

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
2. What you need to know before you take BIO-ATENOLOL
3. How to take BIO-ATENOLOL
4. Possible side effects
5. How to store BIO-ATENOLOL
6. Contents of the pack and other information

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 than 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 dioxide, hydroxypropyl cellulose, 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

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark

Midrand, 1685

Tel no: +27 11 848 3050

This leaflet was last revised in

05 May 2026

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.