SCHEDULING STATUS:
S3

PROPRIETARY NAME AND DOSAGE FORM:
BIO-ATENOLOL 50 (Tablets)
BIO ATENOLOL 100 (Tablets)

COMPOSITION:
BIO-ATENOLOL 50 contains 50 mg atenolol.
BIO ATENOLOL 100 contains 100 mg atenolol.
Excipients: maize starch, lactose monohydrate, povidone, croscarmellose sodium type A, magnesium stearate, pregelatinised starch and opadry orange (consisting of hypromellose; titanium dioxide (E171), hydroxypropyl cellulose, polyethylene glycol, sunset yellow FCF, aluminum lake (E110) and talc).
Contains sugar (lactose monohydrate).

PHARMACOLOGICAL CLASSIFICATION:
A 5.2 Adrenolytics (sympathicolytics)

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
BIO-ATENOLOL is a selective beta-adrenergic blocking agent with insignificant partial agonist activity and weak membrane-stabilizing properties.
Pharmacokinetic properties
It is incompletely absorbed after oral administration and is excreted largely in the urine. It has a plasma half-life of approximately 6-8 hours, but its anti-hypertensive effects appears to last considerably longer. It may thus be administered in a once daily dosage for the treatment of hypertension.

INDICATIONS:
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.

CONTRAINDICATIONS:
Particular caution should be exercised with patients suffering from the following: asthma, bronchitis, chronic respiratory diseases, second and third-degree heart block and bradycardia (less than 50 beats per minute), peripheral vascular diseases and Raynaud's phenomenon.
The normal dose should be reduced in elderly patients, or in patients suffering from renal dysfunction.
In the peri-operative period, it is generally unwise to reduce the dosage to which the patient is accustomed, as there may be danger of aggravation of angina pectoris or hypertension. A patient's normal tachycardic response to hypovolaemia or blood loss may be obscured during or after surgery. Particular caution should be taken in this regard.
Patients with metabolic acidosis. It should only be given to patients with congestive cardiac failure when fully digitalised and only then with extreme caution.
BIO-ATENOLOL is contraindicated in patients with phaeochromocytoma without concomitant alpha-adronoceptor blocking therapy.
Great care should be exercised in giving BIO-ATENOLOL to patients undergoing anaesthesia, and myocardial depressants such as chloroform or ether must be avoided.
BIO-ATENOLOL should not be used with verapamil; and neither medicine should be administered within several days of discontinuing the other.
The effects of BIO-ATENOLOL are diminished by beta-adrenoceptor stimulating agents such as isoprenaline; the hypotensive effect of BIO-ATENOLOL may be dangerously reversed, and the peripheral vasoconstrictor effects enhanced by alpha-adrenoceptor stimulating agents such as noradrenaline or those with mixed alpha- and beta adrenoceptor properties such as adrenaline.

WARNINGS AND SPECIAL PRECAUTIONS:
It is dangerous to administer beta-adrenoceptor blocking agents, such as BIO-ATENOLOL, concomitantly with the following medicines: phenothiazines, hypoglycaemic agents and various anti-arrhythmic agents. Such medicine interactions can have life threatening consequences.
Patients with phaeochromocytoma usually require treatment with an alpha-adrenergic blocker.
Bronchoconstriction may occur in patients suffering from asthma, bronchitis and other chronic pulmonary diseases. Congestive cardiac failure and marked bradycardia may also manifest. A variety of neuropsychiatric disorders, ranging from vague fatigue and nightmares to overt psychosis, have been observed.
The following may occur: exacerbation of peripheral vascular disease, or the development of Raynaud's phenomenon (due to unopposed arteriolar alpha-sympathetic activation), sexual impotence, hypoglycaemia, skeletal muscle weakness and gastro-intestinal disturbances. Severe peripheral vascular disease and even peripheral gangrene may be precipitated. Adverse reactions are more common in patients with renal decompensation, and in patients who receive the medicine intravenously.
Special note: digitalisation of patients receiving long-term beta-blocker therapy may be necessary if congestive cardiac failure is likely to develop. This combination can be considered despite the potentiation of the negative chronotropic effect of the two medicines. Careful control of dosages, and of the individual patient's response (and notably pulse rate), is essential in this situation.
Abrupt discontinuation of therapy may cause exacerbation of angina pectoris in patients suffering from ischaemic heart disease. Discontinuation of therapy should be gradual, and patients should be advised to limit the extent of their physical activity during the period that the medicine is being discontinued.
BIO-ATENOLOL may mask the symptoms of hyperthyroidism. The effects of other myocardial depressant agents such as quinidine, procainamide or lignocaine and medicines which interfere with calcium transport such as verapamil may be enhanced by BIO-ATENOLOL.
The effects of BIO-ATENOLOL may be enhanced by adrenergic neurone blocking agents such as guanethidine and bethanidine, catecholamine depleting agents such as reserpine and the hypotensive effects by diuretics.
BIO-ATENOLOL may enhance some of the cardiac effects of digitalis and diminish others.
Caution should be exercised when transferring a patient from clonidine. The withdrawal of clonidine may result in the release of large amounts of catecholamines that may give rise to a hypertensive crisis. If beta-blockers are administered in these circumstances, the unopposed alpha receptor stimulation may potentiate this effect.
If a beta-blocker 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.
Concurrent administration of BIO-ATENOLOL and nifedipine is not recommended.
Anaesthesia: Awareness by the anaesthetist that beta-adrenoceptor blocking agents are being taken is of greatest importance.
The administration of β-blockers, as in BIO-ATENOLOL, shortly before birth or during labour has resulted in newborn infants being born collapsed, hypotonic and hypoglycaemic.
Adverse effects are more likely to occur in patients with renal decompensation.
Since BIO-ATENOLOL contains lactose monohydrate, it is not recommended for patients with rare hereditary problems of galactose intolerance, severe lactase deficiency or of glucose-galactose malabsorption.

DOSAGE AND DIRECTIONS FOR USE:
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.

SIDE EFFECTS:
The most common side effects are nausea, vomiting, diarrhoea, fatigue and dizziness. Cardiovascular effects include bradycardia, congestive cardiac failure, heart block, hypotension, cold extremities, Raynaud's phenomenon and paraesthesia.
Central nervous system effects include depression, hallucinations, vivid dreams, nightmares and disturbances of sleep and vision.
Bronchospasm may occur (see Contraindications). Blood disorders and skin rashes may also occur. Other adverse effects reported include constipation, fluid retention and weight gain, muscle cramps and dry mouth.
Side effects may be minimised by starting treatment with a small dose and gradually increasing it.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Intensive care may be required for several days since the effect of beta-adrenoceptor blocking agents last longer than their plasma half life.
Overdosage may produce bradycardia and severe hypotension.
Bronchospasm and heart failure may be produced in certain individuals.
Cases of mild overdose should be observed for at least four hours, as apnoea and cardiovascular collapse may appear suddenly. Gastric lavage should be performed within four hours of suspected overdose. Repeated activated charcoal is necessary in severe overdose.
Atropine may be used to treat severe bradycardia. If the response is inadequate, glucagon may be given intravenously. Alternatively, dobutamine or isoprenaline, may be required to reverse beta-blockade.
Intravenous cardiac pacing may be required for severe bradycardia.
Bronchospasm should be treated with IV aminophylline or inhaled, or IV beta-agonist, e.g. salbutamol.
Atropine should be given intravenously in divided doses to reduce unopposed vagal activity. Isoprenaline should be given by infusion according to the response of the pulse and blood pressure, massive doses may be required. Bronchospasm may be treated by intravenous aminophylline and heart failure with digitalis and diuretics.

IDENTIFICATION:
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.

PRESENTATION:
BIO-ATENOLOL 50: Packs of 28 or 30 tablets, packed into PVC/PVDC/Alu blisters.
BIO ATENOLOL 100: Packs of 28 or 30 tablets, packed into PVC/PVDC/Alu blisters.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBERS:
BIO-ATENOLOL 50: W/5.2/0439
BIO ATENOLOL 100: W/5.2/440

NAME AND BUSINESS ADDRESS OF APPLICANT:
Biotech Laboratories (Pty) Ltd.
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
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20 February 2015

Namibia: BIO-ATENOLOL 50 Reg. No.:12/5.2/0010	NS2

PIW0439/40-6

SKEDULERINGSTATUS:
S3

EIENDOMSNAAM (EN DOSEERVORM):
BIO-ATENOLOL 50 (Tablette)
BIO ATENOLOL 100 (Tablette)

SAMESTELLING:
Elke BIO-ATENOLOL 50 tablet bevat 50 mg Atenolol
Elke BIO ATENOLOL 100 tablet bevat 100 mg Atenolol
Onaktiewe bestandele: mieliestysel, laktose monohidraat, povidoon, croscarmellose natrium tipe A, magnesiumstearaat, pregelatiniseerde stysel en opadry oranje (bestaande uit hypromellose; titaniumdioksied (E171), hidroxypropiel sellulose, poliëtileen glikol, songeel FCF, aluminium lake (E110) en talk).
Bevat suiker (laktose monohidraat).

FARMAKOLOGIESE KLASSIFIKASIE:
A 5.2 Adrenolitika (simpatikolitika)

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
BIO-ATENOLOL is 'n selektiewe beta-adrenergiese blokkeringsmiddel met 'n onbeduidende, gedeeltelik agonistiese aktiwiteit en swak membraanstabiliserende eienskappe.
Farmakokinetiese eienskappe
Dit word onvolledig na orale toediening geabsorbeer en word hoofsaaklik in uriene uitgeskei. Dit het 'n plasma halfleeftyd van ongeveer 6 tot 8 uur, maar die anti-hipertensiewe effek daarvan duur heelwat langer. Dit kan dus as 'n daaglikse dosis vir die behandeling van hipertensie gebruik word.

INDIKASIES:
Hipertensie
Behandeling van angina pectoris
Miokardiale infarksie: BIO-ATENOLOL verminder kardio-vaskulêre mortaliteit in pasiënte wat die akute fase van miokardiale infarksie oorleef het en wat klinies in 'n stabiele toestand is.

KONTRA-INDIKASIES:
Sorg moet beoefen word met pasiënte wat aan die volgende ly: asma, brongitis, kroniese respiratoriese toestande, sekondêre en derdegraadse hartblok en bradikardie (minder as 50 slae per minuut), perifere vaskulêre toestande en Raynaud Sindroom.
Die normale dosis moet verminder word in bejaarde pasiënte, of in pasiënte wat aan renale disfunksie ly.
In die peri-operatiewe periode, is dit oor die algemeen nie wenslik om die dosis waaraan die pasiënte gewoond is te verminder nie, want daar is gevaar van verergering van angina pectoris of hipertensie. 'n Pasiënt se normale tagikardie reaksie tot hipovolemie of bloedverlies mag verskans word tydens of na sjirurgie. Besondere voorsorg moet beoefen word in hierdie verband.
Sorg moet geneem word in pasiënte met metaboliese asidose. Dit moet slegs aan pasiënte met kongestiewe hartversaking gegee word, wanneer die pasiënt volledig gedigitaliseer is en dan met uiterste versigtigheid.
BIO-ATENOLOL is teenaangedui in pasiënte met feochromositoom sonder bykomstige alfa-adrenoseptor blokkeringsterapie. BIO-ATENOLOL moet met uiterste sorg aan pasiënte wat narkose kry, toegedien word en miokariale depressante soos chloroform of eter moet vermy word.
BIO-ATENOLOL behoort nie saam met verapamil gebruik te word nie en geeneen van die twee middels behoort binne etlike dae van die staking van die ander toegedien te word nie.
Die effek van BIO-ATENOLOL word deur beta-adrenoseptorstimuler-ingsmiddels soos isoprenalien verminder; die hipotensiewe effekte van BIO-ATENOLOL kan tot 'n gevaarlike mate omgekeer word en die perifere vasokonstriktoriese invloed daarvan kan vermeerder word deur alfa-adrenoseptorstimuleringsmiddels soos noradrenalien, of middels met gemengde alfa- en beta-adrenoseptor eienskappe, soos adrenalien.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Dit kan gevaarlik wees om beta-adrenoseptor-blokkeringsmidels saam met die volgende toe te dien: fenotiasien, hipoglukemiese middels en verskillende anti-aritmiese middels. Hierdie interaksies tussen middels kan lewensgevaarlik wees.
Pasiënte met feochromositoom benodig normaalweg behandeling met 'n alfa-adrenergiese blokkeerder.
Brongokonstriksie mag voorkom in pasiënte wat ly aan asma, brongitis en ander chroniese longsiektes.
Kongestiewe hartversaking en merkbare bradikardie kan ook manifesteer. 'n Verskeidenheid van neuropsigiatriese versteurings, wat wissel van vae moegheid en nagmerries tot openlike psigose, is waargeneem.
Die volgende mag voorkom: verergering van perifere vaskulêre siekte, of die ontwikkeling Raynaud Sindroom (as gevolg van onbestrede arteriolêre alfa-simpatieke aktivering), seksuele impotensie, hipoglisemie, skeletspier swakheid en gastro-intestinale versteurings. Ernstige perifêre vaskulêre siekte en selfs perifêre gangreen kan ontstaan. Negatiewe reaksies is meer algemeen in pasiënte met renale dekompensasie, en in pasiënte wat die medisyne binneaars ontvang.
Spesiale nota: digitalisering van pasiënte wat langtermyn beta-blokker terapie mag nodig wees indien kongestiewe hartversaking geneig is om te ontwikkel. Hierdie kombinasie kan oorweeg word ten spyte van die potensiëring van die negatiewe chronotrope effek van die twee middels. Sorgvuldige beheer van dosisse, en die reaksie van die individuele pasiënt (en veral polsslag), is noodsaaklik in hierdie situasie.
Skielike staking van terapie kan verergering van angina pectoris veroorsaak in pasiënte wat ly aan isgemiese hartsiekte. Staking van terapie moet geleidelik wees, en pasiënte moet ingelig word om die omvang van hul fisiese aktiwiteit te beperk gedurende die tydperk wat die medisyne gestaak word.
BIO-ATENOLOL kan die simptome van hipertiroïedisme verskans. Die effek van ander miokardiale onderdrukkers soos kinidien, prokaïenamied of lignokaïen en geneesmiddels wat met die vervoer van kalsium inmeng, soos verapamil, kan deur BIO-ATENOLOL verhoog word.
Die effek van BIO-ATENOLOL kan deur neuronblokkeringsmiddels soos guanetidien, betanidien of katecholamien-uitputtende middels soos reserpien en die hipotensiewe effekte van diuretika, verhoog word.
BIO-ATENOLOL kan sommige van die kardiale effekte van digitalis verhoog en ander verlaag.
Sorg moet beoefen word tydens omskakeling vanaf klonidien. Die ontrekking van klonidien mag ly tot vrystelling van groot hoeveelhede katecholamien wat tot 'n hipertensiewe krisis kan lei. Onttrekkingsimptome van klonidien in pasiënte wat gelyktydig beta-adrenoseptor-blokkeringsmiddels neem, kan verhoog word, wat tot ernstige terugslag hipertensie kan lei. Indien 'n betablokker onder hierdie omstandighede toegedien word, kan die onbestrede alfa reseptor stimulasie die effek potensiëer.
As 'n beta-blokker en klonidien gelyktydig gegee word, moet die klonidien nie gestaak word tot 'n paar dae ná die onttrekking van die beta-blokker, omdat erge teruglslag hipertensie mag voorkom.
Gelyktydig toediening van BIO-ATENOLOL en nifedipien word nie aanbeveel nie.
Narkose: Dit is van die uiterste belang dat die narkotiseur bewus is dat beta-adrenoseptor-blokkers geneem word.
Die toediening van beta-blokkers kort voor geboorte of gedurende kraam het gelei tot gekollabeerde, hipotoniese en hipoglukemiese pasgebore babas.
Newe-effekte kom meer geredelik voor by pasiënte met renale dekompensasie voor.
BIO-ATENOLOL bevat laktose monohidraat, en word nie aanbeveel in pasiënte met seldsame oorerflike probleme van galaktose-onverdraagsaamheid, erge laktase tekortkoming of van glukose-galaktose wanabsoprsie nie.

DOSIS EN GEBRUIKSAANWYSINGS:
BIO-ATENOLOL word gewoonlik oraal vir die behandeling van hipertensie in dosisse van 100 mg daagliks, as enkel of verdeelde dosisse toegedien.
In die behandeling van angina pectoris word 'n enkel dosis van 100 mg daagliks of 50 mg tweemaal per dag aanbeveel. Dit is onwaarskynlik dat verhoogde dosisse BIO-ATENOLOL enige bykomstige voordele inhou.

NEWE-EFFEKTE:
Die mees algemene newe-effekte is naarheid, braking, diarree, moegheid en duiseligheid. Kardiovaskulêre effekte sluit bradikardie, kongestiewe hartversaking, hartblok, hipotensie, koue ledemate, Raynaud Sindroom en parestesie.
Sentrale senuweestelsel-effekte sluit in depressie, hallusinasies, helder drome, nagmerries en versteurings van slaap en visie.
Brongospasma kan voorkom (sien KONTRAINDIKASIES). Bloedsiektes en veluitslag kan ook voorkom. Ander newe-effekte gerapporteer sluit hardlywigheid, vloeistof retensie en gewigstoename, spierkrampe en droë mond in.
Newe-effekte kan verminder word deur die aanvang van behandeling met 'n klein dosis en geleidelike verhoging daarvan.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Intensiewe sorg vir 'n hele aantal dae kan nodig wees aangesien die invloed van beta-adrenoseptor-blokkeringsmiddels langer duur as hul plasma-halfleeftyd.
Oordosering kan bradikardie en erge hipotensie veroorsaak. Brongospasma en hartversaking kan ook veroorsaak word. Gevalle van matige oordosering moet vir ten minste vier uur onder observasie gehou word, omdat apnee en kardiovaskulêre ineenstorting skielik kan voorkom.
Maagspoeling moet binne vier uur van die vermoede oordosering uitgeoefen word. Herhaalde geaktiveerde houtskool word aanbeveel na erge oordosering.
Atropien kan gebruik word vir die behandeling van erge bradikardie. Indien die respons onvoldoende is, kan glukagon binneaars toegedien word. Alternatiewelik mag dobutamien en isoprenalien benodig word om beta-blokkering om te draai. Binneaarse kardiale pasaangeër terapie mag benodig word vir erge bradikardie. Brongospasma moet behandel word met intraveneuse of inhalasie aminofillien, of intraveneuse beta-agonis, bv. salbutamol.
Atropien moet in verdeelde dosisse binneaars toegedien word om 'n oorreaksie van die vagusaktiwiteit te voorkom. Isoprenalien moet per infusie volgens pols en bloeddruk toegedien word; massiewe dosisse mag benodig word. Brongospasma kan met intraveneuse aminofillien behandel word en hartversaking met digitalis en diuretika.

IDENTIFIKASIE:
BIO-ATENOLOL 50: Oranje gekleurde bikonvekse-filmbedekte tablet, met 'n breek-lyn aan die een kant en glad aan die ander kant.
BIO ATENOLOL 100: Oranje gekleurde bikonvekse-filmbedekte tablet, met breek-lyn aan die een kant en glad aan die ander kant.

AANBIEDING:
BIO-ATENOLOL 50: Pakke van 28 of 30 tablette, verpak in PVC / PVDC / Alu stulpstroke.
BIO ATENOLOL 100: Pakke van 28 of 30 tablette, verpak in PVC / PVDC / Alu stulpstroke.

BERGINGSAANWYSINGS:
Bewaar teen of benede 25 °C. Beskerm teen lig en vog
HOU BUITE BEREIK VAN KINDERS

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

NAAM EN BESIGHEIDSADRES VAN AANSOEKER:
Biotech Laboratories (Edms) Bpk.
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Suid Afrika

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Datum van registrasie: 22 Augustus 1991
Datum van kennisgewing met betrekking tot wysiging Reg. 9 en 10: 20 Februarie 2015

Namibië: BIO-ATENOLOL 50 Reg. Nr.:12/5.2/0010	NS2