

PATIENT INFORMATION LEAFLET

KARDIYOMIL 10 mg / 10 ml I.V. ampoule containing solution for injection / infusion

Sterile

Administered intravenously

- **Active ingredient:**

Each ampoule (10 ml) contains 10 mg of milrinone.

- **Excipients:**

Lactic acid, dextrose anhydrous (glucose), sodium hydroxide and water for injection.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION LEAFLET. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

In this patient information leaflet:

1. *What KARDIYOMIL is and what it is used for?*
2. *Before you are given KARDIYOMIL*
3. *How to use KARDIYOMIL?*
4. *Possible side effects*
5. *How to store KARDIYOMIL*

Headings are included.

1. What KARDIYOMIL is and what it is used for?

KARDIYOMIL is a clear, pale yellow-colorless, sterile, solution containing colorless glass ampoule administered intravenously and used in the treatment of some heart diseases.

KARDIYOMIL is presented in packages containing 1 piece of 10 ml solution in a colorless glass ampoule in a box.

KARDIYOMIL can be used in the following situations:

- In the short-term treatment of severe congestive heart failure that does not respond to conventional treatment (heart cannot pump blood as much as the body needs),
- It is used in the treatment of patients with acute heart failure, including low output (out-put) after cardiac surgery.

KARDIYOMIL can be used in children with:

- In the short-term treatment (up to 35 hours) of severe congestive heart failure (the heart cannot pump blood as much as the body needs), in cases where results cannot be obtained with other drugs.
- In the short-term treatment (up to 35 hours) of patients with acute heart failure after cardiac surgery, for example in cases where there is a problem with the heart pumping blood to the body.

2. Before you are given KARDIYOMIL

DO NOT USE KARDIYOMIL in the following cases:

If;

- You are allergic to the excipients and / or Milrinone in the content of KARDIYOMIL,
- If you have signs of an allergic reaction: rash, swallowing or breathing problems, swelling of your lips, face or throat,
- There is a condition of severe hypovolemia (abnormal decrease in blood plasma volume).

Take SPECIAL CARE with KARDIYOMIL in the following cases:

If;

- You have or have just had a heart attack,
- You have serious heart valve problems such as narrowing, thickening or blocked heart valves.
- You have an irregular or uncontrollable fast heartbeat, palpitations in your heart, lightheadedness, fainting and shortness of breath.
- You have low blood pressure that can cause dizziness, lightheadedness or fatigue (fainting),
- You are taking diuretic tablets (diuretics) because of your heart problems,
- The amount of potassium in your blood is low (your doctor may order a blood test to check this).
- You have kidney problems,

These warnings are valid for you, even at any time in the past, please consult your doctor.

Pediatric Patients

Before using KARDIYOMIL, your doctor will check many parameters such as heart rhythm and blood pressure, and will also ask for blood tests.

If your child's heart rhythm or blood pressure is unstable, the KARDIYOMIL infusion will not be started.

If;

- Your child has kidney problems,
- Your child is a preterm infant or has a low birth interval,
- Your child has a heart condition called Patent Ductus Arteriosus *,

* Patent Ductus Arteriosus: The connection between 2 main blood vessels (aorta and pulmonary artery) (which are open when they should be closed).

In such cases, your doctor will decide whether your child should be treated with KARDIYOMIL.

Use of KARDIYOMIL with food and drink

There is no interaction with food and drinks in terms of administration method.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

There is not enough clinical data on the use of the drug in pregnant women.

KARDIYOMIL should not be used during pregnancy unless necessary.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using the medicine.

The safety of milrinone use in nursing mothers has not been established. Therefore, it is not recommended to use KARDIYOMIL during breastfeeding.

Driving and using machines

There is not enough information.

Important information about some of the excipients contained in KARDIYOMIL content

KARDIYOMIL contains 470 mg anhydrous dextrose (glucose) per dose (10 ml). Therefore, no glucose-related effects are expected.

Using other medicines

KARDIYOMIL may affect the way some other medicines work. At the same time, KARDIYOMIL may be affected by the intake of different drugs. Tell your doctor if you are using the following drugs.

- Medicine used for heart problems such as digoxin
- Diuretic drugs
- Medicines to treat high blood pressure or angina (chest pain), such as amlodipine, nifedipine or felodipine.

If you are currently using or have recently used any prescribed or non-prescribed medicine, please inform your doctor or pharmacist.

3. How to use KARDIYOMIL

Instructions for use and dose/frequency of administration:

Your doctor will determine the dose of your medicine depending on your illness and administer it to you.

Route of administration and method:

KARDIYOMIL will be administered to you by a doctor or nurse. Because this drug should be used by injection.

This drug should be diluted with 0.45% sodium chloride, 0.9% sodium chloride or 5% dextrose and

used within 24 hours.

Different age groups:

Use in adults and elderly:

- Your doctor will administer the first dose of 50 micrograms per kilogram of your body weight within 10 minutes.
- Following this administration, it will apply a lower dose between 0.375 - 0.75 micrograms per minute per kilogram of your weight according to your needs.
- This drug is usually given for 2-3 days, but can be given up to 5 days if necessary.
- If you are taking this medicine after heart surgery, this medicine will usually be given to you for up to 12 hours.

Pediatric Use:

Your doctor will administer the first dose to your child, ranging from 50 to 75 micrograms per kilogram of weight, over 30-60 minutes.

Then, depending on your child's response to the treatment and the occurrence of side effects, your doctor will continue to administer doses ranging from 0.25 to 0.75 per kilogram of weight per minute. KARDIYOMIL can be administered for a maximum of 35 hours.

Conditions of special use:

Renal impairment

If you have problems with your kidneys, a lower dose will be given.

If you have the impression that the effect of KARDIYOMIL is too strong or too weak, talk to your doctor or pharmacist.

If you use more KARDIYOMIL than you should:

Since this medication will be administered by specialist healthcare professionals, it is unlikely that you will be given more or less medication than is necessary.

However, if more KARDIYOMIL is administered than necessary, the following effects may occur: Dizziness, lightheadedness or fainting (due to low blood pressure) and irregular heartbeat.

If you use more KARDIYOMIL than you should, talk to a doctor or pharmacist.

If you forget to use KARDIYOMIL:

Since this medicine will be administered to you by experienced healthcare professionals, it is unlikely that a dose will be missed and this section does not administer to you.

Do not take double doses to make up for forgotten doses.

If KARDIYOMIL treatment ends, effects may occur:

Your doctor will tell you when the medicine will be given to you as long as it is designed and when to stop. Even if you feel better, you should not stop KARDIYOMIL treatment. Stopping KARDIYOMIL treatment may cause your disease to worsen.

Tests:

Your doctor or nurse will use an electrocardiogram (EKG) to check how well your heart is working. In addition, your blood tests will be done and your blood pressure and heart rate will be checked.

4. Possible side effects

Like all other medicines, KARDIYOMIL may cause side effects in patients with hypersensitivity to any component of the drug.

If any of the following occur, stop using KARDIYOMIL and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- Allergic reactions (difficulty breathing, circulatory disturbance, rash, difficulty swallowing or breathing, swelling of lips, face, throat and tongue, fainting or loss of consciousness)
- Wheezing in the chest
- Muscle weakness
- Swelling and redness of the skin

These are all very serious side effects. If you have one of these, it means you have a serious allergy to KARDIYOMIL. You may need urgent medical assistance or hospitalization. All of these very serious side effects are very rare.

If you notice any of the following, inform your doctor immediately or contact the emergency department of your nearest hospital:

Common (affects less than one in 10 people)

- Irregular, increased, or rapid heartbeat. You may experience heartburn, dizziness, fainting, or shortness of breath.

Uncommon (affects less than one in 100 people)

- Ventricular fibrillation - a serious heart rhythm problem. Symptoms include: very fast or irregular heartbeat (palpitations), dizziness and unconsciousness. Also, signs of illness may appear: cold sweats, shortness of breath, chest pain, nausea.
- Thrombocytopenia * - A blood problem. The symptom is that your skin may bruise more easily than usual.
- Chest pain

Unknown: Decrease in hemoglobin concentration and red blood cell count.

* In infants and children, the risk of thrombocytopenia increased significantly with the duration of the infusion.

Very rare (affects less than one in 10,000 people)

- Torsades de Pointes - a serious heart rhythm disorder. Symptoms include: very fast, rapid or irregular heartbeat (palpitations), dizziness and loss of consciousness. You may also feel sick: cold sweats, shortness of breath, unusually pale skin, and chest pain.
- Breathing difficulties, wheezing or tightness in the chest.

All these are serious side effects. Emergency medical attention may be required.
Serious side effects are very rare.

If you notice any of the following, tell your doctor:

Common: (affects less than one in 10 people)

- Low blood pressure: Symptoms such as blackout, dizziness or fainting. Also, if you notice symptoms such as a fast or irregular heartbeat or chest pain, this is a more serious side effect (see above).
- Headache

Uncommon (affects less than one in 100 people)

- Feeling weak
- Low potassium in the blood: Symptom, fatigue, confusion, muscle weakness and muscle cramps.
- A blood test, which can show that the liver is working.

Very rare (affects less than one in 10,000 people)

- Rashes at the injection site, including the skin.

In addition to the side effects observed in adults, the following effects have been reported in children:

Unknown:

- Intraventricular bleeding (internal bleeding in fluid-filled areas (ventricles) surrounding the brain).
- A heart disease known as patent ductus arteriosus (the ductus arteriosus is a vein that provides the connection between the artery, which has very important functions in the circulation before birth, and the pyramidal arteries). When this disease becomes more severe, there is a passage of blood towards the pulmonary artery.
- In addition, compared to adults, a decrease in the number of platelets in the blood is more common in children and the risk of these side effects increases with the duration of the infusion of KARDIYOMIL. Heart rhythm problems are less common in children than in adults.

If you experience any side effects that are not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store KARDIYOMIL

Keep KARDIYOMIL in places out of sight and reach of children and within the packaging.

Store at room temperature below 25 ° C, do not freeze.

Use in accordance with the expiry date.

Do not use KARDIYOMIL after the expiration date which is stated on the package.

If you notice any damage to the product and / or package, do not use KARDIYOMIL.

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This leaflet was approved on 10/06/2016