Patient Information Leaflet for BIO NIFEDIPINE XL 30/60

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BIO NIFEDIPINE XL 30 prolonged-release tablets

BIO NIFEDIPINE XL 60 prolonged-release tablets

Nifedipine

Sugar free.

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

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

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

BIO NIFEDIPINE XL contains nifedipine which is used in the treatment of the following conditions:

- High blood pressure.
- Angina pectoris.

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

Do not take BIO NIFEDIPINE XL:

- If you have previously had an allergic reaction to the active ingredient nifedipine, or to any of the other ingredients of BIO NIFEDIPINE XL (see section 6).
- If you are pregnant or breastfeeding your baby.
- If you are taking the antibiotic rifampicin.
- If you have a liver disease.
- If you suffer from inflammation of the bowel or intestines (such as Crohn's disease).
- If you have, or have had in the past, an obstruction or narrowing of the intestine.
- If you have been told that you have a narrowing (stenosis) of the aortic valve of the heart.
- If you have ever experienced a collapse in the past which was caused by a heart problem (cardiogenic shock), during which you would have become breathless, pale and had a cold sweat and dry mouth.
- During or within one month 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.

Warnings and precautions:

Take special care with BIO NIFEDIPINE XL:

If the severity or frequency of your angina has rapidly worsened over a matter of hours or days, you must contact a doctor. You may be advised not to take this medicine. You should not take BIO NIFEDIPINE XL to treat an angina attack when it occurs, but rather to reduce the frequency of the angina you experience over time.

BIO NIFEDIPINE XL can cause a rise in blood glucose and patients with diabetes should take

special care.

Remind your doctor if you suffer from low blood pressure and he/she prescribes BIO NIFEDIPINE XL for your angina, since your blood pressure may be decreased further by this treatment.

BIO NIFEDIPINE XL must not be used in patients with Kock pouch (ileostomy after proctocolectomy).

If you are to have a barium contrast X-ray, please inform the consultant that you are taking BIO NIFEDIPINE XL. This is because these tablets may affect the results of the test.

If you are a man who has been unable to father a child by *in vitro* fertilisation. Medicines like BIO NIFEDIPINE XL have been shown to impair sperm function.

Children:

BIO NIFEDIPINE XL is not intended to be used in children under the age of 18 years.

Other medicines and BIO NIFEDIPINE XL:

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

In particular, tell your doctor if you are taking:

- other medicine to treat high blood pressure
- cimetidine (treatment of stomach ulcers)
- the medicines digoxin, diltiazem, quinidine or beta-blockers, which are used to treat heart conditions
- the antibiotics rifampicin and combination treatment quinupristin/dalfopristin
- phenytoin, carbamazepine or valproic acid (to treat epilepsy)
- cisapride, a medicine used to treat reduced movements of the gullet and stomach

- magnesium sulphate injections during pregnancy (may cause a severe fall in blood pressure)
- erythromycin (an antibiotic)
- ketoconazole, itraconazole or fluconazole (antifungal medicines).
- indinavir, nelfinavir, ritonavir, saquinavir or amprenavir (to treat HIV)
- fluoxetine or nefazodone (to treat depression)
- tacrolimus (to prevent the rejection of transplanted organs)
- phenobarbitone (usually used to treat insomnia or anxiety)

BIO NIFEDIPINE XL with food and drink

You should not start taking BIO NIFEDIPINE XL within three days of drinking grapefruit juice. If you have, speak to your doctor. In addition, you should not drink grapefruit juice whilst taking BIO NIFEDIPINE XL. This is because grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least three days after the last ingestion of grapefruit juice.

Alcohol should be avoided during BIO NIFEDIPINE XL treatment.

Pregnancy and breastfeeding:

You should not take BIO NIFEDIPINE XL when you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking BIO NIFEDIPINE XL. The safe use of BIO NIFEDIPINE XL during pregnancy and breastfeeding has not been established.

Driving and using machines

BIO NIFEDIPINE XL may make you feel dizzy, faint, extremely tired or have visual disturbances and can therefore impair your ability to drive or to operate machinery, especially during the start of treatment, changing the medication and in combination with alcohol. The intensity of the reaction to BIO NIFEDIPINE XL varies from patient to patient.

BIO NIFEDIPINE XL contains sodium

BIO NIFEDIPINE XL 30 contains 9,52 mg of sodium and BIO NIFEDIPINE XL 60 contains 19,04 mg of sodium.

Increasing the daily dose to 90 mg nifedipine results in an intake of 28,56 mg sodium. This is equivalent to 1,43 % of the WHO recommended maximum daily dietary intake of 2 g sodium for an adult.

Tell your doctor if you are on a low-salt diet.

3. How to take BIO NIFEDIPINE XL

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

Always take BIO NIFEDIPINE XL exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of BIO NIFEDIPINE XL is too strong or too weak, talk to your doctor or pharmacist.

These tablets should not be crushed, chewed or broken.

The tablet is specially formulated so that you only have to take your tablets once a day. Take the tablet as prescribed by your doctor.

Usually this will be one tablet taken at the same time each day, either with or without food, and preferably during the morning. The tablet should be swallowed whole with a glass of water. You should not take your tablet(s) with grapefruit juice.

Continue to take these tablets for as long as your doctor has told you to.

Your doctor will determine the dosage that is appropriate for you. This may be from 30 mg a day up to 90 mg a day.

BIO NIFEDIPINE XL is not recommended for use in children.

If you take more BIO NIFEDIPINE XL 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. Also, it may lead to dizziness, confusion, low blood oxygen levels and possibly unconsciousness.

If you take more than the prescribed dose, or in the event of an overdose, seek medical advice immediately and, if possible, take your tablets or the box with you to show the doctor. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BIO NIFEDIPINE XL:

Do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

4. Possible side effects

BIO NIFEDIPINE XL can have side effects.

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

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

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

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

reaction to BIO NIFEDIPINE XL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequently reported side effects are:

- headache
- eye pain
- flushing
- a general feeling of being unwell
- constipation
- swelling particularly of the ankles and legs.

Less frequently reported side effects are:

- pain particularly in the stomach area (abdomen)
- unspecific pain
- chills
- a low blood pressure when rising to the standing position (symptoms of low blood pressure include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- a fast heartbeat (tachycardia)
- an irregular heartbeat (palpitations)
- migraine
- a dry mouth
- indigestion or an upset stomach
- wind (flatulence)
- feeling sick (nausea)
- muscle cramps
- joint swelling
- sleep disorders

- anxiety or nervousness
- a reddening of the skin
- nose bleeds
- sensation of spinning or whirling motion (vertigo)
- dizziness
- trembling
- allergic reactions, particularly hives that appear on the body, lips, eyes or tongue
- an increase in the need to pass water
- painful or difficult urination
- problems with the eyes that may be painful or cause blurred vision
- a temporary increase in the levels of certain liver enzymes
- inflammation of the gums, tender or swollen gums, bleeding gums
- small, raised areas of bleeding in the skin (palpable purpura).

Other side effects where the frequency cannot be determined:

- being sick (vomiting)
- intestinal blockage or ulcer
- sensitivity to light (photosensitivity allergic reaction)
- heartburn or indigestion (gastroesophageal sphincter insufficiency).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can 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

XL.

5. How to store BIO NIFEDIPINE XL

- Store at or below 25 °C. Protect from light and moisture.
- Keep the blister strips in the outer carton and keep the carton closed until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the container.
- 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 XL contains:

BIO NIFEDIPINE XL 30: The active substance is nifedipine 30 mg per prolonged-release tablet.

BIO NIFEDIPINE XL 60: The active substance is nifedipine 60 mg per prolonged-release tablet.

The other ingredients are: Cellulose acetate, colloidal silicon dioxide, ferric oxide red (colourant), hypromellose, magnesium stearate, Opacode black (colourant), Opadry brown (consisting of hypromellose, iron oxide red (colourant), iron oxide yellow (colourant), polyethylene glycol and titanium dioxide (colourant)), polyethylene glycol, polyethylene oxide, potassium chloride, sodium chloride.

What BIO NIFEDIPINE XL looks like and contents of the pack:

BIO NIFEDIPINE XL 30: Brown coloured, round biconvex film coated tablet free from cracks, plain on one side & laser drilled hole on other side.

BIO NIFEDIPINE XL 60: Brown coloured, round biconvex film coated tablet free from cracks, plain on one side & laser drilled hole on other side.

Plain aluminium (no external colour), transparent and colourless PVC blister strips; 10 tablets per strip.

Three (3) blister strips are packed into an outer cardboard carton.

Holder of the certificate of registration

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This leaflet was last revised in

21 January 2022

Registration numbers

BIO NIFEDIPINE XL 30: 43/7.1/0558

BIO NIFEDIPINE XL 60: 43/7.1/0559

NAMIBIA REGISTRATION ONLY:

NS2 BIO NIFEDIPINE XL 30

Reg. No.: 13/7.1/0228

(Act No. 13 of 2003).

NS2 BIO NIFEDIPINE XL 60

Reg. No.: 13/7.1/0229

(Act No. 13 of 2003).