BIO-ATENOLOL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:
BIO-ATENOLOL 50 (Tablets)
BIO ATENOLOL 100 (Tablets)

Read all of this leaflet carefully before you start taking BIO-ATENOLOL 50 and BIO ATENOLOL 100 tablets.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BIO-ATENOLOL 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.

1. WHAT BIO-ATENOLOL CONTAINS
BIO-ATENOLOL 50: Each tablet contains 50 mg atenolol.
BIO ATENOLOL 100: Each tablet contains 100 mg atenolol.
Inactive ingredients: Maize starch, lactose monohydrate, povidone, croscarmellose sodium type A, magnesium stearate, pregelatinized starch and opadry orange (consisting of hypromellose; titanium dioxide, hydroxypropyl cellulose, polyethylene glycol, sunset yellow FCF aluminum lake and talc).
Contains sugar (lactose monohydrate).

2. WHAT BIO-ATENOLOL IS USED FOR
BIO-ATENOLOL is used in the treatment of the following:
- Hypertension
- Management of angina pectoris
- Myocardial infarction: BIO-ATENOLOL reduces cardiovascular mortality in patients who survived the acute phase of myocardial infarction and are clinically stable.

3. BEFORE YOU TAKE BIO-ATENOLOL
Do not take BIO-ATENOLOL:
- If you have previously had an allergic reaction to the active ingredient atenolol, or to any of the other ingredients of BIO-ATENOLOL.
- If you have phaeochromocytoma, and do not use alpha-adronoceptor blocking therapy.
- Particular caution should be exercised if you suffer from the following:
- Asthma, bronchitis, chronic respiratory diseases, second- and third-degree heart block and bradycardia, peripheral vascular diseases and Raynaud's phenomenon.
- If you are pregnant or breastfeeding your baby.

Take special care with BIO-ATENOLOL
- If you are already on a treatment for hypertension, be aware of what you are taking as certain medicines as combinations can have serious consequences. See below "Taking Other Medicine with BIO-ATENOLOL"
- If you are elderly or suffer from renal dysfunction as the normal dose should be reduced.
- If you are scheduled to have surgery (peri-operative period), the doctor will watch you closely for possible dose adjustments.
- If you undergo surgery and requires anaesthesia, myocardial suppressants such as chloroform or ether must be avoided.
- If you suffer from metabolic acidosis and requires it for congestive heart failure, it will only be given to you when fully diagnosed and only with extreme caution.
- If you are diabetic as the tablets contains lactose monohydrate.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, as this medication should not be given shortly before birth or during labour as it can result in adverse effects in the baby.

Effects on ability to drive and use machines
BIO-ATENOLOL can impair the 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-ATENOLOL varies from patient to patient.

Using other medicines with BIO-ATENOLOL:
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of BIO-ATENOLOL with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

In particular, tell your doctor if you are taking:
- Adrenergic neurone blocking agents such as guanethidine and bethanidine, catecholamine depleting agents such as reserpine and the hypotensive effects by diuretics, as the effects of BIO-ATENOLOL may be enhanced by them.
- Medication for an overactive thyroid, as BIO-ATENOLOL may mask the symptoms of hyperthyroidism.
- Myocardial depressants such as quinidine, procainamide or lignocaine or medicine which interfere with calcium transport such as verapamil, as they may be enhanced by BIO-ATENOLOL
- Concurrent administration of BIO-ATENOLOL and nifedipine is not recommended.
- If a beta-blocker (BIO-ATENOLOL) and clonidine are given concurrently, the clonidine should not be discontinued until several days after the withdrawal of the beta-blocker, as severe rebound hypertension may occur.
- Clonidine, if your healthcare provider needs to transfer you from this medication, as serious withdrawal effects can occur it needs to be monitored
- Digitalis, as BIO-ATENOLOL may enhance some cardiac (heart) effects of digitalis and may diminish (make them less) others. You may need to take them together but this combined treatment will be carefully monitored by your healthcare provider.
- phenothiazines, hypoglycaemic agents and various anti-arrhythmic agents. Such medicine interactions can have life threatening consequences.
- an alpha-adrenergic blocker, prescribed for patients with phaeochromocytoma.
- Asthma medication, medication for bronchitis and for chronic pulmonary diseases, as bronchoconstriction may occur in patients suffering from asthma, bronchitis and other chronic pulmonary diseases.

4. HOW TO TAKE BIO-ATENOLOL
Always take BIO-ATENOLOL 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-ATENOLOL is too strong or too weak, talk to your doctor or pharmacist.
In the treatment of hypertension, BIO-ATENOLOL is usually given orally in a dose of 100 mg daily as a single dose or in divided doses. It is unlikely that additional benefit will be obtained with higher doses of BIO-ATENOLOL.
The treatment of angina pectoris, a single dose of 100 mg daily or 50 mg twice daily has been recommended. It is unlikely that additional benefit will be obtained with higher doses.
Your doctor will determine the dosage that is appropriate for you.
BIO-ATENOLOL is not recommended for use in children.

If you take more BIO-ATENOLOL 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. In this case you should be taken to your nearest hospital for urgent attention and supportive treatment.
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 you forget to take BIO-ATENOLOL:
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.

5. POSSIBLE SIDE EFFECTS
BIO-ATENOLOL can have side effects. Not all side effects reported for BIO-ATENOLOL are included in this leaflet. Should your general health worsen while taking BIO-ATENOLOL, please consult your doctor, pharmacist or other health care professional for advice.
Side effects are more likely to occur in patients with kidney problems or patients who receive medicine intravenously.

If any of the following happens, stop taking BIO-ATENOL and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Slow heart rate or severe low blood pressure
- Severe tightness of the chest (bronchospasm)

Frequently reported side-effects are:
- nausea
- vomiting
- diarrhoea
- fatigue and dizziness

Cardiovascular (heart) effects include:
- a slow haert rate
- congestive heart failure
- Low blood pressure
- Cold extremities (hands and feet)
- Raynaud's phenomenon
- A sensation of "pins and needles"

Central nervous system effects include:
- Depression
- Hallucinations
- Vivid dreams
- Nightmares
- Sleep disturbances
- Vision disturbances

Lung or respiratory system effects include:
- Broncho spasm - tightness of the chest.
  Skin effects like skin rashes may occur.

Less frequently reported side-effects are:
- Constipation
- Retention of water (fluid retention)
- Weight gain
- Muscle cramps
- Dry mouth

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

6. STORING AND DISPOSING OF BIO-ATENOLOL
- 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.
- KEEP 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).

7. PRESENTATION OF BIO-ATENOLOL
BIO-ATENOLOL 50: Packs of 30 tablets, packed into PVC/PVDC/Alu blisters.
BIO ATENOLOL 100: Packs of 30 tablets, packed into PVC/PVDC/Alu blisters.

8. IDENTIFICATION OF BIO-ATENOLOL
BIO-ATENOLOL 50: Orange coloured biconvex film-coated tablet, having a score-line on one side and plain on the other side.
BIO ATENOLOL 100: Orange coloured biconvex film-coated tablet, having score-line on one side and plain on the other side.

9. REGISTRATION NUMBER
BIO-ATENOLOL 50: W/5.2/0439
BIO ATENOLOL 100: W/5.2/440

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road
Randjespark, Midrand, 1685
South Africa
Tel no: +27 11 848-3050

11. DATE OF PUBLICATION:
Date of registration: 22 Augustus 1991
Date of revision of the text: 20 June 2019

NAMIBIA:

BIO-ATENOLOL 50 Reg no. 12/5.2/0010	NS2

BIO-ATENOLOL

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S3

NAAM, STERKTE EN FARMASEUTIESE VORM:
BIO-ATENOLOL 50 (Tablette)
BIO ATENOLOL 100 (Tablette)

Lees die hele pamflet noukeurig deur voordat jy begin om BIO-ATENOLOL 50 en BIO ATENOLOL 100 tablette te neem.
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker.
- BIO-ATENOLOL is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

1. WAT BIO-ATENOLOL BEVAT
BIO-ATENOLOL 50: Elke tablet bevat 50 mg atenolol.
BIO ATENOLOL 100: Elke tablet bevat 100 mg atenolol.
Onaktiewe bestandele: Mieliestysel, laktosemonohidraat, povidoon, kruiskarmellose natrium tipe A, magnesiumstereaat, voorgegelatineerde stysel en opadry oranje (wat bestaan uit hipromellose; titaandioksied, hidroksiepropielsellulose, poliëtileenglikol, sonsondergang geel FCF aluminium lake en talk).
Bevat suiker (laktosemonohidraat).

2. WAARVOOR BIO-ATENOLOL GEBRUIK WORD
BIO-ATENOLOL word gebruik in die behandeling van die volgende:
- Hipertensie
- Die beheer van angina pectoris
- Miokardiale infarksie: BIO-ATENOLOL verlaag die kardiovaskulêre sterflikheid in pasiënte wie die akute fase van die miokardiale infarksie oorleef het en wie klinies stabiel is.

3. VOORDAT JY BIO-ATENOLOL NEEM
Moenie BIO-ATENOLOL neem nie:
- Indien jy al voorheen 'n allergiese reaksie vir die aktiewe bestandeel atenolol gehad het of vir enige van die ander bestandele van BIO-ATENOLOL.
- Indien jy feochromositoom het en nie alfa-adrenoseptor blokkerende terapie gebruik nie.
- Besondere versigtigheid moet aan die dag gelê word as jy aan die volgende ly:
- Asma, bronchitis, chroniese respiratoriese siektes, tweede en derdegraadse hartblok en badikardie, perefere vaskulêre siektes en Raynaud se verskynsel.
- Indien jy swanger is of jou baba borsvoed.

Neem spesiale sorg met BIO-ATENOLOL
- Indien jy alreeds op 'n behandeling is vir hipertensie, wees versigtig oor wat jy neem, aangesien sekere medisyne in kombinasies ernstige nagevolge kan hê. Sien "Neem van ander medisyne met BIO-ATENOLOL" onderaan.
- Indien jy bejaard is of ly aan nierdisfunksie, aangesien die normale dosis verlaag moet word.
- Indien jy geskeduleer is om chirurgie te ondergaan (peri-operatiewe tydperk), sal die dokter jou noukeurig wil dophou vir moontlike dosisaanpassings.
- Indien jy chirurgie ondergaan en narkose benodig, moet miokardiale onderdrukkers soos chloroform of eter vermy word.
- Indien jy aan metaboliese asidose ly en dit benodig vir kongestiewe hartversaking sal dit slegs vir jou gegee word wanneer jy ten volle gediagnoseer is en slegs met uiterste versigtigheid.
- Indien jy 'n diabeet is, aangesien die tablette laktose-monohidraat bevat.

Swangerskap en borsvoeding:
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies omdat hierdie medisyne nie kort voor geboorte of gedurende kraam geneem moet word nie, aangesien dit ongewensde effekte kan veroorsaak in die baba.

Effekte op die vermoë om te bestuur en masjiene te gebruik
BIO-ATENOLOL kan die vermoë om te bestuur of om masjinerie te hanteer benadeel, veral gedurende die begin van behandeling, verandering van medikasie en wanneer dit gekombineer word met alkohol. Die intensiteit van die reaksie vir BIO-ATENOLOL verskil van pasiënt tot pasiënt.

Die neem van ander medisyne saam met BIO-ATENOLOL:
Indien jy ander medisyne op 'n gereelde basis neem, insluitende komplementêre of tradisionele medisyne, mag die neem van BIO-ATENOLOL saam met hierdie medisyne ongewensde interaksies hê. Vertel jou dokter of apteker indien jy enige ander medisyne neem, insluitende enige medisyne wat jy by die apteek, supermark of gesondheidsvoedsel winkel gekoop het. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Vertel veral jou dokter indien jy die volgende neem:
- Adrenergiese neuronblokkerende middels soos guanetidien en betanidien, katekolamienuitputtende middels soos reserpien en die hipotensiewe effekte deur diuretika, omdat die effekte van BIO-ATENOLOL deur hulle verhoog kan word.
- Medikasie vir 'n ooraktiewe skildklier, aangesien BIO-ATENOLOL die simptome van hipertireose mag masker.
- Miokardiale onderdrukkers soos kinidien, prokaïnamied of lignokaïen of medisyne wat inmeng met kalsiumvervoer soos verapamil, aangesien hulle effek mag versterk deur BIO-ATENOLOL
- Gelyktydige toediening van BIO-ATENOLOL en nifedipien word nie aanbeveel nie.
- Indien 'n betablokker (BIO-ATENOLOL) en klonidien gelyktydig gegee word. Die klonidien moet nie gestaak word tot 'n paar dae na die onttrekking van die beta-blokker nie, aangesien ernstige hipertensie mag voorkom.
- Klonidien, indien jou gesondheidsorgverskaffer nodig het om jou van hierdie medisyne af te skuif, aangesien ernstige onttrekkingseffekte mag voorkom en dit moet gemonitor word
- Digitalis, aangesien BIO-ATENOLOL sommige van die kardiale (hart) effekte van digitalis kan versterk en mag ander verminder. Jy mag nodig hê om hulle saam te gebruik, maar die gekombineerde behandeling sal versigtig gemonitor word deur jou gesondheidsorgverskaffer.
- Fenotiasiene, hipoglukemiese middels en verskeie anti-aritmiese middels. Sulke medisyneinteraksies kan lewensbedreigende gevolge hê.
- 'n Alfa-adrenergiese blokker, voorgeskryf vir pasiënte met feochromositoom.
- Asmamedisyne, medisyne vir bronchitis en vir chroniese pulmonêre siektes omdat brongospasma mag voorkom in pasiënte wat aan asma, bronchitis of ander chroniese pulmonêre siektes ly.

4. HOE OM BIO-ATENOLOL TE NEEM
Neem altyd BIO-ATENOLOL presies soos jou dokter jou opdrag gegee het. Jy moet seker maak by jou dokter indien jy onseker is. Indien jy onder die indruk is dat die effek van BIO-ATENOLOL te sterk of te swak is, praat met jou dokter of apteker.
In die behandeling van hipertensie word BIO-ATENOLOL gewoonlik mondelings gegee in 'n dosis van 100 mg daagliks as 'n enkele dosis of verdeelde dosisse. Dit is onwaarskynlik dat addisionele voordeel verkry sal word deur hoër dosisse van BIO-ATENOLOL.
Vir die behandeling van angina pectoris word 'n enkele dosis van 100 mg daagliks of twee keer per dag aanbeveel. Dit is onwaarskynlik dat addisionele voordeel verkry sal word deur hoër dosisse.
Jou dokter sal bepaal watter dosis is toepaslik vir jou.
BIO-ATENOLOL word nie aanbeveel vir die gebruik in kinders nie.

Indien jy meer BIO-ATENOLOL neem as wat jy moet:
Indien jy die korrekte dosis oorskry of 'n oordosis neem, mag dit veroorsaak dat jou bloeddruk te laag en jou hartkloppe onreëlmatig word. Dit mag ook lei tot duiseligheid, verwarring, lae bloedsuurstofvlakke en moontlike verlies van bewussyn. In hierdie geval moet jy na die naaste hospitaal geneem word vir dringende aandag en ondersteunende behandeling.
Indien jy meer as die voorgeskrewe dosis neem of in die geval van 'n oordosis, kry onmiddelik mediese advies en, as moontlik, neem jou tablette of die boks saam met jou om vir die dokter te wys.

Indien jy vergeet om BIO-ATENOLOL te neem:
Moenie 'n dubbele dosis neem om op te maak vir die vergete individuele dosis nie. Hou aan om die volgende tablet op die gewone tyd te neem. Indien jy sukkel om te onthou wanneer om jou medisyne te neem, vra jou apteker vir wenke.

5. MOONTLIKE NEWE-EFFEKTE
BIO-ATENOLOL kan newe-effekte hê. Nie alle newe-effekte wat vir BIO-ATENOLOL aangemeld is word in hierdie pamflet ingesluit nie. Sou jou algemene gesondheid versleg terwyl jy BIO-ATENOLOL neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.
Newe-effekte is meer geneig om voor te kom in pasiënte met nierprobleme of pasiënte wie die medisyne bineaars ontvang.

Indien enige van die volgende gebeur, hou op om BIO-ATENOL te neem en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Stadige hartklop of ernstige lae bloeddruk
- Ernstige styfheid van die bors (brongospasma)

Newe-effekte wat gereeld aangemeld was sluit in:
- naarheid
- braking
- diarree
- moegheid en duiseligheid

Kardiovaskulêre (hart) effekte sluit in:
- 'n Stadige hartklop
- Kongestiewe hartversaking
- Lae bloeddruk
- Koue ledemate (hande en voete)
- Raynaud se verskynsel
- 'n Sensasie van 'naalde en spelde'

Sentrale senuweestelsel effekte sluit in:
- Depressie
- Hallusinasies
- Lewendige drome
- Nagmerries
- Slaapversteurings
- Visie versteurings

Long of respiratoriese stelsel effekte sluit in:
- Brongospasma – styfheid van die bors. Vel effekte soos veluitslag kan voorkom.

Minder gereelde newe-effte sluit in:
- Hardlywigheid
- Waterretensie (vloeistofretensie)
- Gewigstoename
- Spierkrampe
- Droë mond

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

6. BEWARING EN WEGDOENING VAN BIO-ATENOLOL
- 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 gebruik na die vervaldatum wat op die houer gedruk is nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

7. AANBIEDING VAN BIO-ATENOLOL
BIO-ATENOLOL 50: Pakke van 30 tablette, verpak in PVC/PVDC/Alu stulpstroke.
BIO ATENOLOL 100: Pake van 30 tablette, verpak in PVC/PVDC/Alu stulpstroke.

8. IDENTIFIKASIE VAN BIO-ATENOLOL
BIO-ATENOLOL 50: Oranje gekleurde, bikonvekse, filmbedekte tablet, met 'n breeklyn aan een kant en ongedruk aan die ander kant.
BIO ATENOLOL 100: Oranje gekleurde, bikonvekse, filmbedekte tablet, met 'n breeklyn aan een kant en ongedruk aan die ander kant.

9. REGISTRASIENOMMER
BIO-ATENOLOL 50: W/5.2/0439
BIO ATENOLOL 100: W/5.2/440

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
Biotech Laboratories (Edms) Bpk
Grondvloer, Blok K Wes, Central Park
16de Weg, 400
Randjespark, Midrand, 1685
Suid-Afrika
Tel nr: +27 11 848-3050

11. DATUM VAN PUBLIKASIE:
Datum van registrasie: 22 Augustus 1991
Datum van hersiening van die teks: 21 Junie 2019

NAMIBIË:

BIO-ATENOLOL 50 Reg no. 12/5.2/0010	NS2

PIL W0439/40-1