PATIENT INFORAMTION LEAFLET

SCHEDULING STATUS: **S3**

B-BLOCK 50 (TABLETS)

B-BLOCK 100 (TABLETS)

Atenolol

Sugar Free

Each B-BLOCK 50 contains propylene glycol 0,302 mg

Each B-BLOCK 100 contains propylene glycol 0,604 mg

Read all of this leaflet carefully before you start taking

B-BLOCK.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- B-BLOCK 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 B-BLOCK is and what it is used for
2. What you need to know before you take B-BLOCK
3. How to take B-BLOCK
4. Possible side effects
5. How to store B-BLOCK
6. Contents of the pack and other information

1. WHAT B-BLOCK IS AND WHAT IT IS USED FOR

B-BLOCK belongs to a group of medicines called beta blockers. This means that it has effects on your heart and circulation.

B-BLOCK is used in the treatment and control of high blood pressure (hypertension) and to treat severe chest pains that arise from the heart called angina pectoris.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE B-BLOCK

Do not take B-BLOCK:

- if you are hypersensitive (allergic) to atenolol or any of the other ingredients of B-BLOCK (listed in section 6).
- if you are pregnant or breastfeeding.
- if you have any problems with your heart such as second degree or third degree heart block and cardiogenic shock (a condition where the heart is unable to supply enough blood to the organs of the body).
- if you are currently taking verapamil (used for high blood pressure and chest pain) or within several days of taking verapamil.
- if you have not eaten for a prolonged period of time (prolonged fasting).
- if you are suffering from a condition called metabolic acidosis (e.g. common condition in diabetic patients).
- if you suffer from heart failure that is not controlled with digitalis (a type of medicine used to treat heart failure) and/or diuretics (an agent used to treat hypertension and heart conditions by increasing the excretion of urine).
- if you have uncontrolled heart failure, excluding that due to hypertrophic obstructive cardiomyopathy (thickening of heart muscle which blocks blood flow out of the heart).

Do not take B-BLOCK if any of the above apply to you. If you are not sure, talk to your healthcare professional before taking B-BLOCK.

Warnings and precautions

Take special care with B-BLOCK

- if you suffer from bradycardia (abnormally slow pulse rate less than 50 pulse beats per minute).
- if you are elderly, or have kidney problems, as your dosage of B-BLOCK should be reduced. If you are elderly, your doctor will start your treatment with a lesser dose.
- if you are using a medicine called clonidine and are being transferred to B-BLOCK. When stopping clonidine, you may experience extreme high blood pressure. Your doctor will monitor this transfer.
- if you suffer from asthma, bronchitis or any other breathing problem.
- if you suffer from peripheral vascular disease (circulation disorder) and a condition called peripheral gangrene which may be worsened.
- if you suffer from circulatory problems, Raynaud's phenomenon may develop (resulting in temporary discoloration of the skin and numbness of the fingers or toes).
- if you use medicines for diabetes, phenothizines (medicines used to treat mental disorders) and antiarrhythmic agents (medicines used to treat abnormal heart rate), you must tell your doctor.
- if you have any other heart condition such as second or third degree heart block or heart failure.
- if you have increased heart rate.
- if you have low blood sugar (hypoglycaemia).
- if you are pregnant and are due to deliver or have just delivered.
- if you have phaeochromocytoma, which is being treated, your doctor will also prescribe a medicine called an alpha-blocker which should be taken with B-BLOCK.
- if you have an overactive thyroid.

- if you suffer from myasthenia gravis (a muscular disorder causing muscular weakness).
- if you have psoriasis, this condition may be aggravated (worsened).
- if you abruptly discontinue treatment it may exacerbate angina pectoris (type of chest pain) f you suffer from ischaemic heart disease.

If any of the above apply to you (or you are not sure), talk to your healthcare professional before taking this medicine.

While you are taking B-BLOCK tell your doctor, pharmacist or other healthcare professional:

- if you have a history of severe allergic reactions to a variety of allergens (example insect stings), as B-BLOCK 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 are undergoing any surgery or medical procedure where an anaesthetic is being used.
- if you have difficulty in performing sexually.

Children and adolescents

There is no experience in children.

Other medicines and B-BLOCK

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.) Tell your doctor or pharmacist if you are taking any of the following medicines:

- Anaesthetic medicines (medicines to sedate you during an operation).
- Hypoglycaemic medicines, phenothiazines (medicines used to treat mental disorders), antiarrhythmic medicines (medicines used to treat an irregular or rapid heartbeat).
- Digoxin (heart medication).

- Calcium channel blockers e.g. verapamil and diltiazem (for high blood pressure and chest pain), digoxin (heart medication).
- Non-steroidal anti-inflammatory medicines (NSAIDs), e.g. ibuprofen, indomethacin (used to reduce pain and inflammation and decrease fever).
- Sympathomimetics such as adrenaline (also known as epinephrine).

If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions, please consult your doctor, pharmacist or other health care professional for advice.

Pregnancy, breast-feeding and fertility

Pregnancy

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 B-BLOCK.

Breastfeeding

Before taking B-BLOCK, tell your doctor if you are breastfeeding, B-BLOCK is not recommended for use while breastfeeding.

Driving and using machines

B-BLOCK may cause occasional dizziness or fatigue, this must be considered if you drive or want to handle machinery.

B-BLOCK contains Propylene Glycol

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Propylene glycol in this medicine can have the same effects as drinking alcohol and increase the likelihood of side effects.

Use this medicine only if recommended by a doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. HOW TO TAKE B-BLOCK

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

Always take B-BLOCK exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose

The dosage prescribed to you is individualized and may differ from the information contained in this leaflet.

For severe chest pains (angina pectoris):

Adults: Take one B-BLOCK 100 tablet once a day or take 1 B-BLOCK 50 twice a day.

For high blood pressure (hypertension):

Adults: Take 50 – 100 mg B-BLOCK once a day.

If B-BLOCK is used in the elderly or if you have problems with your kidneys, your doctor may reduce the amount of B-BLOCK that has to be taken compared to the adult dose.

If you take more B-BLOCK than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take B-BLOCK

Do not take / receive double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

B-BLOCK can have side effects**.**

Not all side effects reported for B-BLOCK are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking B-BLOCK, please consult your health care provider for advice.

If any of the following happens, stop taking B-BLOCK and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- Skin rashes or itching (pruritus)
- Itchy rash (urticaria)

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to B-BLOCK. 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:

- Chest pain
- Angina
- Changes in the way your heart beats,

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:

- Sleep disturbances (insomnia)
- Unusual tiredness or weakness (fatigue)
- Drowsiness

Less frequent side effects:

- Depression
- Low blood pressure Heart failure or heart block may be precipitated in patients with underlying cardiac disorders.
- Cold fingers and toes
- Tight chest
- Nausea and vomiting
- Runny stomach (diarrhoea), constipation and abdominal cramps

Rare Side effects:

- Confusion
- Nightmares
- Vivid dreams
- Hallucinations
- Numbness

- Muscle cramps
- Dizziness and lassitude
- Dry eyes
- Blurred vision and sore eyes
- Skin rash
- Hair loss
- Itchy skin
- Muscular fatigue and weakness including muscle cramps
- Loss of male sexual ability

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 or 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 B-BLOCK.

5. HOW TO STORE B-BLOCK

Store all medicines out of reach of children.

- Store at or below 25 ºC.
- Protect from light and moisture.
- Do not store in bathrooms in order to protect from light.
- Do not take medicine after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

WHAT B-BLOCK CONTAINS

Each B-BLOCK 50 tablet contains 50 mg atenolol.

The other ingredients are:

Tablet core: magnesium stearate, maize starch, microcrystalline cellulose, purified water, sodium lauryl sulphate, sodium starch glycolate.

Coating: dichloromethane, ethyl cellulose (20 cps), hydroxyl propyl methyl cellulose (5cps), isopropyl alcohol,

polyethylene glycol 400, propylene glycol, purified talc, titanium dioxide.

Each B-BLOCK 100 tablet contains 100 mg atenolol.

The other ingredients are:

Tablet core: magnesium stearate, maize starch,

microcrystalline cellulose, purified water, sodium lauryl sulphate, sodium starch glycolate.

Coating: dichloromethane, ethyl cellulose (20 cps), hydroxyl propyl methyl cellulose (5cps), isopropyl alcohol,

polyethylene glycol 400, propylene glycol, purified talc, sunset yellow lake colour (CI No. 15985), titanium dioxide.

What B-BLOCK looks like and the contents of the pack

B-BLOCK 50 Tablets: White, round shaped, biconvex, film-coated tablets, plain on both sides.

- Cartons containing 10 aluminium foil strip packs of 10 tablets each. i.e. 100 tablets per carton.
- Cartons containing 10 blister packs of 10 tablets each. i.e. 100 tablets per carton.
- Cartons containing 3 blister packs of 10 tablets each. i.e. 30 tablets per carton.

B-BLOCK 100 Tablets: Orange coloured, round, biconvex, film-coated tablets with a breakline on one side.

- Cartons containing 10 blister packs of 10 tablets each. i.e. 100 tablets per carton.
- Cartons containing 3 blister packs of 10 tablets each. i.e. 30 tablets per carton.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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1724

This leaflet was last revised in

23 December 2022

Registration Number

B-BLOCK 50: 31/5.2/0332 (S.A.)

B-BLOCK 100: 32/5.2/0670 (S.A.)

B-BLOCK 50: S2 BOT 0801395 (Botswana)

B-BLOCK 100: S2 BOT 0801396 (Botswana)

B-BLOCK 50: 07/5.2/0073 (Namibia)

B-BLOCK 100: 07/5.2/0074 (Namibia)