BIO NIFEDIPINE XL

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 healthcare 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 healthcare 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 healthcare 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 and laser drilled hole on other side.
BIO NIFEDIPINE XL 60: Brown coloured, round biconvex film coated tablet free from cracks, plain on one side and 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
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark
Midrand, 1685
Tel: +27 (0) 11 848 3050

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:

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).	NS2

BIO NIFEDIPINE XL

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S3

BIO NIFEDIPINE XL 30 verlengde vrystellingstablette
BIO NIFEDIPINE XL 60 verlengde vrystellingstablette
Nifedipien
Suiker vry.

Lees die hele pamflet noukeurig deur voordat jy begin om BIO NIFEDIPINE XL te neem.
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- BIO NIFEDIPINE XL is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit mag hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet
1. Wat BIO NIFEDIPINE XL is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy BIO NIFEDIPINE XL neem
3. Hoe om BIO NIFEDIPINE XL te neem
4. Moontlike newe-effekte
5. Hoe om BIO NIFEDIPINE XL te bewaar
6. Inhoud van die pak en ander inligting

1. Wat BIO NIFEDIPINE XL is en waarvoor dit gebruik word
BIO NIFEDIPINE XL bevat nifedipien wat gebruik word in die behandeling van die volgende toestande:
- Hoë bloeddruk.
- Angina pectoris.

2. Wat jy moet weet voordat jy BIO NIFEDIPINE XL neem
Moenie BIO NIFEDIPINE XL neem nie:
- Indien jy al voorheen 'n allergiese reaksie op die aktiewe bestanddeel nifedipien gehad het, of op enige van die ander bestanddele van BIO NIFEDIPINE XL (sien afdeling 6).
- Indien jy swanger is of jou baba borsvoed.
- Indien jy die antibiotika rifampisien neem.
- Indien jy 'n lewersiekte het.
- Indien jy aan inflammasie van die derm of ingewande ly (soos Crohn se siekte).
- Indien jy 'n obstruksie of vernouing van die derm het, of al in die verlede gehad het.
- Indien daar vir jou vertel is dat jy 'n vernouing (stenose) van die aortaklep van die hart het.
- Indien jy nou of al ooit in die verlede 'n ineenstorting ervaar het wat veroorsaak is deur 'n hartprobleem (kardiogene skok), waartydens jy asemloos, bleek en koue sweet sou gehad het en droë mond.
- Gedurende of binne een maand van 'n hartaanval.
- Indien jy 'n "Kock-sakkie" ('n chirurgies gekonstrueerde dermreservoir met 'n opening deur die buikwand) in jou ingewande het.

Waarskuwings en voorsorgmaatreëls:
Neem spesiale sorg met BIO NIFEDIPINE XL:
Indien die erns of frekwensie van jou angina vinnig vererger het oor 'n kwessie van ure of dae, moet jy 'n dokter kontak. Jy mag dalk aangeraai word om nie hierdie medisyne te neem nie. Jy moet nie BIO NIFEDIPINE XL neem om 'n angina-aanval te behandel wanneer dit voorkom nie, maar eerder om die frekwensie van die angina wat jy ervaar met verloop van tyd te verminder.

BIO NIFEDIPINE XL kan 'n styging in bloedglukose veroorsaak en pasiënte met diabetes moet spesiale sorg aan die dag lê.

Herinner jou dokter as jy aan lae bloeddruk ly en hy/ sy skryf BIO NIFEDIPINE XL vir jou angina voor, aangesien jou bloeddruk verder verlaag kan word deur hierdie behandeling.

BIO NIFEDIPINE XL moet nie by pasiënte met Kock-sakkie (ileostomie na proktokolektomie) gebruik word nie.

As jy 'n bariumkontras X-straal moet kry, stel asseblief die konsultant in kennis dat jy BIO NIFEDIPINE XL neem. Dit is omdat hierdie tablette die resultate van die toets kan beïnvloed.

As jy 'n man is wat nie 'n kind kon verwek deur *in vitro*-bevrugting nie. Daar is getoon dat medisyne soos BIO NIFEDIPINE XL spermfunksie benadeel.

Kinders:
BIO NIFEDIPINE XL is nie bedoel om by kinders onder die ouderdom van 18 jaar gebruik te word nie.

Ander medisyne en BIO NIFEDIPINE XL:
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem.
(Dit sluit komplementêre of tradisionele medisyne in.)
Vertel veral vir jou dokter indien jy die volgende neem:
- ander medisyne om hoë bloeddruk te behandel
- simetidien (behandeling van maagsere)
- die medisyne digoksien, diltiasem, kinidien of betablokkers wat gebruik word om harttoestande te behandel
- die antibiotika rifampisien en die kombinasiebehandeling kinupristien/ dalfopristien
- die anti-epileptiese medisyne fenitoïen, karbamasepien of valproïensuur (om epilepsie te behandel)
- sisapried, 'n medisyne wat gebruik word om verlaagde bewegings van die slukderm en maag te behandel
- magnesiumsulfaatinspuitings gedurende swangerskap (mag 'n ernstige daling in bloeddruk veroorsaak)
- eritromisien ('n antibiotikum)
- ketokonasool, itrakonasool of flukonasool (teenswammedisyne)
- indinavir, nelfinavir, ritonavir, sakinavir of amprenavir (om MIV te behandel)
- fluoksetien of nefasosoon (om depressie te behandel)
- takrolimus (om die verwerping van 'n oorgeplante organe te voorkom)
- fenobarbitoon (gewoonlik gebruik om slapeloosheid of angs te behandel)

BIO NIFEDIPINE XL met kos en drank
Jy moet nie BIO NIFEDIPINE XL begin neem binne drie dae nadat jy pomelosap gedrink het nie. As jy het, praat met jou dokter. Daarbenewens moet jy nie pomelosap drink terwyl jy BIO NIFEDIPINE XL neem nie. Dit is omdat dit bekend is dat pomelosap die bloedvlakke van die aktiewe bestanddeel, nifedipien, verhoog. Hierdie effek kan vir ten minste drie dae na die laaste inname van pomelosap duur.
Alkohol moet vermy word tydens BIO NIFEDIPINE XL behandeling.

Swangerskap en borsvoeding:
Jy moet nie BIO NIFEDIPINE XL neem wanneer jy swanger is of jou baba borsvoed nie. As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy BIO NIFEDIPINE XL neem. Die veilige gebruik van BIO NIFEDIPINE XL tydens swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en die gebruik van masjiene
BIO NIFEDIPINE XL kan jou duiselig, flou, uiters moeg laat voel of visuele versteurings laat hê en kan dus jou vermoë om te bestuur of om masjinerie te bestuur belemmer, veral tydens die aanvang van behandeling, die verandering van die medikasie en in kombinasie met alkohol. Die intensiteit van die reaksie op BIO NIFEDIPINE XL verskil van pasiënt tot pasiënt.

BIO NIFEDIPINE XL bevat natrium
BIO NIFEDIPINE XL 30 bevat 9,52 mg natrium en BIO NIFEDIPINE XL 60 bevat 19,04 mg natrium.
Die verhoging van die daaglikse dosis tot 90 mg nifedipien lei tot 'n inname van 28,56 mg natrium. Dit is gelykstaande aan 1,43 % van die WGO se aanbevole maksimum daaglikse dieetinname van 2 g natrium vir 'n volwassene.
Vertel jou dokter as jy op 'n lae-sout dieet is.

3. Hoe om BIO NIFEDIPINE XL te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd BIO NIFEDIPINE XL presies soos jou dokter jou opdrag gegee het. Jy moet seker maak by jou dokter indien jy nie seker is nie. Indien jy die indruk het dat die effek van BIO NIFEDIPINE XL te sterk of te swak is, praat met jou dokter of apteker.

Hierdie tablette moet nie fyngemaak, gekou of gebreek word nie.

Die tablet is spesiaal geformuleer sodat jy jou tablette net een keer per dag hoef te neem. Neem die tablet soos deur jou dokter voorgeskryf.
Gewoonlik is dit een tablet wat elke dag op dieselfde tyd geneem word, hetsy met of sonder kos, en verkieslik gedurende die oggend. Die tablet moet heel ingesluk word met 'n glas water. Jy moet nie jou tablet(te) met pomelosap neem nie.

Gaan voort om hierdie tablette te neem so lank as wat jou dokter jou aangesê het.

Jou dokter sal die dosis bepaal wat geskik is vir jou. Dit kan van 30 mg per dag tot 90 mg per dag wees.

BIO NIFEDIPINE XL word nie aanbeveel vir gebruik in kinders nie.

Indien jy meer BIO NIFEDIPINE XL neem as wat jy moet:
Indien jy die korrekte dosis oorskry of 'n oordosis neem, kan jou bloeddruk te laag word en jy hartklop onreëlmatig word. Dit kan ook lei tot duiseligheid, verwarring, lae bloed suurstofvlakke en moontlik bewusteloosheid.
Indien jy meer as die voorgeskrewe dosis neem, of in die geval van 'n oordosis, soek onmiddellik mediese advies en, indien moontlik, neem jou tablette of die boks saam om die dokter te wys. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om BIO NIFEDIPINE XL te neem:
Moenie 'n dubbeldosis neem om die vergete individuele dosisse op te maak nie. Gaan voort om die volgende tablet op die gewone tyd te neem. As jy sukkel om te onthou wanneer om jou medisyne te gebruik, vra jou apteker vir 'n paar wenke.

4. Moontlike newe-effekte
BIO NIFEDIPINE XL kan newe-effekte hê.
Nie alle newe-effekte wat vir BIO NIFEDIPINE XL aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy BIO NIFEDIPINE XL neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om BIO
NIFEDIPINE XL te neem en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat moeilike sluk of moeilike asemhaling mag veroorsaak
- veluitslag of jeuk
- floute
- vergeling van jou vel en oë (ook genoem geelsug).

Hierdie is almal baie ernstige newe-effekte. Indien jy hulle het mag jy dalk 'n ernstige allergiese reaksie op BIO NIFEDIPINE XL gehad het. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat gereeld aangemeld is:
- hoofpyn
- oogpyn
- blosing
- 'n algemene onwel gevoel
- hardlywigheid
- swelling van veral die enkels en bene.

Newe-effekte wat minder gereeld aangemeld is:
- pyn veral in die maagarea (buik)
- ongespesifiseerde pyn
- koue rillings
- 'n lae bloeddruk wanneer jy na 'n staande posisie styg (simptome van lae bloeddruk sluit in floute, duiseligheid, lighoofdigheid, af en toe hartkloppings, versteurde visie en soms verwarring in)
- 'n vinnige hartklop (tagikardie)
- 'n onreëlmatige hartklop (kloppings)
- migraine
- 'n droë mond
- slegte spysvertering of 'n omgekrapte maag
- winderigheid
- siek gevoel (naarheid)
- spierkrampe
- gewrig swelling
- slaapversteurings
- angstigheid of senuweeagtigheid
- 'n rooiheid van die vel
- neusbloeding
- sensasie van draaiende of warrelende beweging (vertigo)
- duiseligheid
- bewing
- allergiese reaksies, veral korwe wat op die liggaam, lippe, oë of tong verskyn
- 'n verhoogde drang om water uit te skei
- pynlike of moeilike urinering
- probleme met die oë wat pynlik kan wees of versteurde visie kan veroorsaak
- 'n tydelike verhoging in die vlakke van sekere lewerensieme
- inflammasie van die tandvleis, teer of geswelde tandvleis, bloeiende tandvleis
- klein, verhoogde areas van bloeding in die vel (tasbare purpura).

Ander newe-effekte waar die frekwensie nie bepaal kan word nie:
- siek wees (braking)
- intestinale blokkasie of seer (ulkus)
- sensitiwiteit vir lig (fotosensitiwiteit-allergiese reaksie)
- sooibrand of slegte spysvertering (gastroesofageale sfinkter ontoereikendheid).

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter of apteker daarvan in.

Aanmelding van newe-effekte:
Indien jy newe-effekte kry, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA aanmeld deur die vorm **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van BIO NIFEDIPINE XL te verskaf.

5. Hoe om BIO NIFEDIPINE XL te bewaar
- Bewaar teen of benede 25 °C. Beskerm teen lig en vog.
- Hou die stulpstroke in die buitenste karton en hou die karton toe totdat dit benodig word vir gebruik.
- BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie die tablette na die vervaldatum wat op die houer gedruk is gebruik nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat BIO NIFEDIPINE XL bevat:
BIO NIFEDIPINE XL 30: Die aktiewe stof is nifedipien 30 mg per verlengde vrystellingstablet.
BIO NIFEDIPINE XL 60: Die aktiewe stof is nifedipien 60 mg per verlengde vrystellingstablet.
Die ander bestanddele is: Sellulose-asetaat, kolloïdale silikondioksied, ysteroksiedrooi (kleurstof), hipromellose, magnesiumstearaat, Opacode swart (kleurstof), Opadry bruin (bestaande uit hipromellose, ysteroksied rooi (kleurstof), ysteroksied geel (kleurstof), poliëtileenglikol en titaandioksied (kleurstof)), poliëtileenglikol, poliëtileenoksied, kaliumchloried, natriumchloried.

Hoe BIO NIFEDIPINE XL lyk en die inhoud van die pak:
BIO NIFEDIPINE XL 30: Bruinkleurige, ronde bikonvekse filmbedekte tablet vry van krake, ongedruk aan die een kant en lasergeboorde gat aan die ander kant.
BIO NIFEDIPINE XL 60: Bruinkleurige, ronde bikonvekse filmbedekte tablet vry van krake, ongedruk aan die een kant en lasergeboorde gat aan die ander kant.
Gewone aluminium (geen eksterne kleur), deursigtige en kleurlose PVC stulpstroke; 10 tablette per strook.
Drie (3) stulpstroke word verpak in 'n buitenste kartonhouer.

Houer van die sertifikaat van registrasie
Biotech Laboratories (Edms.) Bpk.
Grondvloer, Blok K Wes, Central Park
16de Weg 400, Randjespark
Midrand, 1685
Tel: +27 (0) 11 848 3050

Hierdie pamflet was laas hersien
21 Januarie 2022

Registrasienommers
BIO NIFEDIPINE XL 30: 43/7.1/0558
BIO NIFEDIPINE XL 60: 43/7.1/0559

NAMIBIË REGISTRASIE ALLEENLIK:

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).	NS2