

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

BILOBLOK 5 mg and 10 mg film-coated tablets

Bisoprolol fumarate.

Sugar free.

Read all of this leaflet carefully before you start taking BILOBLOK.

- 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.
- BILOBLOK 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 BILOBLOK is and what it is used for
2. What you need to know before you take BILOBLOK
3. How to take BILOBLOK
4. Possible side effects
5. How to store BILOBLOK
6. Contents of the pack and other information

1. What BILOBLOK is and what it is used for

BILOBLOK contains a medicine called bisoprolol fumarate, which belongs to a group of medicines called beta-blockers. BILOBLOK is used to treat the following conditions:

- High blood pressure (hypertension)
- A type of chest pain caused by reduced blood flow to the heart (angina pectoris).

2. What you need to know before you take BILOBLOK

Do not take BILOBLOK if:

- you are hypersensitive (allergic) to bisoprolol fumarate or any of the other ingredients of BILOBLOK (see section 6 **What BILOBLOK contains**).
- you have the following conditions:
 - asthma, bronchitis or any other chronic lung disease
 - severe blood circulation problems in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue
 - untreated phaeochromocytoma, which is a rare tumour of the adrenal gland (medulla)
 - metabolic acidosis, which is a condition when there is too much acid in the blood
 - acute heart failure or heart failure that suddenly becomes worse and/or that may require hospital treatment.
- you have one of the following heart problems:
 - heart failure
 - slow heart rate
 - certain heart conditions causing a very slow heart rate or irregular heartbeat
 - cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.
- you are pregnant or breastfeeding.

BILOBLOK should not be given to children.

Warnings and precautions

Take special care with BILOBLOK if you:

- have chronic lung disease or less severe asthma.
- have diabetes.

- are on strict fasting.
- have certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina).
- have less severe blood circulation problems in your limbs.
- have kidney or liver problems.
- have a history of a scaly skin rash (psoriasis).
- have a tumour of the adrenal gland (pheochromocytoma).
- have a thyroid disorder.
- are taking the following medicines:
 - medicines to treat irregular heartbeat such as disopyramide
 - calcium antagonist e.g. verapamil (for high blood pressure)
 - clonidine (for high blood pressure).

In addition, tell your doctor if you are going to have:

- desensitisation therapy (for example for the prevention of hay fever), because BILOBLOK may make it more likely that you experience an allergic reaction, or such reaction may be more severe.
- anaesthesia (for example for surgery), because BILOBLOK may influence how your body reacts to this situation.

While taking BILOBLOK

- If you have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using BILOBLOK.
- See a doctor immediately if you experience symptoms of shortness of breath, fatigue, swollen legs and rapid heartbeat (symptoms of heart failure) or a very slow heart beat with symptoms of faint or nearly faint, have difficulty breathing or chest pain.

Other medicines and BILOBLOK

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

In particular, tell your doctor or pharmacist if you are already taking any of the following medicines:

- medicines to treat irregular or abnormal heartbeat (Class I antidysrhythmic medicines such as quinidine, disopyramide, lignocaine, phenytoin, flecainide, propafenone, Class III antidysrhythmic medicines such as amiodarone)
- medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (calcium antagonists such as verapamil and diltiazem)
- medicines used to treat high blood pressure such as clonidine, methyldopa, moxonodine, rilmenidine
- medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonist such as felodipine and amlodipine)
- beta-blockers applied locally (such as timolol eye drops for glaucoma treatment)
- medicines used to treat for example Alzheimer's disease or glaucoma (parasympathomimetics such as tacrine or carbachol)
- medicines that are used to treat acute heart problems (sympathomimetics such as isoprenaline and dobutamine)
- antidiabetic medicines including insulin
- anaesthetic medicines (for example during surgery)
- digitalis, used to treat heart failure
- non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac)
- any medicine, which can lower blood pressure as a desired or undesired effect such as antihypertensives

- medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline)
- medicines used to treat epilepsy or during anaesthesia (barbiturates such as phenobarbitone)
- medicines to treat mental illness characterised by a loss of contact with reality (phenothiazines such as levomepromazine)
- mefloquine used for prevention or treatment of malaria
- depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide.

BILOBLOK with food and drink and alcohol

Taking BILOBLOK with alcohol should be avoided.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking BILOBLOK.

Do not take BILOBLOK if you are pregnant or breastfeeding your baby. There is a risk that use of BILOBLOK during pregnancy may harm the baby.

It is not known whether bisoprolol passes into human breast milk.

Driving and using machines

BILOBLOK may affect your ability to drive or use machinery, depending on how well you tolerate the medicine. Please be especially cautious at the start of treatment, when the dose is increased or the medicine is changed, as well as in combination with alcohol.

3. How to take BILOBLOK

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

Always take BILOBLOK exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

The usual dose is one 5 mg film-coated tablet once daily in the morning. If necessary, your doctor may increase the dosage to 10 mg or 20 mg in the morning.

Your doctor will tell you how long your treatment with BILOBLOK will last. Do not stop treatment early.

If you have the impression that the effect of BILOBLOK is too strong or too weak, talk to your doctor or pharmacist.

Take BILOBLOK once a day in the morning on an empty stomach or with breakfast.

Swallow each tablet with a glass of water.

Do not crush or chew the tablets.

If you take more BILOBLOK than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of an overdose may include slowed heart rate, severe difficulty in breathing, low blood pressure and heart failure.

If you forget to take BILOBLOK

It is important to take your BILOBLOK regularly at the same time each day. If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

If you stop taking BILOBLOK

Do not stop taking BILOBLOK tablets just because you feel better. Take BILOBLOK for as long as your doctor recommends. Do not stop taking BILOBLOK unless your doctor tells you to.

If you have to stop treatment entirely, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

4. Possible side effects

BILOBLOK can have side effects.

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

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

- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to BILOBLOK. 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:

- Slowing of heart rate, worsening of heart failure, slow or irregular heartbeat. Symptoms include feeling dizzy or weak, or have breathing difficulties.
- Severe blood circulation problems in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.
- The development of gangrene, a serious medical condition in which lack of blood supply to body tissues causes the tissue to die. Although any body tissues can be affected, gangrene most commonly starts in the fingers, toes, hands and feet.

Gangrene can be fatal if left untreated.

- Hypoglycaemia - low sugar (glucose) levels in the blood. Symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat.
- Breathing difficulties if you have asthma or chronic lung disease.
- Tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes (symptoms of abnormal liver function or hepatitis).

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

- dizziness, headache, pins and needles in the hands and feet
- feeling of coldness or numbness in hands or feet
- low blood pressure
- nausea, vomiting, diarrhoea, constipation, mouth sores or ulcers
- weakness, tiredness, swelling of the hands and feet.

Less frequent side effects

- a decrease in the number of white blood cells
- reduction in number of red blood cells (anaemia)
- depression, sleep disturbances, nightmares, hallucinations, restlessness, mental illness
- weight gain
- fainting
- reduced tear flow (use suitable lubricating eye drops if you wear contact lenses), irritation and redness of the eye (conjunctivitis), disturbances of vision
- hearing problems
- dizziness when standing up, high blood pressure
- allergic runny nose

- skin rash, hair loss, perspiration, appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash
- muscle weakness, muscle cramps
- difficulty maintaining an erection in men
- laboratory test may show the following:
 - blood test results for liver function or fat levels differing from normal

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BILOBLOK.

5. How to store BILOBLOK

Store all medicines out of reach of children.

Store at or below 25°C in the original package. Protect from light. Keep blisters in the carton until required for use.

Do not use BILOBLOK after the expiry date which is stated on the 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. toilets).

6. Contents of the pack and other information

What BILOBLOK contains

The active substance is bisoprolol fumarate.

Each BILOBLOK 5 mg tablet contains 5 mg bisoprolol fumarate.

Each BILOBLOK 10 mg tablet contains 10 mg bisoprolol fumarate.

The other ingredients are microcrystalline cellulose, maize starch, pregelatinized, croscarmellose sodium, silica, colloidal anhydrous, magnesium stearate, Opadry® II 24286–beige (5 mg tablet), Opadry® II 24297-brick (10 mg tablet).

What BILOBLOK looks like and contents of the pack

BILOBLOK 5 mg: beige, round, biconvex, uniform film-coated tablets, with breakline on one side.

BILOBLOK 10 mg: brick-colored, round, biconvex, uniform film-coated tablets, with intact edges.

The film-coated tablets are packed in PVC/Aluminium foil blisters strips. The blister strips are packed in cartons containing 30 tablets.

Holder of certificate of registration

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7570

This leaflet was last revised in

29 March 2022

Registration numbers

BILOBLOK 5 mg: 48/5.2/0623

BILOBLOK 10 mg: 48/5.2/0624

BIL/C/PIL/A