

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

AmioCard tablets 200 mg

Each tablet contains: Amiodarone Hydrochloride 200 mg
For inactive ingredients and allergens in the preparation – see section 2 “Important information about some ingredients of the medicine” and section 6 “Additional information”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. 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 babies and children.

1. What is the medicine intended for?

The medicine is intended for treatment of coronary insufficiency and arrhythmias resistant to other treatments.
Therapeutic class: Antiarrhythmic drugs.

The mechanism of action of this 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 this medicine if:

- You are sensitive (allergic) to the active ingredient amiodarone, to iodine or to any of the additional components the medicine contains. Symptoms of an allergic reaction include: rash, swallowing or breathing difficulties, swelling of the lips, face or tongue.
- You have or have had in the past slower than usual heartbeats (a phenomenon called 'sinus bradycardia') or an illness called 'sino-atrial' heart block.
- You have other types of arrhythmias and you **do not** have an implanted pacemaker.
- You suffer or have suffered in the past from thyroid dysfunction. Your doctor should check your thyroid function before beginning treatment with the medicine.
- You are taking other medicines that may cause arrhythmias (see section “Drug interactions”).
- You are taking medicines for treatment of infections (see section “Drug interactions”).
- You are taking medicines for treatment of schizophrenia or other mental conditions (see section “Drug interactions”).
- You are taking medicines for treatment of malaria (see section “Drug interactions”).
- You are taking medicines for treatment of hay fever, rashes or other allergies, called antihistamines (see section “Drug interactions”).
- You are taking medicines for treatment of hepatitis C (see section “Drug interactions”).
- You are pregnant or breastfeeding (see section “Pregnancy, breastfeeding and fertility”).
- You are on a waiting list for a heart transplantation. Your doctor may change your treatment. The reason for that is that taking Amiocard before heart transplantation has shown an increased risk for a life-threatening complication (primary graft dysfunction, PGD), in which the transplanted heart stops functioning properly within the first 24 hours after surgery.

Special warnings regarding the use of the medicine:

⚠ Before treatment with AmioCard, inform the doctor if:

- You have heart failure.
- You suffer from liver problems.
- You have any lung problems or asthma.
- You have visual problems, including optic neuritis.
- You are about to undergo surgery.
- You are elderly (over 65 years old). Your doctor will have to closely monitor your condition.

- You have an implanted cardiac pacemaker or an implantable cardioverter defibrillator (ICD). Your doctor will have to make sure that the device is working properly shortly after beginning treatment with this medicine or if the dosage is changed.
- You have 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’.
- You have 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 feel unwell and have fever, chills and muscle pain (toxic epidermal necrolysis).
- You 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
 - Almost fainting or fainting

⚠ Protection of the skin from sunlight:

You should 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 sunlight exposure and may burn, tingle or develop severe blisters unless you take the following precautions: be sure to use a high SPF sunscreen, and always wear a hat and clothes that cover your arms and legs.

⚠ Tests and follow-up:

During treatment with this medicine, your doctor will perform regular liver function tests, since AmioCard may affect liver function. If such an effect does occur, your doctor will decide whether you should continue taking these tablets. Your doctor may perform regular thyroid function tests during treatment with the medicine, since it contains iodine, which may cause thyroid problems.

Your doctor may perform other regular tests, such as: blood tests, chest x-ray, ECG (an electrical test of your heartbeat) and eye tests before and during treatment with the medicine.

⚠ Drug interactions:

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

Especially inform the doctor or pharmacist if you are taking:

- Sofosbuvir for treatment of hepattitis C.
- Medicines that may prolong QT interval such as medicines for treatment of infections, such as: clarithromycin, ciprofloxacin, ofloxacin or levofloxacin.
- Medicines for treatment of heart disorders called beta blockers, such as: propranolol.
- Medicines called calcium channel blockers for treatment of angina pectoris 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 AmioCard 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, rashes 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 of experiencing side effects when taken together with AmioCard:

- Amphotericin B (when administered intravenously) for treatment of fungal infection.
- Anti-inflammatory agents (corticosteroids), such as: hydrocortisone, betamethasone or prednisolone.
- Diuretics.
- General anesthesia medicines or high-dose oxygen during surgery.
- Tetracosactide for diagnostic treatment of hormonal problems.

AmioCard may increase the effects of the following medicines:

- Cyclosporine, tacrolimus and sirolimus, for prevention of transplant rejection.
- Medicines for treatment of impotence, such as: sildenafil, tadalafil or vardenafil.
- Fentanyl, for pain management.
- Ergotamine, for treatment of migraines.
- Midazolam, for treatment of anxiety or for tranquilizing before surgery.
- Colchicine, for treatment of gout.
- Flecainide, another antiarrhythmic agent. Your doctor should monitor the treatment, and may decrease the dosage of flecainide by half.
- Lidocaine, a local anesthetic.
- Warfarin, for prevention of blood coagulation.
- Digoxin, for treatment of cardiac problems.
- Dabigatran, for blood thinning.

⚠ Use of the medicine and food:

Do not drink grapefruit juice during treatment with this medicine. Consumption of grapefruit juice while taking AmioCard may increase your risk for side effects.

⚠ Use of the medicine and alcohol consumption:

Alcohol consumption should be limited while taking this medicine, since it may increase your risk for liver problems. Consult with the doctor or pharmacist about the amount of alcohol you may be allowed to drink.

⚠ Pregnancy, breastfeeding and fertility:

Before taking the medicine, tell the doctor if you are pregnant, might be pregnant, planning to become pregnant or breastfeeding. This medicine is not normally used during pregnancy.

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

⚠ Driving and operating machinery:

Using this medicine may cause blurred vision. If you feel this effect, do not drive a vehicle or operate dangerous machinery or equipment.

⚠ Important information about some ingredients of the medicine:

The medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine. Each tablet contains 60 mg lactose.

3. How should you use the medicine?

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

Do not exceed the recommended dose.

This medicine is not intended for babies and children.

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

Method of administration: The medicine should be swallowed with some water, with or after a meal.

Crushing/halving/chewing

The tablet may be halved as needed to help swallowing. The tablet may be crushed and all parts should be swallowed immediately.

If you accidentally take a higher dosage the following symptoms may occur: feeling of dizziness, fainting or tiredness, confusion, slow heartbeat, damage to the liver or vomiting. If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forget to take this medicine at the required time, take the next dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose in order to compensate for the dose that you forgot to take.

Follow the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

If you stop taking the medicine the arrhythmia may return. This may be dangerous.

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

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using AmioCard may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them. AmioCard may remain in your body for up to one month after stopping the treatment, you may still suffer from side effects during that time.

Stop using the medicine and refer to a doctor or go to a hospital immediately if you experience:

- An allergic reaction. The symptoms may include: rash, difficulty breathing or swallowing, 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 feel unwell and have fever, chills and muscle pain (toxic epidermal necrolysis).
- Inflammation of the skin characterized by blisters filled with fluid (bullous dermatitis).
- Flu-like symptoms and rash on the face, followed by 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 - side effects that occur in 1-10 out of 100 users:

- Yellowing of the skin or the eyes (jaundice), feeling of tiredness, nausea, loss of appetite, abdominal pain or high fever. These effects could be signs of liver problems or damage, which may be very dangerous.
- Shortness of breath or breathing difficulty (which may gradually worsen), feeling of tightness in the chest, persistent cough, wheezing, weight loss and fever. These may be symptoms of pneumonia that may be very dangerous and can occur at any time after starting the treatment.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:

- Worsening of erratic and unstable heart rate. This condition may lead to a heart attack; therefore, you should proceed to a hospital immediately.

Very rare side effects - side effects that occur in less than one out of 10,000 users:

- Loss of vision in one eye or the vision becomes dim and colorless. Sensation of pain or sensitivity in the eyes and pain when they move. These effects may be symptoms of an illness called 'optic neuropathy' or 'neuritis'.
- Slowing or stopping of heartbeats. If you sense this effect, proceed to a hospital immediately.

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, causing pain, stiffness and swelling of the joints and red skin on the face, sometimes in the shape of butterfly wings).

Stop using this medicine and refer to a doctor immediately if you suffer from the following severe side effects – you may require urgent medical attention:
Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:

- Numbness or weakness, tingling or burning sensation in any part of the body.

Very rare side effects - side effects that occur in less than one out of 10,000 users:

- Skin rash caused by narrowing or blockage of blood vessels (called 'vasculitis').
- Headaches (which usually worsen in the morning or occur after coughing or exertion), nausea, spasms, fainting, visual problems 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 effects may be symptoms of very slow heart rate (especially in people over 65 years of age), or other problems with your natural heart rate.

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Chest pain, shortness of breath and irregular heart rate. These may be symptoms of a condition called “Torsade de pointes”.
- A life-threatening complication following a heart transplantation (primary graft dysfunction), in which the transplanted heart stops functioning properly (see section 2).

Certain cases of lung bleeding have been reported in patients taking the medicine. Refer to the doctor immediately if you cough up any blood.

Contact the doctor as soon as possible if you suffer from the following side effects:

Very common side effects - side effects that occur in more than one out of ten users:

- Blurred vision or seeing a colored halo in dazzling light.
- Feeling extremely restless or agitated, weight loss, increased sweating, intolerance to heat. These could be symptoms of an overactive thyroid (hyperthyroidism).
- Extreme fatigue, weakness or exhaustion, weight gain, intolerance to cold, constipation and muscle pain. These could be symptoms of an underactive thyroid (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 - side effects that occur in 1-10 out of 1,000 users:

- Muscle cramps, stiffness or spasms.

Very rare side effects - side effects that occur in less than one out of 10,000 users:

- Swelling of the testicles.
- Scaly red patches on the skin, hair loss or loosening of nails (called 'exfoliative dermatitis').

- Feeling tired, fainting, dizziness and pale skin. These could be signs of anemia.
- Tendency to bleed or bruise more easily. These effects may be symptoms of blood problems (called 'thrombocytopenia').
- Feeling unwell, confusion or weakness, nausea, loss of appetite, nervousness. These may be symptoms of an illness called 'syndrome of inappropriate anti-diuretic hormone secretion (SIADH)'.

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Intense abdominal pain which may be felt all the way to your back. This effect may be a symptom of pancreatitis.

Refer to the doctor or pharmacist if any of the following side effects worsens or lasts longer than a few days:

Very common side effects - side effects that occur in more than one out of ten users:

- Nausea or vomiting.
- Changes in the sense of taste.
- Changes in the amount of liver enzymes in the beginning of treatment. This can be observed in blood tests.
- Tendency for skin burns upon exposure to the sun (see section 2 “Protection of the skin from sunlight”).

Common side effects - side effects that occur in 1-10 out of 100 users:

- Slightly slower heart rate.
- Nightmares, sleep disturbances.
- Constipation.
- Itchy and scaly rash (eczema).
- Decreased libido.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:

- Dry mouth.

Very rare side effects - side effects that occur in less than one out of 10,000 users:

- Headache.
- Balance disorders and dizziness (vertigo).
- Disturbances in achieving and maintaining an erection or ejaculating.
- Hair loss, balding.
- Skin rash.
- Skin redness due to radiotherapy.

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Hives (itchy, lumpy rash).
- Granulomas, little red masses which appear on the skin or inside the body and can be identified 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).
- Seeing, hearing or sensing things that are not there (hallucinations).
- Catching more infections than usual, which may be caused by a decrease in white blood cells (neutropenia).
- A severe decrease in the number of white blood cells, which increases the risk for infections (agranulocytosis).

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

Reporting side effects:

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor. Do not use the medicine after the expiry date (EXP)

appearing on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C. Store in the original package to protect from light.

6. Additional information:

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

Lactose, Maize starch, Povidone, Magnesium stearate, Colloidal silicone dioxide.

What does the medicine look like and what are the contents of the package:

The package contains 3 blister trays, each containing 10 tablets. Each beige-white tablet has a diameter of 10 mm, is odorless, biconvex, and has a score line.

Address of marketing authorization holder/ manufacturer: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi 83057.

Registration number of the medicine in the national drug registry of the Ministry of Health: 052072351700

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