SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BILOCOR 5 tablets

BILOCOR 10 tablets

Please read this leaflet carefully before using BILOCOR 5 / 10 mg tablets

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

BILOCOR 5: Each tablet contains 5 mg bisoprolol fumarate (2:1).

BILOCOR 10: Each tablet contains 10 mg bisoprolol fumarate (2:1).

Other ingredients in BILOCOR: Lactose monohydrate, microcrystalline cellulose, magnesium stearate, crospovidone and yellow PB 22812 (the colourant for BILOCOR 5) or beige PB 27215 (the colourant for BILOCOR 10).

2. WHAT BILOCOR IS USED FOR

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.

3. BEFORE YOU USE BILOCOR

Do not take BILOCOR if:

- You are allergic (hypersensitive) to any of the ingredients in this medicine (see "WHAT BILOCOR CONTAINS").
- You suffer from acute heart failure or if you are receiving therapy for a weak heart.
- You have a weak, irregular or slow heart beat.
- You have low blood pressure.
- You suffer from severe asthma or from other severe breathing difficulties.
- You suffer from metabolic acidosis (this sometimes occurs as an acute complication of diabetes).
- 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).
- You suffer from phaeochromocytoma (marked by high blood pressure, raised heart rate and headache).

Take special care with BILOCOR:

- If you suffer from asthma or from any other breathing difficulties.
- If you suffer from diabetes mellitus (low blood sugar levels may be masked by this medicine).
- If you suffer from a condition marked by excessive production of thyroid hormones.

- If you suffer from an irregular heart beat, or from circulatory problems: less severe forms of Raynaud's syndrome (resulting in temporary discoloration of the skin and numbness of the fingers or toes).
- If you experience sudden onset of chest pain, or if you already suffer from a mild form of angina.
- 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.
- If you suffer from or have suffered from psoriasis (marked by severe skin rashes).
- If you are due to have an operation; you should inform the hospital doctor that you are taking BILOCOR 5 or BILOCOR 10.

Taking BILOCOR with food or drink:

The tablets can be taken with or without food.

Pregnancy and Breast-feeding

DO NOT use **BILOCOR** if you are pregnant or suspect that you are pregnant. Contact you doctor or healthcare professional immediately.

DO NOT use **BILOCOR** during breastfeeding.

Driving and using machinery:

It is unlikely for **BILOCOR** to make you drowsy. However, please make sure how **BILOCOR** affects you before driving or using machinery.

Using other medicines with BILOCOR:

Consult with your doctor or pharmacist or healthcare professional or advice if you need to take
any other medicines. If you are taking other medicines on a regular basis, including

complementary or traditional medicines, the use of **BILOCOR** with these medicines may cause undesirable interactions.

Consult your doctor or pharmacist before taking such medicines.

- You may experience extremely low blood sugar levels when taking BILOCOR with oral blood sugar lowering medication or insulin.
- You may have myocardial depression (depression of the heart muscle) when taking
 antiarrhythmic medicines (used to treat an irregular or rapid heart beat, such as amiodarone)
- Medicines in the beta-adrenoceptor agonist class (such as isoprenaline) may antagonise the effects of BILOCOR.
- Medicines in the alpha-adrenoceptor agonist class (such as clonidine, phenylephrine, or alphamethyldopa) may antagonise the effects of BILOCOR.
- Using the medicines reserpine or guanethidine with BILOCOR may cause life-threatening vasoconstriction (constricting of the blood vessels).
- 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.

If you are due to have an operation, tell the anaesthetist or the medical staff you are taking **BILOCOR**.

4. PROPER USE OF BILOCOR

You and your doctor should talk about the benefits and risks of treatment with **BILOCOR**.

The dose of **BILOCOR** will be different for different patients and may depend on what the medicine is being used for, your age and if other medicines are also being given or taken at the same time. Your doctor will advise you what the best dosage for you is. In some patients 5 mg per day will be adequate. The normal dose is 10 mg once daily. The maximum recommended dose is 20 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**, ask your doctor.

If you take more BILOCOR 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 centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

5. POSSIBLE SIDE-EFFECTS

BILOCOR may cause some undesired effects or side effects. Most side effects that may occur usually do not need medical attention.

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. Please note that not all side effects reported for this medicine are included in this leaflet.

If any of the following happen, stop taking **BILOCOR** and contact your doctor or healthcare professional immediately:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- a 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. All of these side effects are very serious but are very rare.

Side-effects that may occur more frequently include:

- Drowsiness, trouble in sleeping, unusual tiredness or weakness.
- Decreased sexual ability.

 Headache (these are generally mild especially at the beginning of therapy and often disappear within 1 - 2 weeks).

Less frequent side-effects that may occur include the following:

- Nausea, vomiting, diarrhoea, abdominal pain, constipation.
- Anxiety and/or nervousness.
- Nasal congestion.
- Dry, sore eyes.
- Skin rash.
- Nightmares and vivid dreams.
- Back pain, joint pain or chest pain.

6. STORAGE AND DISPOSAL OF BILOCOR

- Store below 25 °C in well-closed containers. Protect from light
- Keep blister packs in carton until required for use
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)
- KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.