

PATIENT INFORMATION LEAFLET
BILOCOR CO range

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

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

BILOCOR CO 5/6,25 film coated tablet

BILOCOR CO 10/6,25 film coated tablet

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **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.

1. WHAT BILOCOR CO CONTAINS

The active substances are bisoprolol fumarate and hydrochlorothiazide.

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.

PATIENT INFORMATION LEAFLET
BILOCOR CO range

BILOCOR CO 10/6,25:

Each film coated tablet contains 10 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide.

The other ingredients are colloidal silicon dioxide, corn starch, crospovidone, dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose and pregelatinised starch. 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, macrogol/ PEG 400, titanium dioxide and polysorbate 80).

BILOCOR CO film coated tablets are sugar free.

2. WHAT BILOCOR CO IS USED FOR

BILOCOR CO is used to treat high blood pressure.

3. BEFORE YOU TAKE BILOCOR CO

Do not take BILOCOR CO if

- you have a history of previous and/or current cancer of the skin and lip
- you are allergic (hypersensitive) to bisoprolol or to any of the ingredients in **BILOCOR CO** or other sulphonamide derived medicines (see **WHAT BILOCOR CO CONTAINS**)
- you suffer from uncontrolled heart failure or if you are receiving therapy for a weak heart
- you have problems with a very slow heartbeat or a heart block

PATIENT INFORMATION LEAFLET
BILOCOR CO range

- 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 asthma or from another disease causing severe breathing difficulties

- 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 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 suffer from untreated phaeochromocytoma, which is a tumour of the adrenal gland
- you have Addison's disease (your adrenal glands do not produce enough of their hormones)
- you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**)
- you suffer from severe kidney or liver problems
- you have porphyria (a disorder that affects how your body makes red blood cells).

Take special care with BILOCOR CO

- taking **BILOCOR CO** with quinidine may cause life threatening effects on the heart.
- 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).

PATIENT INFORMATION LEAFLET
BILOCOR CO range

Protect your skin from sun exposure and UV rays while taking **BILOCOR CO**.

- if you suffer from any breathing difficulties.
- 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 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 experience sudden onset of chest pain, or if you already suffer from a mild form of angina.
- if you are treated with **BILOCOR CO** and suffer from phaeochromocytoma (a tumour of the adrenal gland); this condition should be treated first, prior to taking **BILOCOR CO**.
- if you suffer from psoriasis (marked by severe skin rashes).
- 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.
- **BILOCOR CO** may decrease tear flow, causing eye irritation to contact lens wearers.
- 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 have high calcium levels in your body.

PATIENT INFORMATION LEAFLET
BILOCOR CO range

- if you have had gout.
- Discuss with your doctor before you stop taking **BILOCOR CO**.

You should stop taking **BILOCOR CO** gradually and limit the amount you exercise during this period.

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

Taking BILOCOR CO with food and drink

The tablets can be taken with or without food.

BILOCOR CO taken together with alcohol may cause dizziness or light-headedness.

Pregnancy and breastfeeding

DO NOT take **BILOCOR CO** if you are pregnant, plan to become pregnant, or suspect that you are pregnant. Contact your 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 machinery

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

PATIENT INFORMATION LEAFLET
BILOCOR CO range

Taking other medicines with BILOCOR CO

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

- 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), calcium channel blockers (such as verapamil or diltiazem) or phenothiazines (used for mental illness).
- You may experience a worsening of heart failure if you take **BILOCOR CO** with other antihypertensives such as methyldopa.
- 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.

PATIENT INFORMATION LEAFLET
BILOCOR CO range

- When **BILOCOR CO** are used for a prolonged time with medication such as corticosteroids, the hypokalemic 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** may decrease the tear flow causing eye irritation to contact lens wearers.

4. HOW TO TAKE BILOCOR CO

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

Always take **BILOCOR CO** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

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.

If you have any questions about the proper dose of **BILOCOR CO**, ask your doctor.

Treatment with **BILOCOR CO** should not be stopped abruptly.

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

PATIENT INFORMATION LEAFLET
BILOCOR CO range

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, seek help at the nearest hospital or poison control center. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to take a dose of 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.

5. POSSIBLE SIDE EFFECTS

BILOCOR CO can have side effects. Not all side effects reported for **BILOCOR CO** are included in this leaflet. Some side effects may occur that usually do not need medical attention. Should your general health worsen or if you experience any untoward effects while taking **BILOCOR CO**, please consult your healthcare provider for advice.

If any of the following happen, stop taking BILOCOR CO and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing.
- a rash or itching.

PATIENT INFORMATION LEAFLET
BILOCOR CO range

- fainting.
- yellowing of the skin and whites of the eyes, also called jaundice.

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. All of these are very serious side effects, but are less frequently encountered.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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.

These are all serious side effects. You may need urgent medical attention. Serious side effects occur less frequently.

Side effects that may occur more frequently include:

- drowsiness, trouble in sleeping, unusual tiredness or weakness
- low amount of platelets in the blood, or reduced amount of salt in the body
- decreased sexual ability.

Less frequent side effects that may occur include the following:

- blood cell disorders
- increase or decrease of sugar in the blood, or sugar in the urine

PATIENT INFORMATION LEAFLET
BILOCOR CO range

- gout (an increase of uric acid in the body)
- inflammation of the pancreas or infection of the salivary glands
- inflammation of the lining of the mouth
- loss of appetite (anorexia), increase in weight
- anxiety and/or nervousness
- nightmares and vivid dreams, depression
- hallucinations (hearing or seeing things that are not there)
- dizziness, headache, restlessness
- extreme tiredness
- tingling or numbness of limbs
- feeling dizzy when standing still, fever
- dry, sore eyes, reduced tear flow
- blurred vision or seeing objects more yellow than they are
- temporary loss of hearing
- blocked nose
- nausea, vomiting, diarrhoea, abdominal pain, constipation,
- skin rash, sensitivity of skin to the sun, sweating, loss of hair
- back pain or joint pain, muscle cramps or muscle weakness
- kidney problems.

Side effects with unknown frequency that may occur include the following:

PATIENT INFORMATION LEAFLET
BILOCOR CO range

- 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.

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

6. STORING AND DISPOSING OF BILOCOR CO

- Store at or below 25 °C.
- Keep the blisters in the carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).
- Do not use after the expiry date stated on the carton.