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

The medicine is dispensed with a doctor's prescription only.

PROCOR

Tablets

Composition:

Each tablet contains:

Amiodarone HCl 200 mg

For a list of the inactive ingredients, please see section 6: "Further Information".

Read this 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.

This medicine is not intended for children and infants.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is intended for the treatment of coronary arterial insufficiency, cardiac arrhythmias resistant to other treatments.

Therapeutic group: Antiarrhythmics.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine if:

- You are sensitive (allergic) to amiodarone hydrochloride or to any of the additional ingredients contained in the medicine (see section 6: "Further Information"), or to iodine. Symptoms of an allergic reaction include rash, difficulty swallowing or breathing, swelling of the lips, face, throat or tongue.
- You are pregnant or breastfeeding, see section "Pregnancy and breastfeeding".
- You are suffering, or have suffered in the past, from thyroid dysfunction. Check thyroid function before beginning treatment with the medicine.
- You are suffering, or have suffered in the past, from arrhythmias manifested mainly by slow heartbeats (sinus bradycardia) or from an arrhythmia called Sino-atrial heart block.
- You are suffering from other arrhythmias and do not have an implanted pacemaker.
- You are taking other medicines that may cause arrhythmias (see section "If you are taking, or have recently taken, other medicines...").

Special warnings regarding use of this medicine:

❗ Before treatment with Procor, tell the doctor if:

- You are suffering, or have suffered in the past, from heart failure.
- You are suffering, or have suffered in the past, from liver problems.
- You are suffering, or have suffered in the past, from lung problems or asthma.
- You are suffering, or have suffered in the past, from vision problems.
- You are about to undergo a surgery (including dental) or any other procedure requiring anesthesia.
- You are 65 years of age or older (it is possible that more closer medical supervision will be required).
- You have an implanted pacemaker or defibrillator. The doctor may check to make sure that the device is working properly after beginning treatment with the medicine or following a change in dosage.

There have been reported cases of dangerous slowing of the heart rate (bradycardia) and disturbed electrical conduction of the heart in patients receiving amiodarone in combination with certain medicines (Harvoni or Sovaldi with Daklinza) to treat hepatitis C. Most of the cases occurred in the first 24 hours of treatment, however some cases occurred approximately two weeks after starting treatment. If you are being treated with the anti-hepatitis C medicines listed above, it is preferable to avoid using amiodarone. If you have no other treatment option, your doctor may hospitalize you for the first 48 hours of treatment to monitor your heart rate.

Symptoms of bradycardia can include: fainting or feeling that you are about to faint, dizziness, malaise, weakness, excessive fatigue, shortness of breath, chest pain, confusion or memory problems.

If you experience bradycardia symptoms, seek medical assistance immediately.

The first stage of treatment (when taking the initial dosage) must be under close medical supervision.

Use of this medicine may cause blurred vision. In such a case, stop treatment and refer to the doctor immediately.

During treatment with this medicine, the following tests should be performed: blood tests to rule out hypokalemia, function of the liver, thyroid, lungs (also before initiating treatment), routine eye examinations including fundoscopy, ECG.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist.

Do not use this medicine and inform the doctor, if you are taking:

- Additional medicines for arrhythmia, such as sotalol, quinidine, procainamide, disopyramide or bretylium.
- Medicines for treating infections, such as intravenous erythromycin, co-trimoxazole, moxifloxacin or pentamidine.
- Medicines used to treat schizophrenia, such as chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpride or sertindole.
- Medicines for additional psychiatric illnesses, such as lithium, doxepin, maprotiline or amitryptyline.
- Medicines for treating malaria, such as quinine, mefloquine, chloroquine or halofantrine.
- Medicines for treating hay fever, rash and other allergies, called antihistamines, e.g., terfenadine, astemizole or mizolastine.

Inform the doctor if you are taking:

- Medicines that extend the QT interval of the heart, such as, medicines to treat infections, such as clarithromycin, ciprofloxacin, ofloxacin or levofloxacin.
- Medicines for heart diseases called beta-blockers, e.g., propranolol.
- Medicines called calcium channel blockers (used to treat angina pectoris or hypertension), e.g., diltiazem or verapamil.
- Medicines to treat constipation (laxatives), e.g., bisacodyl or senna.
- Medicines to reduce cholesterol (statins), e.g., simvastatin or atorvastatin.

The following medicines may increase the risk of side effects when taken together with **Procor**:

- Intravenous amphotericin B (for treating fungal infections).
- Steroidal anti-inflammatory medicines, e.g., hydrocortisone, betamethasone or prednisolone.
- Diuretics.
- General anesthetics or oxygen at high dosages (used during surgery).
- Tetracosactide – a medicine for certain hormonal problems.
- You are taking sofosbuvir together with ledipasvir or with another medicine used to treat hepatitis C.

Procor may increase the effect of the following medicines:

- Cyclosporin and tacrolimus, used for preventing transplant rejection.
- Medicines to treat impotence, such as sildenafil, tadalafil or vardenafil.
- Fentanyl (to alleviate pain).
- Ergotamine (for treating migraine).
- Midazolam (for treating anxiety or for tranquilizing before surgery).
- Colchicine (to treat gout).
- Flecainide (additional medicine for arrhythmias).
- Lidocaine (for local anesthesia).
- Warfarin (a medicine to prevent blood clotting).
- Digitalis (to treat certain heart problems).
- Dabigatran (a medicine to prevent blood clotting).

❗ Use of the medicine and food – take the medicine with or after a meal.

Do not drink grapefruit juice during treatment with the medicine, since grapefruit juice may increase the level of medicine in the blood and increase the risk of side effects.

❗ Use of the medicine and alcohol consumption – limit the amount of alcoholic drinks during treatment with the medicine, since alcohol can increase the risk of hepatic side effects during treatment with the medicine.

❗ Protection from the sun – avoid exposure to the sun during the course of treatment and for a number of months after finishing treatment with the medicine. This precaution is because the medicine increases the sensitivity of the skin to sun rays and unprotected sun exposure can lead to burns, stinging or blisters on the skin. Therefore, the following protective measures should be taken: make sure that you are using high-factor sunscreen, and always wear a hat and clothing that covers the hands and legs.

❗ Pregnancy and breastfeeding – do not use the medicine if you are pregnant or planning to become pregnant.

Do not use this medicine if you are breastfeeding or plan to breastfeed, since small amounts of the medicine pass into breast milk.

❗ Driving and use of machinery – this medicine may cause blurring of vision. In the event that you experience blurred vision, do not drive or operate dangerous machinery.

❗ Important information about some of the medicine's ingredients – this medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

Each **Procor** tablet contains 200 mg of lactose.

This medicine contains iodine, which may cause thyroid problems (see subsection "Tests" in the "How should you use the medicine?" section).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure.

The dosage and treatment regimen will be determined by the doctor only.

Use in children and infants: This medicine is not intended for children and infants.

Elderly patients: A lower dosage of **Procor** may be prescribed for elderly patients. In addition, blood pressure and thyroid function tests should be carried out regularly in these patients.

Do not exceed the recommended dose.

Do not chew! Swallow the medicine with a little water.

If necessary the tablet can be halved or crushed before use.

If you accidentally take 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.

Some of the symptoms that may indicate an overdose are: feeling dizzy, faint or tired, confusion, slow heartbeat, damage to the liver or vomiting.

If you forget to take this medicine at the required time, take a dose as soon as you remember; however, if it is nearly time for the next dose, skip the missed dose and take the next dose at the regular time. Never take two doses together!

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine, the heart rate disturbances may recur, which may be dangerous.

Do not change the dosage without consulting the doctor.

Tests: During the course of treatment with this medicine, the following tests should be performed: blood tests to rule out hypokalemia, function of the liver, thyroid, lungs (also before initiating treatment), routine eye examinations including fundoscopy, ECG. In addition, the doctor may refer you for a chest X-ray.

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 this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

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

Stop use of the medicine and refer to a doctor or proceed to a hospital immediately if you experience:

- An allergic reaction, whose signs may include rash, problems swallowing or breathing, swelling of eyelids, face, lips, throat or tongue.

Common side effects (effects that occur in 1-10 in 100 users):

- Yellowing of skin or eyes (jaundice), fatigue or feeling ill, loss of appetite, stomach pain or high fever. These may be symptoms of liver problems, that may be very dangerous.
- Difficulty breathing or a feeling of tightness in the chest, persistent cough, wheezing, weight loss and fever. These may be symptoms of a lung infection, that may be very dangerous.

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- Worsening of heart rate disturbances, irregular heart rhythm - this can cause a heart attack, therefore, proceed to a hospital immediately.

Very rare side effects (effects that occur in less than one in 10,000 users):

- Loss of vision in one eye or your eyesight becomes dim and colorless, sensation of pain or sensitivity in the eye, and pain when moving the eye. These may be symptoms of an illness called optic neuropathy.
- Significant slowing of heartbeat or cessation of heartbeat. If this happens, immediately proceed to hospital.

Stop use of this medicine and refer to a doctor immediately if you experience the following severe side effects – you may require urgent medical attention:

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- Numbness or feeling weak, tingling or burning sensation in different parts of the body.

Very rare side effects (effects that occur in less than one in 10,000 users):

- Skin rash caused by narrow or blocked blood vessels (vasculitis).
- Headache (which is usually worse in the morning or happens after coughing or straining), nausea, convulsions, fainting, vision disturbances or confusion. These could be symptoms of a problem in the brain.
- Moving unsteadily or staggering, slurred or slow speech.
- Feeling faint, dizziness, unusual fatigue and shortness of breath. These may be symptoms of a very slow heartbeat (especially in patients 65 years of age or older) or of other heartbeat problems.

Cases of lung bleeding have been reported in patients taking **Procor**. Refer to the doctor immediately if you cough up any blood.

Side effects of unknown frequency:

- Chest pain and shortness of breath and heart rate disturbances. These may be symptoms of a condition called "torsade de pointes".

Tell the doctor as soon as possible if you experience one or more of the following side effects:

Very common side effects (effects that occur in more than one in ten users):

- Blurred vision or seeing a colored halo in dazzling light.

Common side effects (effects that occur in 1-10 in 100 users):

- Feeling extremely restless or agitated, weight loss, increased sweating and intolerance to heat. These could be symptoms of hyperthyroidism.
- Feeling extremely tired, weak or 'run-down', weight gain, intolerance to cold, constipation and aching muscles. These could be symptoms of hypothyroidism.
- Trembling when moving the hands or legs.
- Blue or grey marks on parts of the skin that were exposed to sunlight, especially on the face.

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- Muscle cramps, stiffness or spasm.

Very rare side effects (effects that occur in less than one in 10,000 users):

- Swelling of the testicles.
- Red, scaly skin rash, hair loss or loosening of nails (signs of "exfoliative dermatitis").
- Feeling tired, faint, dizzy or having pale skin. These could be signs of anemia.
- Tendency to bleed or bruise more easily than usual (this could be a sign of a blood disorder called thrombocytopenia).
- Feeling unwell, confusion or weakness, nausea, loss of appetite, irritability. These could be signs of a disorder in secreting antidiuretic hormone.

Refer to the doctor or pharmacist if the following side effects worsen or last longer than a few days:

Very common side effects (effects that occur in more than one in ten users):

- Nausea or vomiting.
- Changes in taste sensation.
- Changes in the amount of liver enzymes at the beginning of treatment (as can be seen in blood tests).
- Tendency to develop skin burns when exposed to the sunlight (see section 2 regarding guidelines for protection from the sun).

Common side effects (effects that occur in 1-10 in 100 users):

- Slightly slower heart rate.
- Nightmares.
- Sleep disturbances.

Very rare side effects (effects that occur in less than one in 10,000 users):

- Headaches.
- Balance disorders, vertigo.
- Difficulty in getting or maintaining an erection or in ejaculating.
- Hair loss, balding.
- Skin rash.
- Skin redness during radio-therapy.

Side effects of unknown frequency:

- Hives (itchy, lumpy rash).
- Granulomas (small and red lumps on the skin or in the body that can be seen in an X-ray).

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.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects following drug treatment" found on the Ministry of Health homepage that directs you to the online form for reporting side effects. Alternatively, 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 of children and/or infants in order 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) appearing on the package. The expiry date refers to the last day of that month.
- Store the medicine at a temperature below 25°C and in a place protected from light.

6. FURTHER INFORMATION

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

Lactose, Maize Starch, Povidone, Magnesium Stearate, Colloidal Silicon Dioxide.

- Each **Procor** tablet contains 200 mg lactose.

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

Procor is packaged in trays (blister) which are provided in a carton package. There are 30 tablets in every package of **Procor**.

Procor are white, round, biconvex tablets, with a score line on one side.

License holder: Unipharm Ltd., P.O.B. 21429 Tel Aviv 6121301.

Manufacturer and address: Trima Ltd., Kibbutz Maabarot.

This leaflet was checked and approved by the Ministry of Health in October 2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
038 81 22620 00.

unipharm ltd.

0816G

119118010