Patient Information leaflet for BIO-NIFEDIPINE

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

BIO-NIFEDIPINE 5 capsules, soft

BIO-NIFEDIPINE 10 capsules, soft

Nifedipine

Sugar free.

Contains sweetener:

BIO-NIFEDIPINE 5: Each capsule contains 0,1 mg sodium saccharin.

BIO-NIFEDIPINE 10: Each capsule contains 0,2 mg sodium saccharin.

Read all of this leaflet carefully before you start taking BIO-NIFEDIPINE.

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

1. What BIO-NIFEDIPINE is and what it is used for

The active ingredient in BIO-NIFEDIPINE, nifedipine, belongs to a group of medicines called calcium antagonists. These medicines relax and expand blood vessels.

BIO-NIFEDIPINE is used to treat your chest pain (angina) or to reduce the frequency of your anginal attacks.

2. What you need to know before you take BIO-NIFEDIPINE

Do not take BIO-NIFEDIPINE:

- If you are hypersensitive (allergic) to nifedipine, other calcium antagonists or any of the other ingredients of BIO-NIFEDIPINE (listed in section 6).
- If you have previously had an allergic reaction to any other similar medicines (known as dihydropyridines, such as amlodipine, felodipine, isradipine or nisolidipine).
- If you are pregnant or breastfeeding.
- If you have very high blood pressure (malignant hypertension).
- If you have porphyria.
- If you have liver impairment.
- If you have a history of obstruction in your gastrointestinal tract (oesophagus, intestines).
- If you suffer from inflammatory bowel disease.
- If you have a narrowing (stenosis) of the aortic valve of the heart.
- If you have experienced a collapse of the circulation which was caused by a heart problem (cardiogenic shock), during which you would have become breathless, pale and had a cold sweat and a dry mouth.
- If you are taking the antibiotic rifampicin (used to treat tuberculosis).
- If you have suffered a heart attack less than one month ago.
- If you have unstable angina (chest pain).
- For the prevention of a heart attack.
- If you have a Kock pouch (a surgically constructed intestinal reservoir with an opening through

the abdominal wall) in your gut.

If the severity or frequency of your chest pain (angina) has rapidly worsened over a matter of hours or days, you must contact your doctor.
You should not use BIO-NIFEDIPINE to treat an angina attack when it occurs, but rather to reduce the frequency of the chest pain (angina) you experience over time.

BIO-NIFEDIPINE should not be used in children.

Warnings and precautions

Take special care with BIO-NIFEDIPINE:

- You should not start taking BIO-NIFEDIPINE within three days of drinking grapefruit juice or start drinking grapefruit juice whilst taking BIO-NIFEDIPINE (see BIO-NIFEDIPINE with food and drink).
- If you experience chest pains within 30 – 60 minutes of taking your first dose of BIO-NIFEDIPINE, contact you doctor before you take the next dose.
- If you have a heart condition where your heart cannot cope with increased strain (poor cardiac reserve), you should tell your doctor.
- If you notice increased breathlessness or swelling of the ankles, or if your heart condition gets worse whilst taking BIO-NIFEDIPINE, you should contact your doctor.
- If you have low blood pressure.
- If you are a diabetic, the treatment for your diabetes may need to be adjusted.

Children and adolescents

BIO-NIFEDIPINE should not be used in children.

Other medicines and BIO-NIFEDIPINE

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

Tell your doctor if you are taking:

- Other medicines to treat high blood pressure or other heart conditions, for example: digoxin, diltiazem, quinidine or beta-blockers.
- Cimetidine, used to treat stomach ulcers.
- Macrolide antibiotics, such as erythromycin.
- The antibiotics rifampicin and combination treatment quinupristin/dalfopristin.
- Ketoconazole, itraconazole or fluconazole, used to treat fungal infections.
- Indinavir, nelfinavir, ritonavir, saquinavir or amprenavir, used to treat human immunodeficiency virus (HIV).
- Fluoxetine and nefazodone, used to treat depression.
- Tacrolimus, used to prevent the rejection of transplanted organs.
- Phenytoin, carbamazepine and valproic acid, used to treat epilepsy.
- Phenobarbital, used to treat insomnia and anxiety.
- Cisapride, a medicine used to treat reduced movements of the oesophagus and stomach.
- Magnesium sulphate injections during pregnancy, which may cause a severe fall in blood pressure.

BIO-NIFEDIPINE may interfere with the results of certain urine tests.

BIO-NIFEDIPINE with food and drink

You should not drink grapefruit juice whilst taking BIO-NIFEDIPINE. Grapefruit juice is known to increase the blood levels of BIO-NIFEDIPINE. This effect can last for at least three days after the last ingestion of grapefruit juice.

Pregnancy, breastfeeding and fertility

Do not take BIO-NIFEDIPINE if you are pregnant or 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 BIO-NIFEDIPINE.

Medicines like BIO-NIFEDIPINE have been shown in laboratory experiments to impair sperm function. If you are male and have been unsuccessful in fathering a child, please consult your doctor.

Driving and using machines

BIO-NIFEDIPINE may make you feel dizzy, extremely tired or cause visual disturbances. You should refrain from driving and using machines until you know how your reactions are affected by BIO-NIFEDIPINE.

BIO-NIFEDIPINE contains Sunset Yellow and sodium

BIO-NIFEDIPINE contains Sunset Yellow (C.I. no. 15985) as colourant, which may cause allergic reactions.

BIO-NIFEDIPINE contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially sodium free.

3. How to take BIO-NIFEDIPINE

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

Always take BIO-NIFEDIPINE exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The initial dose is 10 mg per mouth, given three times daily. Your doctor will adjust this dose over a period of 7 to 14 days until the symptoms of your chest pain are controlled.

The usual maintenance dose is 10 to 20 mg three times daily.

Elderly patients and patients on concomitant medicine

The recommended dose for elderly patients or those on concomitant medication is 5 mg taken

three times daily.

Method of administration

BIO-NIFEDIPINE capsules should be taken by mouth. For more rapid onset of action, you could bite the capsule and allow the contents to remain in your mouth for a short time.

Your doctor will tell you how long treatment with BIO-NIFEDIPINE will last.
If you have the impression that the effect of BIO-NIFEDIPINE is too strong or too weak, tell your doctor or pharmacist.

If you take more BIO-NIFEDIPINE than you should

Exceeding the correct dosage or taking an overdose may cause your blood pressure to become too low and your heartbeats to become irregular. It may also lead to an increase in your blood sugar level or an increase in the acidity of your blood, swelling in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BIO-NIFEDIPINE

Do not take a double dose to make up for the forgotten individual doses. Take your capsule as soon as you remember, then continue to take the next capsule as prescribed, waiting 8 hours until you take the next dose. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking BIO-NIFEDIPINE

If you stop taking BIO-NIFEDIPINE suddenly, your anginal attacks may become worse.

4. Possible side effects

BIO-NIFEDIPINE can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Fever.

These are all very serious side effects. If you have them, you may have had a serious reaction to BIO-NIFEDIPINE. 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:

- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Difficulty in breathing.
- Build-up of fluid in the lungs resulting in breathlessness, which may be severe and usually worsens on lying down.
- Chest pain (which may occur at the start of treatment with BIO-NIFEDIPINE).
- Heart attack. Symptoms include chest pain or discomfort, shortness of breath, pain or discomfort in the jaw, neck, back, arm or shoulder, feeling weak, light-headed or faint.
- General swelling of the body.
- Low blood pressure.
- A fast (tachycardia) or irregular heartbeat (palpitations).

- Problems with your digestive system.
- Severe skin reaction, which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.
- Yellowing of the skin and eyes, dark urine and tiredness, which may be symptoms of liver problems (jaundice).

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.
- Flushing.
- Swelling of the ankles and legs.
- Feeling sick (nausea).
- Constipation.
- General feeling of being unwell.

Less frequent side effects:

- Too much glucose in the blood (hyperglycaemia). Symptoms include thirst, resulting in the need to urinate more frequently, loss of body mass and tiredness.
- Anxiety.
- Difficulty in sleeping.
- Weakness or loss of strength and energy.
- Nervousness.
- Insomnia.
- Depression.
- Trembling.
- Dizziness.

- Migraine.
- Tingling or numbness of the hands or feet (pins and needles).
- Abnormal, unpleasant sensation when touched.
- Eye pain.
- Problems with your eyesight.
- Nasal congestion.
- Nosebleed.
- Abdominal pain.
- Indigestion.
- Excessive gas in the stomach or bowel.
- Dry mouth.
- Tender or swollen gums that may bleed.
- Temporary increase in certain liver enzymes, characterised by abdominal pain, dark urine and fatigue.
- Sweating.
- Redness of the skin.
- Joint pain.
- Muscle pain.
- Muscle cramps.
- Swelling of the joints.
- An increase in the need to urinate.
- Passing more urine than normal.
- Pain when passing urine.
- A failure to achieve or maintain an erection (impotence).
- Unspecific pain.
- Chills.

Side effects which may occur, but the frequency is unknown:

- Decreased feeling or sensitivity, especially in the skin.
- Sleepiness.
- Vomiting.
- Heartburn or indigestion (gastro-oesophageal sphincter insufficiency).
- Sensitivity to light (photosensitivity allergic reaction).
- Small, raised areas of bleeding in the skin (palpable purpura).

All of the symptoms above usually go away when treatment is stopped.

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 doctor, 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 BIO-NIFEDIPINE.

5. How to store BIO-NIFEDIPINE

- Store at or below 25 °C. Protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the capsule after the expiry date printed on the container or blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIO-NIFEDIPINE contains

The active substance is nifedipine.

Each BIO-NIFEDIPINE 5 capsule contains 5 mg nifedipine.

Each BIO-NIFEDIPINE 10 capsule contains 10 mg nifedipine.

The other ingredients are: gelatine, glycerine, peppermint oil, polyethylene glycol 400, polysorbate 80, purified water and sodium saccharin, Sunset Yellow dye (C.I. no. 15985; colourant) and titanium dioxide (C.I. no. 77891; colourant).

What BIO-NIFEDPINE looks like and contents of the pack

BIO-NIFEDIPINE 5: Light orange one piece oval capsule with glossy surface and median sealing line.

BIO-NIFEDIPINE 10: Light orange one piece oblong capsule with glossy surface and median sealing line.

PVC and foil blister strips in cartons containing 84, 100 and 250 capsules or 100 or 250 capsules in polypropylene containers.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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