APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

BILOCOR 5 tablets

BILOCOR 10 tablets

Bisoprolol fumarate

BILOCOR 5 contains sugar (lactose monohydrate 136,16 mg)

BILOCOR 10 contains sugar (lactose monohydrate 130,86 mg)

Read all of this leaflet carefully before you start taking BILOCOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- BILOCOR 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

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1. What BILOCOR is and what it is used for

The active substance in BILOCOR is bisoprolol. Bisoprolol belongs to a group of medicines called beta-blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart. As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

BILOCOR is used to treat mild to moderate high blood pressure and recurring angina pectoris. Angina pectoris is a disease in which the cardiac muscles receive less oxygen than is necessary. This generally occurs during exercise and the most common symptom is chest pain.

2. What you need to know before you take BILOCOR

Do not take BILOCOR:

- if you are hypersensitive (allergic) to bisoprolol or any of the other ingredients of BILOCOR (see section 6)
- if you suffer from severe asthma or from other severe breathing difficulties
- if you suffer from acute heart failure or if you are receiving therapy for a weak heart

- if you have a weak, irregular or slow heartbeat
- if you have cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure
- if you have low blood pressure
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding)
- if you suffer from metabolic acidosis, which is a condition when there is too much acid in the blood (this sometimes occurs as an acute complication of diabetes)
- if you suffer from late stage peripheral arterial occlusive disease, including severe forms of Raynaud's syndrome (a condition where the blood supply to the tips of the fingers or toes may become restricted as to cause tissue damage)
- if you suffer from phaeochromocytoma, which is a rare tumour of the adrenal gland (marked by high blood pressure, raised heart rate and headache)
- if you have a thyroid problem, as BILOCOR may hide symptoms of an overactive thyroid
- do not use BILOCOR in children as safety and efficacy have not been proven.

Warnings and precautions

Do not stop BILOCOR therapy abruptly, especially if you have coronary heart disease as this may lead to transitional worsening of your heart condition.

Take special care with BILOCOR:

- if you suffer from asthma or from any other breathing difficulties

- if you suffer from less severe blood circulation problems in your limbs (resulting in temporary discoloration of the skin and numbness of the fingers or toes)
- if you suffer from diabetes mellitus as BILOCOR may mask low blood sugar levels
- if you experience sudden onset of chest pain, or if you already suffer from a mild form of angina or heart conditions as BILOCOR may make your angina worse if you stop taking it abruptly
- if you are due to have an operation; you should inform the hospital doctor that you are taking BILOCOR 5 or BILOCOR 10 because it may influence how your body reacts to this situation
- if you have liver or kidney problems
- if you are following a strict fasting program
- if you are receiving ongoing desensitisation therapy. BILOCOR may increase both the sensitivity to allergens and the severity of anaphylactic reactions
- if you have any heart problems such as disturbances in heart rhythm, or severe chest pain or severe chest pain at rest (Prinzmetal's angina), or heart failure
- if you suffer from or have suffered from psoriasis (marked by severe skin rashes)
- if you suffer from phaeochromocytoma (marked by high blood pressure, raised heart rate and headache); this condition should be treated first, prior to taking BILOCOR 5 or BILOCOR 10.

In addition, tell your doctor if:

- you are due to receive an anaesthetic (for example for an operation)
- you are going to have desensitisation therapy (for example to prevent hay fever), since BILOCOR may make it more likely that you will experience an allergic reaction, or more severe reaction.

Children and adolescents

Safety and efficacy of BILOCOR have not been established in children.

Other medicines and BILOCOR

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

Do not take the following medicines with BILOCOR:

- medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (calcium antagonists such as verapamil and diltiazem)
- medicines used to treat irregular or abnormal heartbeat (Class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone)
- medicines used to treat high blood pressure such as clonidine, methyldopa, moxonidine, rilmenidine. However, do not stop taking these medicines without checking with your doctor first.

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Check with your doctor before taking the following medicines with BILOCOR as they may interact with BILOCOR, and your doctor may need to check your condition more frequently:

- medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonists such as felodipine and amlodipine)
- medicines used to treat irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone), as you may have depression of the heart muscle
- 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 that stimulate or suppress your nervous system)
- oral blood sugar lowering medicine or insulin, as you may experience extremely low blood sugar levels when taking BILOCOR
- anaesthetic medicines, as BILOCOR may lower the heart's reflex response to a decrease in blood pressure and reduce your blood pressure. If you are due to have an operation, tell the anaesthetist or the medical staff you are taking BILOCOR
- digitalis glycosides such as digoxin (used improve the strength and efficiency of the heart or control the rate and rhythm of the heart) may be used with BILOCOR. Your doctor should monitor your pulse rate and response regularly
- non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac as they may decrease the effect of BILOCOR

- medicines in the beta-adrenoceptor agonist class used to treat acute heart problems (such as isoprenaline, dobutamine) may stop BILOCOR from working correctly
- sympathomimetics such as epinephrine and norepinephrine which are used in the treatment of heart attack and low blood pressure. Epinephrine is also used to treat allergic reactions. Higher doses of adrenaline may be necessary for treatment of allergic reactions if BILOCOR is taken at the same time
- using the medicines reserpine or guanethidine with BILOCOR may cause life-threatening vasoconstriction (constricting of the blood vessels)
- medicines which can lower blood pressure such as other antihypertensives, certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (barbiturates such as phenobarbitone), or certain medicines to treat mental illness characterised by a loss of contact with reality (phenothiazines such as levomepromazine). These medicines used with BILOCOR may lower your blood pressure further
- mefloquine, used for prevention or treatment of malaria may slow your heart rate when taken with BILOCOR
- medicines to treat depression called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide as they may increase the effect of BILOCOR or cause a severe increase in blood pressure

- ergotamine derivatives, used to treat severe, throbbing headaches, such as migraine and cluster headaches may affect the way both medicines work.

BILOCOR with food and drink

The tablets can be taken with or without food.

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 healthcare provider for advice before taking this medicine.

Pregnancy

You should not take BILOCOR if you are pregnant or suspect that you are pregnant. There is a risk that BILOCOR may harm the baby. Contact you doctor or healthcare provider immediately.

Breastfeeding

You should not take BILOCOR if you are breastfeeding your baby.

Driving and using machines

BILOCOR has no or negligible influence on the ability to drive or use machinery.

It is unlikely for BILOCOR to make you drowsy, however, it may cause dizziness or fatigue (see Possible side effects) and, therefore, may adversely affect your ability to drive or use machinery.

Be especially careful at the beginning of the treatment, when the dose is increased or when the medication is changed, and when combined with alcohol.

It is not always possible to predict to what extent BILOCOR 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 BILOCOR affects them.

BILOCOR contains lactose

BILOCOR contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take BILOCOR

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

Always take BILOCOR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is 5 mg to 10 mg once daily. The maximum recommended dose is 20 mg daily.

The tablets should be taken in the morning, with or without food. Swallow the tablet whole with some liquid. The tablet can be divided into equal halves if advised to do so by your doctor or pharmacist. Your doctor will advise you what the best dosage for you is.

Children

The safety and efficacy of BILOCOR in children have not yet been established.

Your doctor will tell you how long your treatment with BILOCOR will last. Do not stop treatment early because your symptoms may return.
If you have the impression that the effect of BILOCOR is too strong or too weak, tell your doctor or pharmacist.

If you take more BILOCOR than you should

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

Symptoms of overdose may include:

- a slowed heart rate, severe difficulty in breathing, feeling dizzy, or trembling (due to decreased blood sugar). Patients with heart failure are probably more sensitive to overdose.

If you forget to take BILOCOR

If you forget to take BILOCOR, take the missed dose as soon as possible. However, if it is time for your next dose, continue to take the next tablet at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking BILOCOR

Do not stop taking BILOCOR without talking to your doctor first. If you have to stop BILOCOR treatment early, your doctor will usually advise you to reduce the dose gradually, as your condition may become worse.

4. Possible side effects

BILOCOR can have side effects.

Not all side effects reported for BILOCOR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using BILOCOR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using BILOCOR and tell 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
- rash or itching.

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

- worsening of pre-existing heart failure which can cause shortness of breath due to a build-up of fluid in the lungs
- worsening of symptom of decreased blood flow to some areas of your body such as your fingers and toes which may get pale, cold and numb (Raynaud's phenomenon)
- yellowing of the skin and whites of the eyes (jaundice), abdominal pain in the upper right portion of the abdomen, fatigue, fever (signs of inflammation or serious damage to your liver)
- changes to heart rate which may cause dizziness and weakness.

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:

- drowsiness, unusual tiredness or weakness, dizziness, mild headache
- slow or irregular heart rate

- feeling of coldness or numbness in hands or feet, low blood pressure
- nausea, vomiting, diarrhoea, constipation
- abnormal physical weakness or lack of energy, feeling of constant tiredness or weakness (fatigue).

Less frequent side effects:

- blood disorders such as low white blood cell count (leucopenia characterised by frequent infections, infections that don't resolve fatigue, feeling unwell), low blood platelet count (thrombocytopenia characterised by easy or excessive bruising, bleeding gums, rash of pinpoint-sized reddish-purple spots usually on lower legs, prolonged bleeding)
- sleeping problems, depression, nightmares, hallucinations, vivid dreams, confusion
- anxiety, nervousness, fainting
- dry, sore eyes, irritation and redness of the eye (conjunctivitis), reduced tear flow (can be a problem if you wear contact lenses)
- feeling faint or dizzy when standing up from a sitting or lying position
- breathing problems in patients with asthma or chronic lung disease, stuffy nose (nasal congestion), allergic runny nose (blocked or runny nose)
-
- skin rash, itching of skin, appearance or worsening of scaly skin rash (psoriasis), swelling under the skin (angioedema), hair loss
- back pain, joint pain or chest pain, muscle cramps, muscle weakness

- impaired erection (reduced sexual performance), problems during sexual intercourse (sexual dysfunction)
- some blood test for liver function and fat content are different from normal value.

The following side effects have been reported but the frequency for them to occur is not known:

- low blood sugar levels, increased uric acid levels in the blood, high cholesterol levels
- hallucinations, delusions, confused and disturbed thoughts (symptoms of psychosis)
- restlessness, lack of energy, abnormal sensation, typically tingling or pricking ('pins and needles')
- problems seeing
- temporary loss of hearing
- dizziness, palpitations, fatigue, chest pressure or pain, shortness of breath, fainting spells (symptoms of heart block), fluid retention
- weight gain, painful swelling and sores inside the mouth (stomatitis)
- sweating
- disorder affecting the muscles that control voluntary movement in the body (myopathy).

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. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the followinglinks: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/ or https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of BILOCOR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store BILOCOR

Store all medicines out of reach of children.

Store below 25 °C. Protect from light.

Keep blister packs in carton until required for use.

Do not use after the expiry date stated on the carton.

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 BILOCOR contains

The active substance is bisoprolol fumarate.

BILOCOR 5: Each tablet contains 5 mg bisoprolol fumarate.

BILOCOR 10: Each tablet contains 10 mg bisoprolol fumarate.

BILOCOR 5: Contains sugar (lactose monohydrate 136,16 mg).

BILOCOR 10: Contains sugar (lactose monohydrate 130,86 mg).

The other ingredients are

Crospovidone, iron oxide red (BILOCOR 10 only), iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

What BILOCOR looks like and contents of the pack

BILOCOR 5: Pale yellow, mottled round normal convex tablet debossed with BI over break-line and 5 on one side and plain on the reverse.

BILOCOR 10: Mottled beige round normal convex tablet debossed with BI over break-line and 10 on one side and plain on the reverse.

BILOCOR tablets are available in opaque or clear Al/PVC/PVdC blister packs containing 30 tablets.

Holder of Certificate of Registration

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BILOCOR 10: A38/5.2/0051

www.pharmadynamics.co.za

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NAMIBIA

BILOCOR 5: NS2 06/5.2/0061

BILOCOR 10: NS2 06/5.2/0062

BOTSWANA

BILOCOR 5: S2 1101939

BILOCOR 10: S2 1101940

MOZAMBIQUE

BILOCOR 5: 4353

BILOCOR 10: 4354

ZIMBABWE

BILOCOR 5: P.P. 2018/12.3.2/5552

BILOCOR 10: P.P. 2018/12.3.2/5553