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 and allergenic ingredients in the preparation, please 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.
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, arrhythmias resistant to other treatments.
Therapeutic group: Anti-arrhythmics.
The mechanism of action of the medicine controls irregular heartbeats (a phenomenon called "arrhythmia"). Taking the tablet helps the heartbeats to return to normal.

2. BEFORE USING THE MEDICINE

Do not use the medicine if you:
- are sensitive (allergic) to iodine, amiodarone or to any of the additional ingredients contained in the medicine (see section 6: "Further information"). Symptoms of an allergic reaction include rash, difficulty swallowing or breathing, swelling of the lips, face or tongue.
- are pregnant or breastfeeding; see section "Pregnancy, breastfeeding and fertility".
- are suffering, or have suffered in the past, from thyroid dysfunction. Your doctor should check thyroid function before beginning treatment with the medicine.
- are suffering, or have suffered in the past, from slower heartbeats than usual (a phenomenon called "sinus bradycardia") or from a disease called sino-atrial heart block.
- are suffering from other arrhythmias and **do not** have a pacemaker implanted in your body.
- are taking other medicines that may cause arrhythmias (see section "Drug interactions").
- are taking medicines to treat infections (see section "Drug interactions").
- are taking medicines to treat schizophrenia or other mental diseases (see section "Drug interactions").
- are taking medicines for treatment of malaria (see section "Drug interactions").
- are taking medicines for treatment of hay fever, rashes or other allergies, called antihistamines (see section "Drug interactions").
- are taking medicines for treatment of hepatitis C (see section "Drug interactions").

Special warnings regarding use of the medicine
Before treatment with Procor, tell the doctor if you:
- are suffering from heart failure.
- are suffering from liver problems.
- are suffering from any lung problems or asthma.
- are suffering from vision problems, including inflammation of the optic nerve ("optic neuritis").
- are due to undergo surgery.
- are elderly (over 65 years of age). Your doctor will have to monitor your condition closely.
- have an implanted pacemaker or an automatic defibrillator (ICD). Your doctor will need to check to make sure that the device is working well shortly after beginning treatment with the medicine or following a change in the dosage of the medicine.
- are suffering from blisters or peeling of the skin around the lips, eyes, nose and genitals, from flu-like symptoms and fever. These effects can be indicative of a condition called "Stevens-Johnson syndrome".
- are suffering from a severe rash accompanied by blisters, where skin layers may peel off and leave large areas of exposed skin over the body. In addition, you may experience the following symptoms: malaise, fever, chills and achy muscles (symptoms of toxic epidermal necrolysis).
- are taking a medicine containing sofosbuvir for treatment of hepatitis C, since it may cause a life-threatening slowing of your heart rate. Your doctor may consider alternative treatments. If you require treatment with a combination of amiodarone and sofosbuvir, you may need additional heart monitoring. **Inform the doctor immediately if you are taking a medicine containing sofosbuvir for treatment of hepatitis C and during the treatment you feel:**
  - Slow or irregular heartbeats or arrhythmias.
  - Shortness of breath or exacerbation of existing shortness of breath.
  - Chest pain.
  - Dizziness.
  - Palpitations.
  - Fainting or pre-fainting.

Protection of the skin from sunlight
Avoid direct exposure to sunlight while taking the medicine and for several months after you finish taking the medicine. This is because your skin will become more sensitive to sun exposure and may burn, tingle or develop severe blisters unless you take the following precautions: be sure to use a high-SPF sunscreen, always wear a hat and wear clothes that cover the arms and legs.

Tests and follow-up
During treatment with this medicine, your doctor will routinely perform liver function tests, since **Procor** may affect liver function. If such an effect occurs, your doctor will decide whether you should continue taking these tablets.
Your doctor may routinely perform thyroid function tests during treatment with the medicine, since the medicine contains iodine, which may cause thyroid problems.
Your doctor may routinely perform other tests, such as: blood tests, chest x-ray, ECG (an electrical test of your heartbeat) and eye tests before/during treatment with the medicine.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
In particular, inform the doctor or pharmacist if you are taking:
- Sofosbuvir for treatment of hepatitis C.
- Medicines that prolong the QT interval such as medicines for treatment of infections, such as: clarithromycin, ciprofloxacin, ofloxacin or levofloxacin.
- Medicines for treatment of heart problems, called beta blockers, such as: propranolol.
- Medicines called calcium channel blockers for treatment of angina or hypertension, such as: diltiazem or verapamil.
- Medicines for treatment of constipation (laxatives), such as: bisacodyl or senna.
- Medicines for treatment of high cholesterol levels (statins), such as: simvastatin or atorvastatin.

Inform the doctor or pharmacist and do not take Procor in combination with the following medicines:
- Other medicines for treatment of arrhythmias, such as: sotalol, quinidine, procainamide, disopyramide or bretylium.
- Medicines for treatment of infections, such as: intravenous erythromycin, co-trimoxazole, moxifloxacin or pentamidine.
- Medicines for treatment of schizophrenia, such as: chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpride or sertindole.
- Medicines for treatment of other mental conditions, such as: lithium, doxepin, maprotiline or amitriptyline.
- Medicines for treatment of malaria, such as: quinine, mefloquine, chloroquine or halofantrine.
- Medicines for treatment of hay fever, rash or other allergies, called antihistamines, such as: terfenadine, astemizole or mizolastine.
- Medicines for treatment of hepatitis C, such as: sofosbuvir, daclatasvir, simeprevir or ledipasvir.

The following medicines may increase the risk for side effects when taken together with Procor:
- Amphotericin B (when administered intravenously) for treatment of fungal infections.
- Anti-inflammatories (corticosteroids), such as: hydrocortisone, betamethasone or prednisolone.
- Diuretics.
- General anesthesia medicines or high-dose oxygen during surgery.
- Tetracosactide for diagnostic treatment of hormonal problems.

Procor may increase the effects of the following medicines:
- Cyclosporine and tacrolimus, used to prevent transplant rejection.
- Medicines for treatment of impotence, such as: sildenafil, tadalafil or vardenafil.
- Fentanyl (painkiller).
- Ergotamine (for treatment of migraine).
- Midazolam (for treatment of anxiety or sedation before surgery).
- Colchicine (for treatment of gout).
- Flecainide (another anti-arrhythmic agent). Your doctor should monitor the treatment, and may decrease the dosage of flecainide to half the dosage you are currently taking.
- Lidocaine (for local anesthesia).
- Warfarin (a medicine for prevention of blood coagulation).
- Digoxin (from a group of agents called digitalis; for treatment of cardiac problems).
- Dabigatran (a medicine for blood thinning).

Use of the medicine and food
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 number of alcoholic drinks during treatment with the medicine, since alcohol can increase the risk of liver problems during treatment with the medicine. Consult the doctor or pharmacist regarding the amount of alcohol you can drink.

Pregnancy, breastfeeding and fertility
Before starting to use the medicine, tell the doctor if you are pregnant, may be pregnant, are planning a pregnancy or are breastfeeding.
The medicine usually is not recommended for use during pregnancy.
Do not use this medicine if you are breastfeeding or plan to breastfeed, since small amounts of the medicine may pass into the breast milk.

Driving and operating 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 ingredients of the medicine
- This medicine contains **lactose (a kind of sugar)**. 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 lactose monohydrate.
- This medicine contains **iodine**, which may cause thyroid problems (see section "Do not use the medicine if you").

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 treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.
Swallow the medicine with a little water, with or after a meal.
If necessary, the tablet can be halved for immediate use. There is no information about crushing or chewing the tablet.
Use in children and infants: This medicine is not intended for children and infants.
If you feel that the effect of the medicine is too weak or strong, do not change the dosage on your own. Consult your doctor.

Elderly patients: A lower dosage of **Procor** may be prescribed for elderly patients. In addition, blood pressure should be monitored and thyroid function tested regularly in these patients.
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 that may occur when taking an overdose are: feeling dizzy, faint or tired, confusion, slow heartbeat, damage to the liver or vomiting.
If you forgot 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 forgotten dose and take the next dose at the regular time. Never take two doses together!
If you stop taking the medicine, the heart rate disturbances may recur, which may be dangerous.
Even if there is an improvement in your health, **do not stop treatment with the medicine without consulting the doctor or pharmacist.**
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 **Procor** 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.
Procor may remain in your body for up to one month after discontinuation of the treatment; you may still suffer from side effects in this period.
Stop using the medicine and refer to a doctor or proceed to a hospital immediately if you experience:
- An allergic reaction, whose signs may include rash, swallowing or breathing difficulties, swelling of eyelids, face, lips, throat or tongue.
- Blisters or skin exfoliation around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. These effects may indicate a condition called "Stevens-Johnson syndrome".
- Severe rash accompanied by blisters, where skin layers may peel off and leave large areas of exposed skin over the body. In addition, you may suffer from the following symptoms: malaise, fever, chills and achy muscles (toxic epidermal necrolysis).
- Dermatitis characterized by blisters filled with fluid (bullous dermatitis).
- Flu-like symptoms and rash on the face, followed by worsening of these symptoms (extensive rash with high fever), elevated levels of liver enzymes that are observed in blood tests and elevation in a certain type of white blood cells (eosinophilia) and enlarged lymph nodes (DRESS).

Common side effects (effects that occur in 1-10 in 100 patients):
- Yellowing of skin or whites of the eyes (jaundice), fatigue, nausea, lack of appetite, stomach pain or high fever. These may be symptoms of liver problems or damage, which 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 inflammation, which may be very dangerous.

Uncommon side effects (effects that occur in 1-10 in 1,000 patients):
- Worsening of irregularities in and instability of heart rhythm. This condition may cause a heart attack; therefore, proceed to a hospital immediately.

Very rare side effects (effects that occur in less than one in 10,000 patients):
- Loss of vision in one eye or blurred vision and color blindness, sensation of pain or sensitivity in the eye, and pain when moving the eye. These may be symptoms of an illness called "optic neuropathy" or "neuritis".
- Slowing or cessation of heartbeats. If you experience this effect, immediately proceed to hospital.

Side effects with unknown frequency (effects whose frequency has not yet been determined):
- Lupus-like syndrome (a condition in which the immune system attacks different parts of the body, and causes pain, stiffness and swelling of the joints and red skin on the face, sometimes in the shape of butterfly wings).

Stop use of the 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 patients):
- 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 patients):
- Skin rash caused by narrow or blocked blood vessels (vasculitis).
- Headaches (which usually worsen in the morning or happen after coughing or straining), nausea, convulsions, fainting, vision disturbances or confusion. These symptoms could be indicative of a problem in the brain.
- Motor problems, including instability, 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 heart rhythm problems.

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- Chest pains, shortness of breath and heart rate disturbances. These may be symptoms of a condition called "torsade de pointes".

Cases of pulmonary bleeding have been reported in patients who took **Procor**. Refer to a doctor immediately if you have a bloody cough.
Refer to a 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 patients):
- Blurred vision or seeing a colored halo in dazzling light.

Common side effects (effects that occur in 1-10 in 100 patients):
- 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 gray 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 patients):
- Muscle cramps, stiffness or spasm.

Very rare side effects (effects that occur in less than one in 10,000 patients):
- 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 effects could be symptoms of anemia.
- Tendency to bleed or bruise more easily than usual (may be a symptom of a blood disorder called thrombocytopenia).
- Feeling unwell, confusion or weakness, nausea, loss of appetite, irritability. These effects could be symptoms of a disorder in secreting antidiuretic hormone (syndrome of inappropriate anti-diuretic hormone secretion (SIADH)).

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- Intense stomachache which may be felt all the way to your back. This effect may be a symptom of pancreatitis.

Refer to a 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 patients):
- 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 "Protection of the skin from sunlight").

Common side effects (effects that occur in 1-10 in 100 patients):
- Slightly slowed heart rate.
- Nightmares, sleep disturbances.
- Constipation.
- Itchy, scaly rash (eczema).

Uncommon side effects (effects that occur in 1-10 in 10,000 patients):
- Dry mouth.

Very rare side effects (effects that occur in less than one in 10,000 patients):
- Headaches.
- Balance problems and dizziness, vertigo.
- Difficulty in getting or maintaining an erection or in ejaculating.
- Hair loss, balding.
- Skin rash.
- Skin redness during radiotherapy.

Side effects of unknown frequency (effects whose frequency has not been determined):
- Urticaria (itchy, lumpy rash).
- Granulomas (small and red lumps on the skin or in the body that can be seen in an x-ray).
- Decrease in hunger sensation.
- Uncontrolled movements, especially of the tongue, mouth, jaw, arms and legs (Parkinsonism).
- Feeling of confusion or seeing or hearing non-existing things.
- Distorted sense of smell (parosmia).

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), 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 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.
- Do not discard medicines in the wastewater or household waste bin. Consult a pharmacist as to 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:
Lactose Monohydrate, Maize Starch, Povidone, Magnesium Stearate, Colloidal Silicon Dioxide.
The preparation contains lactose
Each **Procor** tablet contains 200 mg lactose monohydrate.
What the medicine looks like and the contents of the package:
Procor is packaged in trays (blisters) which are provided in a carton package. Each **Procor** package has 30 tablets.
Procor tablets are white, circular and biconvex, 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: 038 81 22620 01.
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