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 healthcare 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
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 healthcare 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 healthcare 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 healthcare 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.

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BIO-NIFEDIPINE

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS

S3

BIO-NIFEDIPINE 5 kapsules, sag
BIO-NIFEDIPINE 10 kapsules, sag
Nifedipien
Suiker vry.
Bevat versoeter:
BIO-NIFEDIPINE 5: Elke kapsule bevat 0,1 mg natriumsakkarien.
BIO-NIFEDIPINE 10: Elke kapsule bevat 0,2 mg natriumsakkarien.

Lees die hele pamflet noukeurig deur voordat jy begin om BIO-NIFEDIPINE 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 is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander persone deel nie. Dit mag hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat BIO-NIFEDIPINE is en waarvoor dit gebruik word
Die aktiewe bestanddeel in BIO-NIFEDIPINE, nifedipien, behoort aan 'n groep medisyne wat kalsiumantagoniste genoem word. Hierdie medisyne ontspan en brei bloedvate uit.
BIO-NIFEDIPINE word gebruik om jou borspyn (angina) te behandel of om die frekwensie van jou angina aanvalle te verminder.

2. Wat jy moet weet voordat jy BIO-NIFEDIPINE neem
Moenie BIO-NIFEDIPINE neem nie:
- Indien jy hipersensitief (allergies is vir nifedipien, ander kalsiumantagoniste of vir enige van die ander bestanddele van BIO-NIFEDIPINE (gelys in afdeling 6).
- Indien jy voorheen 'n allergiese reaksie op enige ander soortgelyke medisyne gehad het (bekend as dihidropiridiene, soos amlodipien, felodipien, isradipien of nisolidipien).
- Indien jy swanger is of borsvoed.
- Indien jy baie hoë bloeddruk (maligne hipertensie) het.
- Indien jy porferie het.
- Indien jy lewerontoereikendheid het.
- Indien jy 'n geskiedenis van obstruksie in jou spysverteringskanaal (slukderm, ingewande) het.
- Indien jy aan inflammatoriese dermsiekte ly.
- Indien jy 'n vernouing (stenose) van die aortaklep van die hart het.
- Indien jy 'n ineenstorting van die sirkulasie ervaar het wat veroorsaak is deur 'n hartprobleem (kardiogene skok), waartydens jy asemloos, bleek en koue sweet en 'n droë mond sou gehad het.
- Indien jy die antibiotika rifampisien (wat gebruik word om tuberkulose te behandel) neem.
- Indien jy minder as 'n maand gelede 'n hartaanval gehad het.
- As jy onstabiele angina (borspyn) het.
- Vir die voorkoming van 'n hartaanval.
- As jy 'n Kock-sakkie ('n chirurgies saamgestelde dermreservoir met 'n opening deur die buikwand) in jou ingewande het.

Indien die erns of frekwensie van jou borspyn (angina) vinnig vererger het oor 'n kwessie van ure of dae, moet jy jou dokter kontak.
Jy moet nie BIO-NIFEDIPINE gebruik om 'n angina-aanval te behandel wanneer dit voorkom nie, maar eerder om die frekwensie van die borspyn (angina) wat jy ervaar met verloop van tyd te verminder.

BIO-NIFEDIPINE moet nie in kinders gebruik word nie.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met BIO-NIFEDIPINE:
- Jy moet nie BIO-NIFEDIPINE begin neem binne drie dae nadat jy pomelosap gedrink het of pomelosap begin drink terwyl jy BIO-NIFEDIPINE neem nie (sien BIO-NIFEDIPINE met kos en drank).
- Indien jy borspyn ervaar binne 30 - 60 minute nadat jy jou eerste dosis BIO-NIFEDIPINE geneem het, kontak jou dokter voordat jy die volgende dosis neem.
- Indien jy 'n harttoestand het waar jou hart nie verhoogde spanning kan hanteer nie (swak hartreserwe), moet jy jou dokter vertel.
- Indien jy meer gereelde asemloosheid of swelling van die enkels opmerk, of as jou harttoestand vererger terwyl jy BIO-NIFEDIPINE neem, moet jy jou dokter kontak.
- Indien jy lae bloeddruk het.
- Indien jy 'n diabeet is, moet die behandeling vir jou diabetes dalk aangepas word.

Kinders en adolessente
BIO-NIFEDIPINE moet nie by kinders gebruik word nie.

Ander medisyne en BIO-NIFEDIPINE
Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Vertel jou dokter as jy die volgende neem:
- Ander medisyne om hoë bloeddruk of ander harttoestande te behandel, byvoorbeeld: digoksien, diltiazem, kinidien of betablokkers.
- Simetidien, gebruik om maagsere te behandel.
- Makrolied-antibiotika, soos eritromisien.
- Die antibiotika rifampisien en kombinasiebehandeling quinupristien/dalfopristien.
- Ketokonasool, itrakonasool of flukonasool, wat gebruik word om swaminfeksies te behandel.
- Indinavir, nelfinavir, ritonavir, saquinavir of amprenavir, wat gebruik word om menslike immuniteitsgebrekvirus (MIV) te behandel.
- Fluoksetien en nefasodoon, gebruik om depressie te behandel.
- Takrolimus, gebruik om die verwerping van oorgeplante organe te voorkom.
- Fenitoïen, karbamasepien en valproïensuur, gebruik om epilepsie te behandel.
- Fenobarbital, gebruik om slapeloosheid en angs te behandel.
- Sisapried, 'n medisyne wat gebruik word om verminderde bewegings van die slukderm en maag te behandel.
- Magnesiumsulfaatinspuitings tydens swangerskap, wat 'n ernstige daling in bloeddruk kan veroorsaak.

BIO-NIFEDIPINE kan inmeng met die resultate van sekere urienetoetse.

BIO-NIFEDIPINE met kos en drank
Jy moet nie pomelosap drink terwyl jy BIO-NIFEDIPINE neem nie. Dit is bekend dat pomelosap die bloedvlakke van BIO-NIFEDIPINE verhoog. Hierdie effek kan vir ten minste drie dae na die laaste inname van pomelosap duur.

Swangerskap, borsvoeding en vrugbaarheid
Moenie BIO-NIFEDIPINE neem as jy swanger is of borsvoed nie. As jy swanger is of jou baba borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy BIO-NIFEDIPINE neem.

Daar is in laboratoriumeksperimente getoon dat medisyne soos BIO-NIFEDIPINE spermfunksie benadeel. As jy manlik is en onsuksesvol was om 'n kind te verwek, raadpleeg asseblief jou dokter.

Bestuur en die gebruik van masjiene
BIO-NIFEDIPINE kan jou duiselig, uiters moeg laat voel of visuele versteurings veroorsaak. Jy moet jou daarvan weerhou om te bestuur en masjiene te gebruik totdat jy weet hoe jou reaksies deur BIO-NIFEDIPINE beïnvloed word.

BIO-NIFEDIPINE bevat Sonsondergang geel en natrium
BIO-NIFEDIPINE bevat Sonsondergang geel (C.I. no. 15985) as kleurstof, wat allergiese reaksies kan veroorsaak.
BIO-NIFEDIPINE bevat minder as 1 mmol natrium (23 mg) per kapsule, dit wil sê in wese natriumvry.

3. Hoe om BIO-NIFEDIPINE te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem BIO-NIFEDIPINE altyd presies soos jou dokter of apteker vir jou gesê het. Jy moet jou dokter of apteker raadpleeg as jy nie seker is nie.
Die aanvanklike dosis is 10 mg per mond, drie keer per dag toegedien.
Jou dokter sal hierdie dosis oor 'n tydperk van 7 tot 14 dae aanpas totdat die simptome van jou borspyn beheer is.
Die gewone onderhoudsdosis is 10 tot 20 mg drie keer per dag.

Bejaarde pasiënte en pasiënte op gelyktydige medisyne
Die aanbevole dosis vir bejaarde pasiënte of diegene op gelyktydige medikasie is 5 mg drie keer per dag geneem.

Metode van toediening
BIO-NIFEDIPINE kapsules moet per mond geneem word. Vir vinniger begin van werking, kan jy die kapsule byt en die inhoud vir 'n kort rukkie in jou mond laat bly.
Jou dokter sal jou vertel hoe lank behandeling met BIO-NIFEDIPINE sal duur.
As jy die indruk het dat die effek van BIO-NIFEDIPINE te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer BIO-NIFEDIPINE neem as wat jy moet
As jy die korrekte dosis oorskry of 'n oordosis neem, kan jou bloeddruk te laag word en jou hartklop onreëlmatig word. Dit kan ook lei tot 'n toename in jou bloedsuikervlak of 'n verhoging in die suurheid van jou bloed, swelling in die longe, lae bloed suurstofvlakke en versteurings in bewussyn, wat moontlik tot bewusteloosheid lei. In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om BIO-NIFEDIPINE te neem
Moenie 'n dubbeldosis neem om die vergete individuele dosisse op te maak nie. Neem jou kapsule sodra jy onthou, gaan dan voort om die volgende kapsule te neem soos voorgeskryf, wag 8 uur totdat jy die volgende dosis neem. As jy sukkel om te onthou wanneer om jou medisyne te gebruik, vra jou apteker vir 'n paar wenke.

Indien jy ophou om BIO-NIFEDIPINE te neem
Indien jy skielik ophou om BIO-NIFEDIPINE te neem, kan jou angina-aanvalle erger word.

4. Moontlike newe-effekte
BIO-NIFEDIPINE kan newe-effekte hê.

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

Indien enige van die volgende gebeur, hou op om BIO-NIFEDIPINE te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal.
- Veluitslag of jeuk.
- Floute.
- Koors.

Hierdie is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie op BIO-NIFEDIPINE gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
- Gereelde infeksies soos koors, erge kouekoors, seer keel of mondsere.
- Moeilike asemhaling.
- Opbou van vloeistof in die longe wat lei tot asemloosheid, wat ernstig kan wees en gewoonlik vererger wanneer jy gaan lê.
- Borspyn (wat mag voorkom aan die begin van behandeling met BIO-NIFEDIPINE).
- Hartaanval. Simptome sluit in borspyn of ongemak, kortasem, pyn of ongemak in die kakebeen, nek, rug, arm of skouer, swak, lighoofdig of flou voel.
- Algemene swelling van die liggaam.
- Lae bloeddruk.
- 'n Vinnige (tagikardie) of onreëlmatige hartklop (kloppings).
- Probleme met jou spysverteringstelsel.
- Ernstige velreaksie, wat begin met pynlike rooi areas, dan groot blase en eindig met afskilfering van lae vel. Dit gaan gepaard met koors en kouekoors, seer spiere en voel oor die algemeen onwel.
- Vergeling van die vel en oë, donker uriene en moegheid, wat simptome van lewerprobleme (geelsug) kan wees.

Hierdie is almal ernstige newe-effekte. Jy mag dalk dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- Hoofpyn.
- Blosing.
- Swelling van die enkels en bene.
- Siek gevoel (naarheid).
- Hardlywigheid.
- Algemene gevoel van ongesteldheid.

Minder gereelde newe-effekte:
- Te veel glukose in die bloed (hiperglisemie). Simptome sluit in dors, wat lei tot die behoefte om meer gereeld te urineer, verlies aan liggaamsmassa en moegheid.
- Angstigheid.
- Moeilike slaap.
- Swakheid of verlies aan krag of energie.
- Senuweeagtigheid.
- Slapeloosheid.
- Depressie.
- Bewing.
- Duiseligheid.
- Migraine.
- Tinteling of gevoelloosheid van die hande of voete (spelde en naalde).
- Abnormale, onaangename sensasie wanneer dit aangeraak word.
- Oogpyn.
- Probleme met jou sig.
- Neusverstopping.
- Neusbloeding.
- Maagpyn.
- Slegte spysvertering.
- Oormatige gas in die maag of derm.
- Droë mond.
- Seer of gesweld tandvleise wat mag bloei.
- Tydelike toename in sekere lewerensieme, gekenmerk deur abdominale pyn, donker uriene en moegheid.
- Sweet.
- Rooiheid van die vel.
- Gewrigspyn.
- Spierpyn.
- Spierkrampe.
- Swelling van die gewrigte.
- 'n Toename in die behoefte om te urineer.
- Gee meer uriene deur as normaalweg.
- Pyn wanneer jy urineer.
- 'n Versuim om 'n ereksie te bereik of in stand te hou (impotensie).
- Ongespesifiseerde pyn.
- Koue rillings.

Newe-effekte wat mag voorkom, maar die frekwensie is onbekend:
- Verminderde gevoel of sensitiwiteit, veral in die vel.
- Slapeloosheid.
- Braking.
- Sooibrand of slegte spysvertering (gastro-esofageale sfinkter ontoereikendheid).
- Sensitiwiteit vir lig (fotosensitiwiteit allergiese reaksie).
- Klein, verhoogde areas van bloeding in die vel (tastbare purpura).

Al die bogenoemde simptome gaan gewoonlik weg wanneer behandeling gestaak word.

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

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. 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 te verskaf.

5. Hoe om BIO-NIFEDIPINE te bewaar
- Bewaar teen of benede 25 °C. Beskerm teen lig.
- BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie die kapsule na die vervaldatum wat op die houer of stulpstrook 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 bevat
Die aktiewe stof is nifedipien.
Elke BIO-NIFEDIPINE 5 kapsule bevat 5 mg nifedipien.
Elke BIO-NIFEDIPINE 10 kapsule bevat 10 mg nifedipien.
Die ander bestanddele is: gelatien, gliserien, pepermentolie, poliëtileenglikol 400, polisorbaat 80, gesuiwerde water en natriumsakkarien, Sunset Yellow-kleurstof (C.I.-nr. 15985; kleurstof) en titaandioksied (C.I.-nr. 77891; kleurstof).

Hoe BIO-NIFEDPINE lyk en die inhoud van die pak
BIO-NIFEDIPINE 5: Lig oranje een stuk ovaal kapsule met blink oppervlak en mediaan seëllyn.
BIO-NIFEDIPINE 10: Ligoranje een stuk langwerpige kapsule met blink oppervlak en mediaan seëllyn.
PVC en foelie stulpstroke in kartonne wat 84, 100 en 250 kapsules of 100 of 250 kapsules in polipropileenhouers bevat.
Nie alle pakgroottes word dalk bemark nie.

Houer van die Sertifikaat van Registrasie
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Hierdie pamflet is laas hersien
27 Mei 2022.

Registrasienommers
BIO-NIFEDIPINE 5: X/7.1/102
BIO-NIFEDIPINE 10: X/7.1/103

Datum van registrasie
16 Augustus 1990