC is suikervry.

Lees hierdie hele inligtingsblad noukeurig deur, voordat u begin om BESYLOC te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u enige verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer.
- BESYLOC is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad
1. Wat BESYLOC is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u BESYLOC gebruik
3. Hoe om BESYLOC te gebruik
4. Moontlike newe-effekte
5. Hoe om BESYLOC te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat BESYLOC is en waarvoor dit gebruik word
BESYLOC behoort aan 'n groep medisyne bekend as kalsiumkanaal-blokkerende medisyne (dihidropiridien kalsiumantagoniste).

BESYLOC mag alleen gebruik word, of in kombinasie met ander medisyne wat gebruik word om hoë bloeddruk en angina mee te behandel.

By pasiënte wie hoë bloeddruk het, werk hierdie medisyne deur bloedvate te ontspan, sodat bloed meer vrylik daardeur beweeg. By pasiënte met angina, werk BESYLOC deur bloedtoevoer na die hartspier te verbeter, wat sodoende meer suurstof ontvang en gevolglik, borspyn verhoed. Hierdie medikasie voorsien nie onmiddellike verligting van borspyn as gevolg van angina nie.

2. Wat u nodig het om te weet, voordat u BESYLOC gebruik
Moet nie BESYLOC neem:
- indien u hipersensitief (allergies) is vir amlodipien, dihidropiridien (gebruik om bloeddruk te verlaag), of vir enige van die ander bestanddele van BESYLOC nie (sien afdeling 6)
- indien u aan erge hipotensie ly nie (emstige lae bloeddruk, waarvan simptome lighoofdigheid, of duiseligheid, insluit)
- indien u voorheen skok, wat kardiogene skok mag insluit, ervaar het nie (die term word gebruik wanneer bloeddruk so laag daal, dat u hart nie behoorlik werk nie, en mediese aandag benodig word)
- indien u onlangs (binne die vorige 28 dae), 'n hartaanval gehad het nie
- indien die bloedvloei vanuit die linkerkant van u hart, versper is nie (bv. aortiese klepvernouing)
- indien u onstabiele angina het nie (borspyn wat tydens u rustende toestand mag voorkom)
- wanneer u pomelosap ingeneem het nie (kyk neem spesiale sorg met BESYLOC)
- indien u swanger is, of u baba borsvoed nie
- indien u jonger as 18 jaar oud is nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met BESYLOC:
- indien u dokter u met erge hoë bloeddruk gediagnoseer het
- indien u aan aortiese stenose ly, met simptome soos uitputting, 'n lighoofdige gevoel of floute, wat tydens oefening voorkom en asemnood
- indien u borspyn ervaar wanneer u BESYLOC neem
- indien u aan diabetes ly
- indien u nodig het om bloedtoetse te ondergaan, aangesien die gebruik van BESYLOC met die resultate mag inmeng
- indien u 'n bejaarde pasiënt is
- indien u aan erge nierprobleme ly
- indien aan lewerprobleme ly
- indien u lae bloeddruk of ander harttoestande het
- indien u swamwerende medikasie, of sekere MIV medisyne neem, aangesien dit die bloeddrukverlagende uitwerking van BESYLOC mag versterk (kyk Ander medisyne en BESYLOC)
- indien u jonger as 18 jaar oud is
- indien u binnekort 'n prosedure wat algemene narkose verels, moet ondergaan.

Kinders
Die veiligheid en doeltreffendheid van BESYLOC by kinders jonger as 6 jaar oud, is nog nie vasgestel nie.

Ander medisyne en BESYLOC
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem.
(Dit sluit aanvullende, of tradisionele medisyne in).

Medisyne wat BESYLOC mag beïnvloed:
- ander medisynes vir hipertensie (hoë bloeddruk) of angina (borspyne), soos ondertongse nitrogliserien tablette, langwerkende nitrate, beta blokkers of kalsiumkanaalblokkers (soos verapamiel, diltiasem), aangesien dit die bloedvlakke van BESYLOC mag verhoog
- aldesleukien, wat gebruik word vir die behandeling van nierkanker en velmelanoom, of medisyne wat gebruik word om gemoedstoestande te behandel (antipsigotika), aangesien dit die bloedvlakke van BESYLOC mag verhoog
- pomelo of pomelosap mag die bloeddrukverlagende uitwerking van BESYLOC versterk
- medisyne wat gebruik word om diabetes te behandel, aangesien dosisaanpassings van hierdie medisynes benodig mag word
- medisyne wat die harttempo verander (soos kinidien of prokaïenamied).
- sommige medisyne wat gebruik word om aanvalle te behandel (karbamasepien, fenobarbital, fenitoïen), aangesien dit die uitwerking van BESYLOC mag verswak
- natriumvalproaat (gebruik vir epilepsie), aangesien dit die bloedvlakke van BESYLOC mag verhoog. (Bespreek met u dokter, indien u onseker is)
- medisyne wat gebruik word om virus-, swam- en bakteriële infeksies te behandel (soos klaritromisien, eritromisien, ketokonasool, itrakonasool of rifampisien), of Johanneskruid ('n kruiemiddel, wat angstigheid behandel), aangesien dit mag lei tot 'n verhoging of verlaging van die bloedvlakke van BESYLOC
- ritonavir wat gebruik word vir die behandeling van MIV-infeksies, aangesien dit mag lei tot 'n toename in BESYLOC bloedvlakke
- dantroleeen ('n spierverslapper), mag die kaliumvlakke in die bloed beïnvloed.
- litium, aangesien dit mag lei tot toksiese bloedkonsentrasies, indien dit in kombinasie met BESYLOC gebruik word
- simvastatien (gebruik om cholesterol te verlaag), aangesien dit mag lei tot 'n toename in simvastatienvlakke in die bloed. Dit mag nodig wees om die dosis van simvastatien te verlaag
- takrolimus, sirolimus, temsirolimus en everolimus (medisyne wat gebruik word om die werking van u immuunstelsel te wysig), aangesien BESYLOC die werking van hierdie medisyne mag beïnvloed.

Vertel u dokter voordat u narkose ontvang, dat u BESYLOC neem.

BESYLOC saam met kos en drinkgoed
BESYLOC kan mét of sonder kos geneem word.
Pomelo en pomelosap moet vermy word (sien Ander medisyne en BESYLOC).

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is, of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies, voordat u BESYLOC gebruik.

Indien u swanger is, of swanger raak, terwyl u BESYLOC neem, staak die gebruik van BESYLOC en praat met u dokter so gou as moontlik (sien Moet nie BESYLOC neem).

U moet nie BESYLOC neem tydens borsvoeding nie (sien Moet nie BESYLOC neem).

Bestuur en die hantering van masjiene
Amlodipien mag 'n lig tot matige invloed op die vermoë om te bestuur en masjiene te hanteer, uitoefen.
BESYLOC mag duiseligheid hoofpyn, uitputting of naarheid veroorsaak, en mag dus u vermoë om te reageer, belemmer.

Dit is nie altyd moontlik om te voorspel tot watter mate BESYLOC met die daaglikse aktiwiteite van 'n pasiënt mag inmeng nie. Pasiënte moet verseker dat hulle nie by die bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is hoe BESYLOC hulle beïnvloed nie.

3. Hoe om BESYLOC te gebruik
Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie. Neem BESYLOC altyd presies soos deur u dokter aanbeveel is. U moet u dokter of apteker raadpleeg, indien u onseker is.

Volwassenes
'n Normale aanvangsdosis van 5 mg BESYLOC een maal per dag, geneem op dieselfde tyd, mét of sonder kos. Pomelo en pomelosap moet vermy word.
Die tablette moet heel, met 'n glas water, gesluk word.
Indien geen verbetering na 10 - 14 dae opgemerk word nie, mag u dokter die dosis verhoog na 10 mg BESYLOC per dag (geneem as 'n enkeldosis).

U dokter sal besluit op die dosis, in ooreenstemming met u toestand.

U dokter sal u vertel hoe lank u behandeling met BESYLOC sal duur. Moet nie behandeling vroegtydig staak nie, omdat u toestand mag vererger. Indien u onder die indruk is dat die uitwerking van BESYLOC té sterk, of té swak is, vertel u dokter of apteker.

Gebruik deur kinders en adolessente
Die normale aanvangsdosis vir kinders en adolessente (6 – 17 jaar oud), is 2,5 mg per dag. Die maksimum aanbevole dosis is 5 mg per dag.

Die effek van BESYLOC op bloeddruk by pasiënte jonger as 6 jaar oud, is onbekend.

Indien u meer BESYLOC neem as wat u behoort
In die geval van 'n oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Simptome van oordosering mag die volgende insluit:
- verlaagde bloeddruk, wat lei tot erge duiseligheid en floute
- moeilsame asemhaling, uiterste asemnood, gevoel van versmoring of verdrinking, hoes, met skuimerige speeksel (wat somtyds bloed bevat), vinnige, onreëlmatige hartklop, angstigheid, rusteloosheid, koue en klammerige vel, gehyg.

Indien u vergeet om BESYLOC te neem
Indien u vergeet om BESYLOC te neem, neem die dosis so gou as wat u onthou. Indien dit amper tyd is vir u volgende dosering, slaan die vergete dosis oor, en hou aan om die tablet of tablette, op die gewone tydstip te neem.
Moet nie 'n dubbeldosis neem, om op te maak vir die vergete individuele dosisse nie.

Indien u die gebruik van BESYLOC staak
Dit is belangrik dat u voortgaan met die behandelingskursus, selfs al begin u om beter te voel na 'n paar dae. Indien behandeling met BESYLOC skielik gestaak word, mag u borspyn vererger.

4. Moontlike newe-effekte
BESYLOC kan newe-effekte hê.
Nie alle newe-effekte wat vir BESYLOC aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid vererger, of indien u enige ongunstige effekte ervaar terwyl u BESYLOC gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van BESYLOC en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat asemhaling of die slukproses mag bemoeilik
- uitslag of gejeuk
- floute
- geelsug (geel verkleuring van die vel en oë).

Hierdie is alles baie emstige newe-effekte. Indien u dit het, kon u moontlik 'n emstige allergiese reaksie teenoor BESYLOC ervaar het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- stadige hartklop (bradikardie) of vinnige hartklop (tagikardie), palpitasies, hartaanval
- lae bloeddruk (hipotensie), met simptome soos floute of lighoofdigheid
- hoë bloedsuikervlakke (hiperglisemie)
- hepatitis, 'n lewertoestand, met simptome soos maagpyn, koors, naarheid, braking of aptytverlies
- swakheid, uitputting, gewigsverlies, hoofpyn (simptome van 'n toestand genaamd vaskulitis)
- erge velreaksies, insluitend intense veluitslag, urtikarie, rooiwording van die vel oor u hele liggaam, erge gejeuk, blaasvorming, afskilfering en swelling van die vel, inflammasie van die mukusmembrane (Stevens-Johnson-sindroom, toksiese epidermale nekrolise)
- nierprobleme (u urineer minder as wat normaal is vir u)
- pankreatitis (inflammasie van die pankreas, met simptome soos maagpyn, verhoging in harttempo en koors).

Hierdie is alles emstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- hoofpyn, duiseligheid en uitputting
- blosvorming
- naarheid, maagpyn, verandering in dermgewoontes
- enkelswelling, swelling in enige gedeelte van die liggaam.

Minder algemene newe-effekte:
- gewrigspyn, rugpyn, spierkrampe of swakheid
- gemoeds- en/of slaapversteurings, depressie, angstigheid
- afname in tasgevoel of sensasie (gevoelloosheid)
- tintelende sensasie in hande, voete of lippe (gevoel van "spelde en naalde")
- onwillekeurige bewing (tremors), toename in sweet
- spierstyfheid, stadige beweging, tremor en onreëlmatige, rukkerige bewegings
- versteurde visie, sig wat vererger
- gelui in die ore (tinnitus)
- hoes
- inflammasie van die mukusmembrane in die neus (rinitis)
- konstipasie, braking, diarree, slegte spysvertering
- droë mond, swelling van die tandvleis
- urineer meer gereeld as wat normaal is vir u, veral snags
- veltoestande soos uitslag, uitermatige velpigmentasie, galbulte, jeukende vel, haarverlies
- verandering in smaaksensasie (insluitend smaakverlies)
- abnormale fisiese swakheid of energietekort, algemene gevoel van ongemak, siekte of onrustigheid, algemene pyn
- probleme met seksuele prestasie, vergroting in borste by mans
- gewigsverlies of gewigstoename.

Indien u enige newe-effek wat nie in hierdie inligtingsblad genoem is nie, opmerk, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA via die aanlynskakels vir ongewenste geneesmiddelreaksie rapporteer: https://www.sahpra.org.za/Publications/Index/8 of http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van BESYLOC in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

5. Hoe om BESYLOC te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 30 °C.
Bewaar in die oorspronklike verpakking (hou die stulpstroke in die kartonhouer totdat dit benodig word vir gebruik, beskerm teen lig).
Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in dreine of riooIstelsels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat BESYLOC bevat:
Die aktiewe bestanddeel is amlodipienbesilaat.
Elke BESYLOC 5 mg bevat amlodipienbesilaat gelykstaande aan 5 mg amlodipien.
Elke BESYLOC 10 mg bevat amlodipienbesilaat gelykstaande aan 10 mg amlodipien.

Die ander bestanddele is:
Tabletkerne:
Magnesiumstearaat, mikrokristallyne sellulose, vooraf-gegelatineerde stysel, natriumstyselglikolaat, watervrye kolloïdale silika,

Hoe BESYLOC lyk en die verpakkingsinhoud
BESYLOC 5 mg: n Wit, ronde (deursnee 8,0 mm), effens bikonvekse, skuinskantige tablet, gegroef aan die een kant.
BESYLOC 10 mg: Wit, ronde (deursnee 10,5 mm), effens bikonvekse, skuinskantige tablet.

BESYLOC 5 mg: Ondeursigtige PVC/Aluminiumfoelie stulpstroke van 30 tablette word verpak in 'n gedrukte buitenste kartonhouer.
BESYLOC 10 mg: Ondeursigtige PVC/Aluminiumfoelie stulpstroke van 30 tablette word verpak in 'n gedrukte buitenste kartonhouer.

Elenaar van die Registrasiesertifikaat
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Kaapstad, Suid-Afrika
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Hierdie inligtingsblad was voorheen voorsien
29 Januarie 2024

Registrasienommers
BESYLOC 5 mg: A41/7.1/0560
BESYLOC 10 mg: A41/7.1/0561

NAMIBIË
BESYLOC 5 mg: NS2 08/7.1/0155
BESYLOC 10 mg: NS2 08/7.1/0156