PATIENT INFORMATION LEAFLET (APPROVED)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

BILOCOR CO 2,5/6,25 film coated tablets

BILOCOR CO 5/6,25 film coated tablets

BILOCOR CO 10/6,25 film coated tablets

Bisoprolol fumarate and hydrochlorothiazide

BILOCOR CO is sugar free

Read all of this leaflet carefully before you start taking BILOCOR CO

- 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.
- BILOCOR CO 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 CO is and what it is used for

BILOCOR CO is a combination tablet containing two active ingredients:

- bisoprolol fumarate, a type of medicine called a beta blocker. Bisoprolol works by changing the way your body responds to some nerve impulses, especially in the heart. It slows down your heart rate and makes it easier for your heart to pump blood around your body.
- hydrochlorothiazide a class of medications called diuretics ('water pills'). It works by causing the kidneys to get rid of unneeded water and salt from the body into the urine.

BILOCOR CO is used to treat high blood pressure.

2. What you need to know before you take BILOCOR CO

Do not take BILOCOR CO if:

- you are hypersensitive (allergic) to bisoprolol, hydrochlorothiazide, or other sulphonamide derived medicines, or to any of the ingredients of BILOCOR CO (see section 6)
- you have a history of previous and/or current cancer of the skin and lip
- you have problems with a very slow heartbeat or a heart block

- you are pregnant or breastfeeding (see Pregnancy and breastfeeding)
- you suffer from uncontrolled heart failure or if you are receiving therapy for a weak heart
- you have cardiogenic shock which is a heart condition causing low blood pressure and circulatory failure
- you have very low blood pressure
- you suffer from metabolic acidosis, a condition in which the blood is too acidic
- you suffer from a condition marked by excessive production of thyroid hormones
- you suffer from asthma or from another disease causing severe breathing difficulties
- you suffer from 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
- you have Addison's disease (your adrenal glands do not produce enough of their hormones)
- you suffer from severe kidney or liver problems
- you suffer from untreated phaeochromocytoma, which is a tumour of the adrenal gland
- you suffer from sick sinus syndrome causes slow heartbeats, pauses (long periods between heartbeats) or irregular heartbeats (dysrhythmias)

Warnings and precautions

Take special care with BILOCOR CO:

- if you have been diagnosed with peripheral vascular disease (a circulatory condition in which narrowed blood vessels reduce blood flow to the limbs)

- treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking BILOCOR CO
- taking BILOCOR CO with quinidine may cause life threatening effects on the heart
- if you are due to have an operation, tell the anaesthetist or the medical staff you are taking BILOCOR CO tablets, at least 48 hours before the operation
- if you suffer from diabetes and are taking anti-diabetic medicines such as insulin you should monitor your blood for low blood glucose levels. Signs of low blood sugar, such as fast heartbeat, may be masked by BILOCOR CO
- if you have high calcium levels in your body
- if you have had gout
- if you have a history of allergies, BILOCOR CO may make it more likely that you experience an allergic reaction, or that a reaction may be more severe
- if you suffer from kidney or liver problems
- if you are taking certain medicines to treat irregular heartbeat, angina pectoris or to treat high blood pressure (e.g. disopyramide, clonidine, myocardial depressants or calcium antagonists such as verapamil)
- if you suffer from psoriasis (marked by severe skin rashes)
- if you experience sudden onset of chest pain, or if you already suffer from a mild form of angina
- BILOCOR CO may decrease tear flow, causing eye irritation to contact lens wearers

- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye.

  This can lead to permanent vision loss, if not treated. If you have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this
- if you are experiencing a dry mouth, thirst, weakness, tiredness, drowsiness, restlessness, confusion, fits, muscle pains, cramps or weakness, low blood pressure, passing a reduced amount of urine, a fast, irregular heartbeat or nausea and vomiting as these may be signs of disturbances of the amount of different salts in your body (electrolyte imbalances). You should be carefully observed for signs of fluid and electrolyte imbalance, especially if you are vomiting or receiving parenteral fluid (intravenous) therapy. If you are an elderly patient, you may be more prone to electrolyte imbalances
- if you have Prinzmetal's angina (caused by a spasm in the heart's arteries that temporarily reduces blood flow)

DO NOT give BILOCOR CO to children younger than 12 years as safety and efficacy have not been established.

Other medicines and BILOCOR CO

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

The following medicines must not be taken with BILOCOR CO:

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- You may have impaired myocardial function (problems of the heart muscle or a heart block) when taking calcium channel blockers such as verapamil (used to treat chest pain and irregular heartbeats) or diltiazem (used to treat high blood pressure and to control angina (chest pain)).
- You may experience a worsening of heart failure if you take BILOCOR CO with other antihypertensives such as methyldopa.
- You may experience extremely low blood sugar levels when taking BILOCOR CO with oral blood sugar lowering medicine or insulin.
- You may have impaired myocardial function (problems of the heart muscle or a heart block) when taking antidysrhythmic medicines used to treat an irregular or rapid heartbeat (such as lidocaine, quinidine, disopyramide, flecainide and propafenone) phenothiazines (used for mental illness).
- Medicines in the beta-adrenoceptor agonist class (such as dopamine, dobutamine and isoprenaline) may alter the effects of BILOCOR CO.
- Nasal decongestants used for colds such as phenylephrine, pseudoephedrine or phenylpropanolamine may increase your blood pressure.
- Using reserpine with BILOCOR CO may cause life-threatening vasoconstriction (constricting of the blood vessels causing an increase in blood pressure.
- Digoxin (used to improve the strength and efficiency of the heart or control the rate and rhythm of the heart) may be used with BILOCOR CO. Your doctor should monitor your pulse rate and response regularly.
- The effects of strong muscle relaxants used together with general anaesthesia may be enhanced by BILOCOR CO.

- A form of low blood pressure called orthostatic hypotension (that happens when standing up from sitting or lying down) may be increased when BILOCOR CO is taken with alcohol, sedatives, sleeping tablets and narcotics.
- When BILOCOR CO are used for a prolonged time with medication such as corticosteroids, the hypokalaemic effect (a condition in which an inadequate amount of potassium is found in the circular bloodstream and may lead to weakness, confusion and mental depression) may be enhanced.
- Anti-inflammatory medication, (NSAID painkillers such as indomethacin) may reduce the blood pressure lowering effects of BILOCOR CO and may cause sodium and fluid retention (the ability of the digestive system to retain salt and fluid).
- Low salt content in the body may occur in patients taking trimethoprim or carbamazepine with BILOCOR CO.

BILOCOR CO with food and drink

The tablets can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using BILOCOR CO.

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DO NOT take BILOCOR CO if you are pregnant, plan to become pregnant, or suspect that you are pregnant. Contact you doctor, pharmacist or other healthcare professional immediately.

DO NOT take BILOCOR CO during breastfeeding.

Administration of BILOCOR CO to pregnant mothers shortly before giving birth or during labour may result in the baby being born with low blood sugar, low muscle tone and/or a slow heartbeat.

Driving and using machines

BILOCOR CO may make you drowsy. Therefore, please make sure you know how BILOCOR CO affects you before driving or using machinery.

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

3. How to take BILOCOR CO

Do not share medicines prescribed for you with any other person. Always use BILOCOR CO exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adults:

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Your doctor will advise you what the best dosage for you is. Therapy begins with the lowest dose of 2,5/6,25 mg per day. The maximum recommended dose is 10/6,25 mg per day.
The tablets should be taken at about the same time each day.

Treatment with BILOCOR CO should not be stopped abruptly.

Children:
BILOCOR CO should not be given to children less than 12 years old (see Take special care with BILOCOR CO).

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

If you take more BILOCOR CO 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:

- Irregular heartbeat, dizziness, low blood sugar, severe low blood pressure, wheezing, coughing, asthma, heart failure, electrolyte depletion, dehydration.

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If you forget to take BILOCOR CO

Take the missed dose as soon as possible. However, if it is almost 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.

4. Possible side effects

BILOCOR CO can have side effects.

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

If any of the following happens, stop using BILOCOR CO 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
- fainting

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

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- chest pain
- slow or irregular heartbeat
- difficulty breathing
- discolouration of the skin and numbness of the fingers or toes
- unusual bruising and nosebleeds, or bleeding in the mouth and gums
- yellowing of the skin and whites of the eyes, also called jaundice
- skin and lip cancer (non-melanoma skin cancer), with abnormal growth of skin, bump or sores on the lips that persist for a long period of time
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS)
- fever, flu-like symptoms, a painful red rash (may include purplish spots) that spreads, and blisters follows where the top part of the skin dies and peels off known as toxic epidermal necrolysis (TEN)
- seizures (fits)
- high blood pressure
- hallucinations (hearing or seeing things that are not there), depression, psychosis (mental disorder characterised by a disconnection from reality)
- blood cell disorders (characterised by pale skin colour, weakness, frequent infections, generally feel unwell)
- kidney failure, swelling and inflammation in between the kidney tubules

These are all serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following:

Frequent side effects:

- low amount of platelets in the blood, or reduced amount of salt in the body abnormal blood test results
- drowsiness, trouble in sleeping, unusual tiredness or weakness
- or reduced amount of salt in the body electrolyte imbalance (shown in blood tests), low potassium and chloride blood levels
- restlessness
- decreased sexual ability
- dry mouth stomach problems
- vertigo (spinning sensation), fever
- muscle pain and cramps
- low urine output
- thirst, weakness

Less frequent side effects:

- anxiety and/or nervousness, nightmares and vivid dreams
- dizziness, headache, restlessness, tingling or numbness of limbs
- fluid retention, circulation disorders, feeling dizzy when standing still
- blocked nose, hay fever
- increase or decrease of sugar in the blood, or sugar in the urine
- dry, sore eyes, reduced tear flow, pink eye (conjunctivitis)

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- nausea, vomiting, diarrhoea, abdominal pain, constipation cramping, stomach irritation, intestinal ulcer
- skin rash, sensitivity of skin to the sun, sweating
- back pain or joint pain, chest pain
- feeling weak
- inflammation of the pancreas
- loss of appetite (anorexia), increased or decreased blood mineral content
- gout (an increase of uric acid in the body)
- muscle spasm
- the urinary excretion of calcium is reduced
- impotence

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

- hypoglycaemia (decrease of sugar in the blood)
- low levels of cholesterol in the blood
- physical or mental weariness, lack of energy
- blurred vision or seeing objects more yellow than there are
- temporary loss of hearing
- increase in weight
- painful swelling and sores in the mouth
- raised liver enzymes (seen in blood test results)

- loss of hair, sweating
- muscle stiffness, soreness, spasms, fatigue, lack of energy (myopathy), weakness
- an inflammation of blood vessel walls (inflammation of blood vessels, often with skin rash, inflamed blood vessels in the skin), anaemia, increase of sugar in the blood, or sugar in the urine
- bone marrow depression
- infection of the salivary glands
- light headedness
- small purple coloured spots caused by bleeding into the skin, worsening of psoriasis, skin rash
- increases in blood levels of fat in your blood called cholesterol and triglycerides

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

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If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drugreactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of BILOCOR CO.

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 CO

Store all medicines out of reach of children.

Store at or below 25 °C

Keep blisters 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 CO contains:

The active substances are bisoprolol fumarate and hydrochlorothiazide.

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BILOCOR CO 2,5/6,25: Each film coated tablet contains 2,5 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide.

BILOCOR CO 5/6,25: Each film coated tablet contains 5 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide.

BILOCOR CO 10/6,25: Each film coated tablet contains 10 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide.

The other ingredients are:

Tablet cores

Colloidal silicon dioxide, corn starch, crospovidone, dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose and pregelatinised starch.

Film-coating:

The following colourants are also included: iron oxide red (5/6,25 tablets only) iron oxide yellow (2,5/6,25 tablets only) and Opadry white (hypromellose 6 cps, macrogol/PEG 400, titanium dioxide and polysorbate 80).

What BILOCOR CO looks like and contents of the pack

BILOCOR CO 2,5/6,25: Yellow coloured, film coated, round tablets debossed with “2,5” on one side and plain on the other side.

BILOCOR CO 5/6,25: Pink coloured, film coated, round tablets debossed with “5” on one side and plain on the other side.

BILOCOR CO 10/6,25: White to off white coloured, film coated, round tablets debossed with “10” on one side and plain on the other side.

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BILOCOR CO tablets are available in clear PVC/PVDC/Aluminium foil blister strips in a pack size of 30 tablets,

placed with a leaflet in a outer carton.

Holder of Certificate of Registration

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BILOCOR CO 5/6,25: A44/7.1.3/1011

BILOCOR CO 10/6,25: A44/7.1.3/1012

NAMIBIA:	

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BILOCOR CO 2,5/6,25: NAM NS2 13/7.1.3/0260 BILOCOR CO 5/6,25: NAM NS2 13/7.1.3/0261 BILOCOR CO 10/6,25: NAM NS2 13/7.1.3/0262 **MOZAMBIQUE:** BILOCOR CO 2,5/6,25: C5078 BILOCOR CO 5/6,25: C5079 BILOCOR CO 10/6,25: C5080	