Patient Information Leaflet

SCHEDULING STATUS:

S3

CARDICOR® 2,5 film-coated tablets

CARDICOR® 5 film-coated tablets

CARDICOR® 10 film-coated tablets

Bisoprolol fumarate

Read this entire leaflet carefully before you start taking CARDICOR.

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

1. What CARDICOR is and what it is used for

The active substance in CARDICOR 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, CARDICOR slows down the heart rate and makes the heart more efficient at pumping blood around the body.

CARDICOR is used to treat stable chronic heart failure, in combination with other medicines.

CARDICOR is also indicated for the management of mild to moderate hypertension and angina pectoris.

2. What you need to know before you take CARDICOR

Do not take CARDICOR:

- if you are allergic to Bisoprolol fumarate or any of the other ingredients of CARDICOR (listed in section 6).
- if you have severe asthma.
- If you have severe blood circulation problem in limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.
- if you have untreated phaeochromocytoma, which is a rare tumour of the adrenal gland (medulla).
- if you have metabolic acidosis, which is a condition when there is too much acid in the blood.
- if you are pregnant (see Pregnancy and Breast feeding).
- if you are below 18 years of age.

Do not take CARDICOR if you have the following heart problems:

- acute heart failure.
- worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart
- slow heart rate

- low blood pressure
- 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.

Warnings and precautions

Take special care with CARDICOR:

If you have any of the following conditions, tell your doctor before taking CARDICOR; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- diabetes
- strict fasting
- certain heart diseases such as disturbances in heart rhythm, severe chest pain at rest (Prinzmetal's angina)
- less severe asthma or chronic lung disease
- blood circulation problems in your limbs
- desensitizing therapy (for example for the prevention of hay fever)
- concomitant treatment with inhalation anaesthetics
- if you are going to have an anaesthetic (for example for surgery), because bisoprolol may influence how your body reacts to this situation
- if you are taking verapamil or diltiazem, medicines used to treat heart conditions. Concomitant use is not recommended, see also section Taking other medicines with CARDICOR
- have or have had psoriasis (a recurring skin rash)
- have a thyroid problem. The tablets can hide symptoms of an overactive thyroid.

Do not stop CARDICOR therapy abruptly, especially if you have coronary heart disease as this may lead to temporary worsening of your heart conditions including angina and increase in blood pressure.
A variety of disorders from fatigue and nightmares to psychosis may be observed during your treatment with CARDICOR.
Severe blood circulation problems in the vessels of your arms and limbs, as even gangrene, may be observed.
Careful control of dosages, and of the response to the treatment (especially pulse rate) is very important when taking concomitantly certain medicines used to treat heart failure (e.g. digoxin).

Children and adolescents

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

Other medicines and CARDICOR

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

Do not take CARDICOR if you are using:

- certain medicines used to treat irregular or abnormal heartbeat (Class I antidysrhythmic medicines) such as quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone (in patients with chronic heart failure)
- certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (calcium antagonists such as verapamil and diltiazem)
- certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonodine, rilmenidine.

However, do not stop taking these medicines without checking with your doctor first.

Check with your doctor before taking the following medicines with CARDICOR; your doctor may need to check your condition more frequently:

- Certain medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonists) such as nifedipine, feldipine and amlodipine
- Certain medicines used to treat irregular or abnormal heartbeat (Class III antidysrhythmic medicines) such as amiodarone
- Certain medicines used to treat irregular or abnormal heartbeat (Class I antidysrhythmic medicines) such as quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone (in patients with hypertension or angina pectoris)
- Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment)
- Certain medicines used to treat for example Alzheimer's disease or glaucoma (parasympathomimetics) such as tacrine or carbachol
- Medicines used to treat acute heart problems (sympathomimetics) such as isoprenaline and dobutamine
- Antidiabetic medicines including insulin
- Anaesthetic agents (for example during surgery)
- Certain medicines used to treat heart failure (digoxin)
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation, such as ibuprofen or diclofenac
- Any medicine that can lower blood pressure as a desired or undesired effect, such as blood pressure medicines, 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)

- Mefloquine, used for prevention of malaria
- Depression treatment medicines called monoamine oxidase inhibitors such as moclobemide.

CARDICOR with food and drink

CARDICOR may be taken with or without food but must be taken in the morning.

Pregnancy and breastfeeding

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 CARDICOR.
There is a risk that use of CARDICOR during pregnancy may harm the baby. If you are pregnant or planning to become pregnant, tell your doctor.
CARDICOR is not recommended during pregnancy and breastfeeding.

Driving and using machines

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

3. How to take CARDICOR

Do not share medicines prescribed for you with any other person.
Always use CARDICOR exactly as your doctor has instructed you. Your doctor will decide which dose is applicable to you. You should check with your doctor or pharmacist if you are unsure.
Treatment with CARDICOR requires regular monitoring by your doctor. This is particularly necessary at the start of treatment and during dose increase.
Treatment with CARDICOR is usually long-term.

Treatment of stable chronic heart failure

Adults including the elderly:

Treatment with CARDICOR must be started at a low dose and increased gradually.

Your doctor will decide how to increase the dose, and this will normally be done in the following way:

- 1.25 mg once daily for two weeks or longer
- 2.5 mg once daily for two weeks or longer
- 3.75 mg once daily for two weeks or longer
- 5 mg once daily for two weeks or longer
- 7.5 mg once daily for two weeks or longer
- 10 mg once daily for maintenance (on-going) therapy.

The maximum recommended daily dose is 10 mg once daily.

Depending on how well you tolerate the medicine, your doctor may decide to lengthen the time between dose increases. If your condition gets worse or you no longer tolerate CARDICOR, it may be necessary to reduce the dose again or to interrupt treatment. In some patients a maintenance dose lower than 10 mg CARDICOR may be sufficient.

Your doctor will tell you what to do.

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.

Treatment of hypertension or angina pectoris

The recommended dosage is 5 mg CARDICOR once daily.

If necessary, the dosage may be increased to 10 mg once daily.

The maximum recommended dosage is 20 mg once daily.

Administration

CARDICOR tablets should be taken in the morning and can be taken with food. They should be swallowed with liquid and should not be chewed.

Children

CARDICOR is not recommended for use in children.

If you take more CARDICOR 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.
Symptoms of an overdose may include slowed heart rate, severe difficulty in breathing feeling dizzy, or trembling (due to decreased blood sugar).

If you forget to take CARDICOR:

Do not take a double dose to make up for a forgotten individual dose. Take your usual dose the next morning.

If you stop taking CARDICOR:

Never stop taking CARDICOR unless on your doctor's advice, or your condition could become much worse.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

CARDICOR can have side effects.

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

Adverse reactions reported are listed below according to seriousness.

To prevent adverse reactions becoming serious, speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse quickly.

The most serious side effects are related to the heart function:

- slowing of heart rate
- worsening of heart failure
- slow or irregular heartbeat
- gangrene of the fingers or toes

If you feel dizzy or weak or have breathing difficulties, please contact your doctor as soon as possible.

Further side effects are listed below according to how frequently they may occur:

Side effects appearing frequently:

- tiredness, feeling weak, dizziness, headache
- feeling of coldness or numbness in hands or feet
- low blood pressure
- stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation.

Side effects appearing less frequently:

- sleep disturbances
- depression, restlessness
- dizziness when standing up
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps.
- tingling and colour change (from white to red) in fingers and toes when exposed to the cold
- hearing problems
- allergic runny nose
- reduced tear flow
- inflammation of the liver which can cause yellowing of the skin or whites of the eyes
- certain blood test results for liver function or fat levels differing from normal
- allergy-like reactions such as itching, flush, rash. You should see your doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.
- impaired erection
- nightmares, hallucinations
- fainting
- irritation and redness of the eye (conjunctivitis)
- hair loss
- appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash.

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.

You can also report side effects to SAHPRA the Med Safety APP (Medsafety X SAHPRA) & eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store CARDICOR

Store all medicines out of the reach of children.

Store at or below 25 °C in airtight containers and protect from light.

Blisters should not be removed from the carton until they are 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 CARDICOR contains

The active ingredient is bisoprolol fumarate.

The other ingredients are anhydrous calcium hydrogen phosphate, maize starch, anhydrous silica colloidal, cellulose microcrystalline, crospovidone, magnesium stearate, dimethicone, hypromellose, iron oxide, macrogol, titanium dioxide.

What CARDICOR looks like and contents of the pack

CARDICOR 2,5 are white, heart-shaped biconvex film-coated tablets, scored on both sides.

CARDICOR 5 are yellowish-white, heart-shaped biconvex film-coated tablets, scored on both sides.

CARDICOR 10 are pale orange-light orange, heart-shaped biconvex film-coated tablets, scored on both sides.

CARDICOR is available in blister packs containing 30 tablets.

Holder of Certificate of Registration

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Name and address of the manufacturer

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