

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

## CARDILOC 1.25/2.5/5/10 Tablets

### Composition:

Each film-coated tablet of **Cardiloc 1.25** contains:

Bisoprolol Fumarate 1.25 mg

Each tablet of **Cardiloc 2.5** contains:

Bisoprolol Fumarate 2.5 mg

Each tablet of **Cardiloc 5** contains:

Bisoprolol Fumarate 5 mg

Each tablet of **Cardiloc 10** contains:

Bisoprolol Fumarate 10 mg

For inactive and allergenic ingredients in the preparation, see section 6: "Further information" and section 2: "Before using the medicine".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

If you experience any side effects, refer to your doctor or pharmacist. This includes any possible side effects not included in the leaflet. See section 4: "Side effects".

**This medicine is not intended for children.**

**1. WHAT IS THE MEDICINE INTENDED FOR? Cardiloc 1.25/Cardiloc 2.5:** For the treatment of heart failure.

**Cardiloc 5/Cardiloc 10:** For the treatment of heart failure. For the treatment of hypertension. For the treatment of angina pectoris.

**Therapeutic group:** The medicine belongs to the selective beta blockers group.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine if:

- You are sensitive to bisoprolol or to any of the additional ingredients contained in the medicine (see section 6: "Further information").
- You suffer from severe asthma.
- You suffer from a severe blood circulation problem in the limbs (such as Raynaud's syndrome), which may cause your fingers or toes to tingle or turn pale or blue.
- You suffer from untreated pheochromocytoma – a rare tumor of the adrenal gland.
- You suffer from metabolic acidosis – a condition when there is too much acid in the blood.
- You suffer from acute heart failure.
- You suffer from worsening heart failure requiring injection of medicines into the vein that increase the force of contraction of the heart.
- You suffer from a slow heart rate.

- You suffer from low blood pressure.
- You suffer from certain heart conditions causing a very slow heart rate or irregular heartbeat.
- You suffer from cardiogenic shock (originating in the heart), which is a serious heart condition causing low blood pressure and circulatory failure.

#### Special warnings regarding use of the medicine

**Before starting treatment with Cardiloc, tell the doctor if:**

- You are suffering from certain heart diseases, such as heart rhythm disturbances or severe chest pains at rest (a coronary artery disease called Prinzmetal's angina).
- You are suffering from kidney or liver problems.
- You are suffering from chronic lung disease or less severe asthma.
- You are suffering from a thyroid disturbance.
- You are suffering from diabetes.
- You have a less severe blood circulation problem in the limbs.
- You are suffering from adrenal gland tumors (pheochromocytoma).
- You have suffered from a scaly skin rash (psoriasis).
- You are on a complete fast.

The doctor may want to take special care (for example, give additional treatment or perform more frequent checks).

**In addition, tell the doctor if you are due to undergo:**

- Desensitization therapy (e.g., to prevent hay fever), because **Cardiloc** may make it more likely that you experience an allergic reaction, or that this reaction may be more severe.
- Anesthesia (e.g., before surgery). **Cardiloc** may affect your body's response to the anesthesia process.

If you are suffering from a chronic lung disease or from less severe asthma, inform your doctor immediately if you start to experience new difficulties in breathing, coughing, wheezing after exercise or similar effects when using **Cardiloc**. **Children and adolescents**

This medicine is not intended for use by children and adolescents.

#### Tests and follow-up

Treatment with **Cardiloc** requires routine monitoring by your doctor. Monitoring is primarily essential at the beginning of treatment, when the dosage is increased and when the treatment is discontinued.

#### Drug interactions

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist to avoid risks or inefficacy resulting from drug interactions.**

#### Do not take the following medicines without consulting with your doctor:

- Certain medicines to treat high blood pressure, or angina pectoris or heart rhythm irregularities (calcium channel blockers, such as verapamil and diltiazem).
- Certain medicines to treat high blood pressure, such as clonidine, methyldopa, moxonidine and rilmenidine. However, **do not stop taking these medicines** before consulting your doctor.
- Certain medicines to treat irregular or abnormal heart rate (class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone).

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

- Medicines to treat high blood pressure or angina pectoris (dihydropyridine-type calcium channel blockers such as felodipine and amlodipine).
- Medicines to treat heart rate disturbances (belonging to class III antiarrhythmic medicines, such as amiodarone).
- Anesthetics (e.g., during surgery).
- Digitalis, to treat heart failure.
- Medicines to treat diabetes, including insulin.
- Beta blockers for topical use (such as in eye drops to treat glaucoma).
- Non-steroidal anti-inflammatory drugs (NSAIDs) to treat arthritis, pain or inflammation (e.g., ibuprofen or diclofenac).
- Any medicine which can lower blood pressure intentionally or unintentionally, such as medicines for lowering blood pressure, certain medicines to treat depression (tricyclic antidepressants, such as imipramine or amitriptyline), certain medicines to treat epilepsy or during anesthesia (barbiturates, such as phenobarbital), or certain medicines to treat mental illnesses characterized by a loss of contact with reality (phenothiazines, such as, levomepromazine).
- Certain medicines to treat Alzheimer's disease or glaucoma (parasympathomimetics such as tacrine or carbachol) or medicines used to treat severe heart problems (sympathomimetics, such as dobutamine, isoprenaline).
- Mefloquine, a medicine used to treat or prevent malaria.
- Antidepressants such as moclobemide (MAO inhibitors, except for MAO-B).

#### Use of the medicine and food

Take the tablet in the morning, with or without food.

#### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult a doctor or pharmacist before using medicines.

There is a risk that use of **Cardiloc** during pregnancy may harm the unborn baby. If you are pregnant or plan to become pregnant, tell your doctor and he will decide if you can take **Cardiloc** during pregnancy.

It is not known whether bisoprolol is secreted into breast milk. Therefore, breastfeeding is not recommended during treatment with **Cardiloc**.

#### Driving and operating machinery

Your ability to drive or operate machinery may be affected by the use of **Cardiloc**, depending on your tolerance of the medicine. Be cautious, especially at the beginning of treatment, when the dosage of the medicine is increased, when changes are being made to the medicinal therapy, or as a result of alcohol consumption.

#### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation. The dosage and the treatment regimen will be determined by the doctor only.

#### Do not exceed the recommended dose.

Swallow the medicine in the morning, with water.

**Cardiloc 2.5, 5, 10:** If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

**Cardiloc 1.25:** Do not halve the tablet. There is no information regarding crushing or chewing the tablet.

Wait at least two hours between taking the medicine and taking antacids.

**Cardiloc** treatment is generally long-term.

Depending on your tolerance of the medicine, your doctor may extend the time until increasing the dosage.

If your condition worsens or if you are unable to tolerate the medicine, it may be necessary to reduce the dosage of the medicine again or stop the treatment.

If you have to stop the treatment entirely, your doctor will usually advise you to gradually lower the dosage; otherwise, your condition may worsen.

#### Dosage in patients with liver and kidney function disorders

In patients with liver or kidney function disorders of mild to moderate severity, no dosage adjustment is normally required. In patients with severe liver or kidney function disorders, do not exceed a daily dose of 10 mg.

#### Use in elderly patients

No dosage adjustment is required.

#### Use in children and adolescents

**Cardiloc** is not intended for use in children since the efficacy and safety have not been tested in this age group.

**If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine,** refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

The symptoms of **Cardiloc** overdose can include slowed heart rate, severe breathing difficulties, dizziness or tremor (due to a drop in blood sugar).

**If you forgot to take this medicine at the required time,** never take a double dose to "compensate" for the single forgotten dose. Take the usual dose the next morning.

Adhere to the treatment regimen as recommended by the doctor.

Do not change or discontinue **Cardiloc** treatment without consulting the doctor. Otherwise, your condition may worsen.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

#### 4. SIDE EFFECTS

As with any medicine, use of **Cardiloc** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

To avoid severe reactions, refer to a doctor immediately if you experience severe side effects, a side effect that occurs suddenly or that quickly worsens.

The most serious side effects are related to heart function:

- Slowed heart rate (may affect more than 1 in 10 patients)
- Worsening of heart failure (may affect up to 1 in 10 patients)
- Slowed or abnormal heart rate (may affect up to 1 in 100 patients)

If you experience dizziness, weakness or breathing difficulties – refer to a doctor as soon as possible.

#### Additional side effects:

**Common side effects (may affect up to 1 in 10 patients):**

- Tiredness, weakness, dizziness, headache
- Low blood pressure
- Stomach or intestinal problems, such as nausea, diarrhea, vomiting, constipation
- Feeling of coldness or loss of sensation in hands and feet.

**Uncommon side effects (may affect up to 1 in 100 patients):**

- Breathing problems in patients with asthma or with chronic lung diseases
- Muscle weakness or muscle spasms
- Sleep disturbances
- Depression
- Dizziness when standing up.

**Rare side effects (may affect up to 1 in 1,000 patients):**

- Results of blood tests for liver function or fat levels different than usual
- Inflammation of the liver which can cause yellowing of the skin or whites of the eyes
- Fainting

- Reduced tear secretion
- Hearing disturbances
- Allergic rhinitis

- Allergy-like reactions, such as itching, redness, rash. Refer to a doctor immediately if you experience more serious allergic reactions, which may include swelling of the face, neck, tongue, mouth or throat, or breathing difficulties

- Erection problems
- Nightmares, hallucinations.

**Very rare side effects (may affect up to 1 in 10,000 patients):**

- Irritation and redness of the eye (conjunctivitis)
- Hair loss

- Appearance or worsening of scaly skin rash (psoriasis), psoriasis-like rash.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

#### Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)), that directs you to the online form for reporting side effects.

Additionally, you can report to "Unipharm Ltd."

#### 5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C and in a place protected from light.

Do not store different medicines in the same package.

Do not discard this medicines in the wastewater or a household waste bin. Consult a pharmacist how to dispose of medicines that are no longer needed. These measures will help protect the environment.

#### 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Anhydrous Dicalcium Phosphate, Microcrystalline Cellulose, Crospovidone, Colloidal Silicon Dioxide, Magnesium Stearate, Opadry.

**What the medicine looks and the contents of the package:**

**Cardiloc** is packaged in trays (blisters) inserted into a carton package.

**Cardiloc 1.25 and Cardiloc 2.5** come in package sizes of 10, 15, 20 or 30 tablets. Not all package sizes are marketed.

**Cardiloc 5 and Cardiloc 10** come in package sizes of 7, 10, 14, 20, 28 or 30 tablets. Not all package sizes are marketed.

**Cardiloc 1.25** is a film-coated, circular, biconvex, orange tablet.

**Cardiloc 2.5, 5, 10** are film-coated, circular, biconvex, white tablets, with a break line on one side.

**Registration holder and address:** Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

**Manufacturer and address:** Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

**Cardiloc 1.25:** 148 63 33513 01

**Cardiloc 2.5:** 128 07 30654 02

**Cardiloc 5:** 119 61 29988 01

**Cardiloc 10:** 119 62 29989 06

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