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CLINICAL APPROVAL LETTER: POST REGISTRATION APPLICATIONS

Clinical approval date	05 May 2026
Applicant's cover letter date	18 October 2024
Applicant	Biotech Laboratories (PTY) Ltd
Proprietary name(s) (including duplicates)	Bio-Atenolol 50 Bio-Atenolol 100
API(s)	Atenolol
Registration number(s)	W/5.2/0439 W/5.2/0440
Sequence no	0005

Dear Sir/Madam,

Kindly be informed that the Authority has completed the evaluation of the above-mentioned Professional Information (PI) and Patient Information Leaflet (PIL) variation application.

1. The amendments to the PI and PIL are approved.
2. The PI and PIL be accepted as the currently approved PI and PIL
3. The date of revision reflected on this PI and PIL should be**:05 May 2026**
4. The final dated version of the above PI and PIL must be submitted via docubridge in a closing sequence using the Sequence Type "Closing sequence" and Sequence Description "Approved " updated PI and PIL within 10 working days.
5. The approved PI and PIL must be uploaded into the SAHPRA repository within 10 working days.

Note to applicant: Amendments to any quality aspects of the medicine within the PI and PIL are subject to P&A unit approval and may only be implemented in the PI if approved by the P&A unit.

Yours Faithfully,

L.DHLAMINI

MANAGER: CLINICAL POST-REGISTRATION UNIT

SCHEDULING STATUS

S3

1 NAME OF THE MEDICINE

BIO-ATENOLOL 50 (Tablets)

BIO-ATENOLOL 100 (Tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

BIO-ATENOLOL 50 contains 50 mg atenolol.

BIO-ATENOLOL 100 contains 100 mg atenolol.

Contains sugar (BIO-ATENOLOL 50 contains 90 mg and BIO-ATENOLOL 100 contains 180 mg lactose monohydrate).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

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.

4 CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Posology and method of administration

Posology

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.

Special Populations

Elderly and renal dysfunction:

The normal dose should be reduced in elderly patients and may need to be reduced in patients suffering from renal dysfunction.

Renal failure:

Since BIO-ATENOLOL is excreted via the kidneys, dosage should be adjusted in cases of severe impairment of renal function. No significant accumulation of BIO-ATENOLOL occurs at a glomerular filtration rate (GFR) greater than 35 mL/min/1,73 m^2 (normal range is 100-150 mL/min/1,73 m^2). For patients with a creatinine clearance of 15-35 mL/min/1,73m^2 (equivalent to serum creatinine of 300-600 micromol/litre) the oral dose should be 50 mg daily or 100 mg once every two days.

For patients with a creatinine clearance of < 15 mL/min/1,73 m^2 (equivalent to serum creatinine of > 600 micromol/litre) the oral dose should be 25 mg daily or 50 mg on alternate days or 100 mg once every four

days. Patients on haemodialysis should be given 50 mg orally after each dialysis; this should be done under hospital supervision as marked falls in blood pressure can occur.

Paediatric population

There is no experience in children with BIO-ATENOLOL and for this reason it is not recommended for use in children.

Method of administration

For oral administration.

4.3 Contraindications

BIO-ATENOLOL should not be used in patients:

- who are hypersensitive to atenolol or to any of the excipients of BIO ATENOLOL listed in section 6.1.
- with cardiogenic shock
- with second- or third-degree heart block
- with bradycardia
- with severe peripheral arterial circulatory disturbances.
- with uncontrolled heart failure
- with untreated phaeochromocytoma
- with sick sinus syndrome
- with hypotension
- with metabolic acidosis (e.g., in diabetes)
- after prolonged fasting.

4.4 Special warnings and precautions for use

Patients with phaeochromocytoma usually require treatment with an alpha-adrenergic blocker (see section

4.3).

Particular caution should be exercised with patients suffering from the following: asthma, bronchitis and chronic respiratory diseases. Bronchoconstriction may occur in patients suffering from asthma, bronchitis and other chronic pulmonary diseases.
Congestive cardiac failure and marked bradycardia may also manifest (see section 4.3). A variety of neuropsychiatric disorders, ranging from vague fatigue and nightmares to overt psychosis, have been observed.

Although cardio selective ($beta_1$) beta-blockers may have less effect on lung function than non-selective beta-blockers, these should be avoided in patients with reversible obstructive airway disease, unless there are compelling clinical reasons for their use. Where such reasons exist BIO-ATENOLOL may be used with caution (see section 4.3).

Occasionally, some increase in airways resistance may occur in asthmatic patients however, this may usually be reversed by commonly used dosage of bronchodilators such as salbutamol or isoprenaline.

The following may occur: exacerbation of peripheral vascular disease, or the development of Raynaud's phenomenon (due to unopposed arteriolar alpha-sympathetic activation) (see section 4.3), 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.

It is dangerous to administer beta-adrenoceptor blocking medicines, such as BIO-ATENOLOL, concomitantly with the following medicines: phenothiazines, hypoglycaemic medicines and various anti-dysrhythmic medicines. Such medicine interactions can have life threatening consequences (see section 4.5).

Although contraindicated in uncontrolled heart failure (see section 4.3), BIO-ATENOLOL may be used in patients whose signs of heart failure have been controlled. Caution must be exercised in patients whose cardiac reserve is poor.

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.
It should only be given to patients with congestive cardiac failure when fully digitalised and only then with extreme caution.

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. Patients should be followed during withdrawal, especially those with ischaemic heart disease.

BIO-ATENOLOL may increase the number and duration of angina attacks in patients with Prinzmetal's angina due to unopposed alpha-receptor mediated coronary artery vasoconstriction. BIO-ATENOLOL is a $beta_1$ selective betablocker; consequently, its use may be considered although utmost caution must be exercised.

Due to its negative effect on conduction time, caution must be exercised if it is given to patients with first-degree heart block.

BIO-ATENOLOL may mask the symptoms of hyperthyroidism. The effects of other myocardial depressant

medicines such as quinidine, procainamide or lignocaine and medicines which interfere with calcium transport such as verapamil may be enhanced by BIO-ATENOLOL (see section 4.5). Myocardial depressants such as chloroform or ether must be avoided.

May mask the symptoms of hypoglycaemia, in particular, tachycardia.

BIO-ATENOLOL may mask the signs of thyrotoxicosis.

The effects of BIO-ATENOLOL may be enhanced by adrenergic neurone blocking medicines such as guanethidine and bethanidine, catecholamine depleting medicines such as reserpine and the hypotensive effects by diuretics.

BIO-ATENOLOL may enhance some of the cardiac effects of digitalis and diminish others (see section 4.5).

BIO ATENOLOL will reduce heart rate as a result of its pharmacological action. In the rare instances when a treated patient develops symptoms which may be attributable to a slow heart rate and the pulse rate drops to less than 50-55 bpm at rest, the dose should be reduced.

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 BIO-ATENOLOL is administered in these circumstances, the unopposed alpha receptor stimulation may potentiate this effect (see section 4.5). If a BIO-ATENOLOL and clonidine are given concurrently, the clonidine should not be discontinued until several days after the withdrawal of BIO-ATENOLOL, as severe rebound hypertension may occur (see section 4.5).

Anaesthesia: Awareness by the anaesthetist that BIO-ATENOLOL are being taken is of greatest importance **(**see section 4.3). Great care should be exercised in giving BIO-ATENOLOL to patients undergoing anaesthesia.

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.

When a patient is scheduled for surgery, and a decision is made to discontinue BIO-ATENOLOL therapy, this should be done at least 24 hours prior to the procedure. The risk-benefit assessment of stopping beta-blockade should be made for each patient. If treatment is continued, and anaesthetic with little negative inotropic activity should be selected to minimise the risk of myocardial depression. The patient may be protected against vagal reactions by intravenous administration of atropine.

The effects of BIO-ATENOLOL are diminished by beta-adrenoceptor stimulating medicines such as isoprenaline; the hypotensive effect of BIO-ATENOLOL may be dangerously reversed, and the peripheral vasoconstrictor effects enhanced by alpha-adrenoceptor stimulating medicines such as noradrenaline or those with mixed alpha- and beta adrenoceptor properties such as adrenaline.

Administration to pregnant mothers shortly before giving birth or during labour may result in the newborn infants being born hypotonic, collapsed and hypoglycaemic.

Adverse effects are more likely to occur in patients with renal decompensation. Since BIO-ATENOLOL is excreted via the kidneys, dosage should be reduced in patients with a creatinine clearance of below 35 ml/min/1,73 m^2.

BIO-ATENOLOL may cause a more severe reaction to a variety of allergens when given to patients with a history of anaphylactic reaction to such allergens. Such patients may be unresponsive to the usual doses of adrenaline (epinephrine) used to treat the allergic reactions.

BIO-ATENOLOL may cause a hypersensitivity reaction including angioedema and urticaria.

Lactose warning

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take BIO ATENOLOL (see section 4.5).

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that it is to say essentially 'sodium-free'.

4.5 Interaction with other medicines and other forms of interaction

Combined use of beta-blockers and calcium channel blockers with negative inotropic effects, e.g., verapamil and diltiazem, can lead to an exaggeration of these effects particularly in patients with impaired ventricular function and/or sinoatrial or atrioventricular conduction abnormalities. This may result in severe hypotension, bradycardia and cardiac failure. Neither the beta-blocker nor the calcium channel blocker should be administered intravenously within 48 hours of discontinuing the other.

Concomitant therapy with dihydropyridines, e.g., nifedipine, may increase the risk of hypotension, and cardiac failure may occur in patients with latent cardiac insufficiency.

Digitalis glycosides, in association with beta-blockers, may increase atrioventricular conduction time.

Special note:

Digitalisation of patients receiving long term BIO-ATENOLOL therapy may be necessary if congestive cardiac failure is likely to develop. This combination can be considered despite the potentiation of 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.

Beta-blockers may exacerbate the rebound hypertension which can follow the withdrawal of clonidine. If the two medicines are co-administered, the beta-blocker should be withdrawn several days before discontinuing clonidine. If replacing clonidine by beta-blocker therapy, the introduction of beta-blockers should be delayed for several days after clonidine administration has stopped (refer to prescribing information for clonidine).

Class I anti-dysrhythmic medicine (e.g., disopyramide) and amiodarone may have a potentiating effect on atrial-conduction time and induce negative inotropic effect.

It can be dangerous to administer BIO-ATENOLOL concomitantly with the following medicine: phenothiazines. N.B. Such drug-drug interactions can have life-threatening consequences (see section 4.4).

Concomitant use of sympathomimetic medicines, e.g., adrenaline (epinephrine), may counteract the effect of beta-blockers.

Concomitant use with insulin and oral antidiabetic medicine may lead to the intensification of the blood sugar lowering effects of these medicines. Symptoms of hypoglycaemia, particularly tachycardia, may be masked (see section 4.4).

Concomitant use of prostaglandin synthetase-inhibiting medicine, e.g., ibuprofen and indomethacin, may decrease the hypotensive effects of beta-blockers.

Caution must be exercised when using anaesthetic medicines with BIO-ATENOLOL. The anaesthetist should be informed and the choice of anaesthetic should be a medicine with as little negative inotropic activity as possible. Use of beta-blockers with anaesthetic medicine may result in attenuation of the reflex tachycardia and increase the risk of hypotension. Anaesthetic medicines causing myocardial depression are best avoided.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety and/or efficacy of BIO-ATENOLOL in women who are, or may become, pregnant has not been established, particularly in the first and second trimesters, since beta-blockers such as BIO-ATENOLOL, in general, have been associated with a decrease in placental perfusion which may result in intra-uterine deaths, immature and premature deliveries.

BIO-ATENOLOL crosses the placental barrier and appears in the cord blood. No studies have been performed on the use of BIO-ATENOLOL in the first trimester and the possibility of foetal injury cannot be excluded.

BIO-ATENOLOL has been used under close supervision for the treatment of hypertension in the third trimester. Administration of BIO-ATENOLOL to pregnant women in the management of mild to moderate hypertension has been associated with intra-uterine growth retardation.

Breastfeeding

There is significant accumulation of BIO-ATENOLOL in breast milk.

Neonates born to mothers who are receiving BIO-ATENOLOL at parturition or breastfeeding may be at risk of hypoglycaemia and bradycardia.

Caution should be exercised when BIO-ATENOLOL is administered during pregnancy or to a woman who is breastfeeding.

4.7 Effects on ability to drive and use machines

BIO-ATENOLOL has no or negligible influence on the ability to drive and use machines. However, dizziness and fatigue has been reported during treatment with BIO-ATENOLOL. Patients should not drive or use machines until they have determined how they are affected.

4.8 Undesirable effects

MedDRA System organ class	**Frequency**	**Undesirable Effect**
Blood and lymphatic system disorders	*Less frequent*	Purpura, thrombocytopenia.
Psychiatric disorders	*Less frequent*	Sleep disturbances of the type noted with other beta-blockers, mood changes, depression, nightmares, vivid dreams, confusion, psychoses and hallucinations, depression and malaise.
Nervous system disorders	*Less frequent*	Dizziness, headache, paraesthesia.
Eye disorders	*Less frequent*	Dry eyes, visual disturbances.
Cardiac disorders	*Frequent*	Congestive cardiac failure, marked bradycardia.
	Less frequent	Heart failure deterioration, precipitation of heart block.
Vascular disorders	*Frequent*	Cold extremities.
	Less frequent	Postural hypotension which may be associated with syncope, intermittent claudication may

		be increased if already present, in susceptible patients Raynaud's phenomenon (due to unopposed arteriolar alpha-sympathetic activation).
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Bronchospasm may occur in patients with bronchial asthma or a history of asthmatic complaints.
Gastrointestinal disorders	*Frequent*	Gastrointestinal disturbances, nausea, vomiting, diarrhoea.
	Less frequent	Dry mouth.
Hepato-biliary disorders	*Less frequent*	Elevations of transaminase levels, hepatic toxicity including intrahepatic cholestasis.
Skin and subcutaneous tissue disorders	*Less frequent*	Alopecia, psoriasiform skin reactions, exacerbation of psoriasis, skin rashes.
	Frequency not known	Hypersensitivity reactions, including angioedema and urticaria.
Discontinuation of the medicine should be considered if any such reaction is not otherwise explicable.		
Musculoskeletal and connective tissue disorders	*Frequency not known*	Lupus-like syndrome.
Reproductive system and breast disorders	*Less frequent*	Impotence.
General disorders and administration site conditions	*Frequent*	Fatigue.
Investigations	*Less frequent*	An increase in ANA (Antinuclear Antibodies) has been observed, however the clinical relevance of this is not clear.

Adverse reactions are more frequent in patients with renal decompensation.

Discontinuance of the medicine should be considered if, according to clinical judgement, the well-being of the patient is adversely affected by any of the above reactions.

Side effects may be minimised by starting treatment with a small dose and gradually increasing it.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Intensive care may be required for several days since the effect of beta-adrenoceptor blocking medicines 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. 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.

5 PHARMACOLOGICAL PROPERTIES

Category and class: A 5.2 Adrenolytics (sympathicolytics)

Pharmacotherapeutic group: Beta-blocking agents, plain, selective, ATC code: CO7A B03.

5.1 Pharmacodynamic properties

BIO-ATENOLOL is a selective beta-adrenergic blocking agent with insignificant partial agonist activity and weak membrane-stabilizing properties.

5.2 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium type A

Lactose monohydrate

Maize starch

Magnesium stearate

Povidone

Pregelatinised maize starch

Opadry orange (consisting of hypromellose; titanium dioxide, hydroxypropyl cellulose, polyethylene glycol, sunset yellow FCF aluminium lake and talc).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light and moisture.

6.5 Nature and contents of container

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

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

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark

Midrand, 1685

8 REGISTRATION NUMBER(S)

BIO-ATENOLOL 50: W/5.2/0439

BIO-ATENOLOL 100: W/5.2/0440

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Date of registration: 22 Augustus 1991

10 DATE OF REVISION OF THE TEXT

To be allocated.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

BIO-ATENOLOL 50, 50 mg tablets

BIO-ATENOLOL 100, 100 mg tablets

atenolol

Contains sugar (BIO-ATENOLOL 50 contains 90 mg and BIO-ATENOLOL 100 contains 180 mg lactose monohydrate).

Read all of this leaflet carefully before you start taking BIO-ATENOLOL

- 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-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.

What is in this leaflet

1. What BIO-ATENOLOL is and what it is used for

BIO-ATENOLOL is used to:

- Treat high blood pressure (hypertension).

- Help prevent chest pain (angina).

It works by making your heartbeat more slowly and with less force.

2. What you need to know before you take BIO-ATENOLOL

Do not take BIO-ATENOLOL:

- If you are hypersensitive (allergic) to atenolol or any of the other ingredients of BIO-ATENOLOL (listed in section 6).
- If you have second or third degree heart block.
- If you have a slow heart rate.
- If you suffer from severe blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue).
- If you have shock caused by heart problems.
- If you have uncontrolled heart failure.
- If you suffer with heart conduction or rhythm problems, second- or third-degree heart block (a condition which may be treated by a pacemaker).
- If you have low blood pressure.
- If you suffer from an increased acidity of the blood (metabolic acidosis).
- If you have not eaten over a long period of time (fasting).
- If you suffer from untreated phaeochromocytoma (high blood pressure due to a tumour near the kidney).

Warnings and precautions

Take special care with BIO-ATENOLOL:

- If you suffer from treated phaeochromocytoma (high blood pressure due to a tumour near the kidney).
- If you have asthma, wheezing, any other similar breathing problems or reversible obstructive airways disease. Consult your doctor first before taking BIO-ATENOLOL.
- If you suffer from blood circulation problems (which may cause your fingers and toes to tingle or turn

pale or blue) or cramping pain causing limping (intermittent claudication) or controlled heart failure.

- If you take medicine to treat mental disorders and/or antidysrhythmic medicines (medicines used to treat abnormal heart rate).
- if you abruptly discontinue treatment, it may exacerbate angina pectoris (type of chest pain) if you suffer from ischaemic heart disease.
- If you suffer from a type of chest pain (angina) called Prinzmetal's angina, BIO-ATENOLOL may increase the number and duration of attacks.
- If you have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster.
- If you have first-degree heart block.
- If you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.
- If you have low blood sugar (hypoglycaemia).
- If you have any problems with your thyroid.
- BIO-ATENOLOL will reduce your heart rate, if your pulse drops to less that 50 – 55 beats per minute, your dosage should be reduced.
- If you have kidney problems, your dosage of BIO-ATENOLOL should be reduced, and you may need to have some check-ups during your treatment.
- If you have a history of severe allergic reactions to any allergens (example insect stings), as BIO-ATENOLOL may cause a more severe reaction and you may be unresponsive to usual doses of medicine (adrenaline) used to treat your allergic reaction.
- If you have psoriasis, as BIO-ATENOLOL may aggravate (worsen) your psoriasis.
- If you are undergoing any surgery or medical procedure where an anaesthetic is being used.
- If you have difficulty in performing sexually.

Children and adolescents

BIO-ATENOLOL is not recommended for children to use.

Other medicines with BIO-ATENOLOL:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

BIO-ATENOLOL may interact with the following medicines:

- verapamil, diltiazem and nifedipine (for high blood pressure or chest pains)
- isoprenaline or dobutamine (widens blood vessels)
- digitalis glycosides such as digoxin (to treat heart conditions)
- clonidine (for high blood pressure or migraine). If you are taking clonidine and BIO-ATENOLOL together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will give you careful instructions about how to do it.
- disopyramide, quinidine or amiodarone (for an uneven heartbeat)
- adrenaline, also known as epinephrine (medicine that stimulates the heart), medicines to treat nose or sinus congestion or other cold remedies
- medicines to treat diabetes including insulin
- Non-Steroidal Anti-Inflammatory Drug (NSAIDs) e.g., indomethacin
- barbiturates e.g., phenobarbital (used for insomnia, epilepsy or as an anaesthetic)
- chloroform or ether
- phenothiazines e.g., chlorpromazine (for mental illness).

BIO-ATENOLOL with food or drink

The tablets can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 this medicine.

There is significant accumulation of the active ingredient of BIO-ATENOLOL (atenolol) in breast milk. Caution should be exercised if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent BIO-ATENOLOL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BIO-ATENOLOL affects them.

It is unlikely for BIO-ATENOLOL to affect your ability to drive and use machinery. BIO-ATENOLOL may cause dizziness or tiredness. You should make sure how BIO-ATENOLOL affects you before driving or using machinery.

3. How to take BIO-ATENOLOL

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

Always take BIO-ATENOLOL exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

For the treatment of high blood pressure:

The recommended dose is 100 mg a day as a single dose or 50 mg two times per day.

For the treatment of angina:

The recommended dose is 100 mg a day or 50 mg two times per day.

Elderly:

If you are an elderly person, your doctor may decide to give you a lower dose, particularly if you have problems with your kidneys.

People with severe kidney problems:

If you have severe kidney problems your doctor may decide to give you a lower dose.

Use in children:

BIO-ATENOLOL must not be given to children.

Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets.

Your doctor will tell you how long your treatment with BIO-ATENOLOL will last. If you have the impression that the effect of BIO-ATENOLOL is too strong or too weak, tell your doctor or pharmacist.

If you take more BIO-ATENOLOL than you should

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 a dose of BIO-ATENOLOL

If you forget to use a dose of BIO-ATENOLOL, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking BIO-ATENOLOL

Do not stop taking BIO-ATENOLOL without talking to your doctor. In some cases, you may need to stop taking it gradually.

4. 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 or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

If any of the following happen, stop taking BIO-ATENOLOL and contact your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing.
- A rash or itching.
- Fainting
- Yellowing of the 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-ATENOLOL. You may need urgent medical attention or hospitalisation.

Frequent side effects that may occur include:

- Unusual tiredness or weakness
- Nausea or vomiting
- An upset stomach or stomach pain
- Cold hands and feet
- the heart is weakened or damaged, and as a result, it struggles to push enough blood forward, and leads to a backup or congestion of blood in the veins and fluid accumulation in different parts of the body (congestive heart failure)
- Slower pulse rate.

Tell your doctor if you notice any of the following:

Less frequent side effects that may occur include:

- Purplish marks on your skin.
- Reduced numbers of platelets in your blood (this may make you bruise more easily).
- Depressive mood, confusion, changes in personality (psychoses) and hallucinations, mood changes, nightmares and sleep disturbances.
- A general feeling of being unwell.
- Dizziness, headache and tingling of your hands.
- Dry eyes and vision disturbances.
- Heart block (which can cause dizziness, abnormal heartbeat, tiredness or fainting).
- Low blood pressure.
- Numbness and spasm in your fingers which is followed by warmth and pain, temporary discoloration of the skin (Raynaud's disease).
- Difficulty breathing if you are suffering from asthma or a lung disease.
- Dry mouth.
- Increased liver enzymes (transaminases) which may be a sign of liver problems.
- Hair loss.
- Skin rash, plaquelike lesions (psoriasis).
- Fluid retention and mass gain.
- Being unable to get an erection (impotence).
- Changes to some of the cells or other parts of your blood, your doctor may do blood tests to check if BIO-ATENOLOL has had any effect on your blood.

Side effects, frequency not known that may occur include:

- Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BIO-ATENOLOL.

5. How to store BIO-ATENOLOL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store your tablets in the original package. Keep the blister strip in the carton. This will protect your medicine from light and moisture.
- Do not use after the expiry date stated on the label and carton. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilet).

6. Contents of the pack and other information

What BIO-ATENOLOL contains:

The active substance of each tablet is 50 mg or 100 mg atenolol respectively.

The other ingredients are: croscarmellose sodium type A, lactose monohydrate, maize starch, magnesium stearate, povidone, pregelatinised maize starch and opadry orange (consisting of hypromellose; titanium diozide, hydroxypropyl sellulose, polyethylene glycol, sunset yellow FCF aluminium lake and talc).

What BIO-ATENOLOL looks like and contents of the pack

BIO-ATENOLOL 50 is an orange coloured biconvex film-coated tablet, having a score-line on one side and plain on the other side.

BIO-ATENOLOL 100 is an orange coloured biconvex film-coated tablet, having a score-line on one side and plain on the other side.

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

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

Holder of Certificate of Registration

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To be allocated

Registration number

BIO-ATENOLOL 50: W/5.2/0439

BIO-ATENOLOL 100: W/5.2/0440

Access to the corresponding Professional Information

The Professional Information is available from Biotech Laboratories (Pty) Ltd. To request a digital copy please email info@biotechlabs.co.za.