

## PATIENT INFORMATION LEAFLET

### CARDIPASSIVE cardioplegic solution for cardiac perfusion

#### Intracardiac use.

#### Sterile

- **Active ingredient:** Each 1000 ml contains 6430 mg Sodium Chloride 176 mg Calcium Chloride Dihydrate, 3253 mg Magnesium Chloride Hexahydrate and 1193 mg Potassium Chloride.
- **Excipients:** Hydrochloric acid (pH adjuster), sodium hydroxide (pH adjuster), Water for Injection.

**Please read this PATIENT INFORMATION LEAFLET carefully before starting to use the drug; because important information is included here.**

- *Keep this PATIENT INFORMATION LEAFLET. You may need to re-read it later.*
- *In case you have additional questions, please consult your doctor or pharmacist.*
- *This drug is prescribed personally for you, do not give to others.*
- *During the use of this drug, please tell your doctor that you are using this drug when you visit your doctor or a hospital.*
- *Please follow these instructions strictly. Do not use dosages **higher or lower** than the dosage recommended to you.*

#### In this leaflet:

- 1. What is CARDIPASSIVE and what it is used for**
- 2. Before you are given CARDIPASSIVE**
- 3. How you will be given CARDIPASSIVE**
- 4. Possible side effects**
- 5. How to store CARDIPASSIVE**

#### headlines are included.

#### 1. What is CARDIPASSIVE and what it is used for?

- CARDIPASSIVE is offered for use in PP bag with plastic container.
- Each 1000 mL bag contains 6430 mg calcium chloride, 176 mg Calcium chloride dihydrate, 3253 mg magnesium chloride hexahydrate, 1193 mg potassium chloride as active ingredients.
- CARDIPASSIVE is used to induce cardiac arrest during open heart surgeries performed by ischemia and hypothermia.

## **2. What you need to know before you use *CARDIPASSIVE***

### **DO NOT USE *CARDIPASSIVE* under the following conditions:**

- If you are allergic to any of the active ingredients or excipients in the composition of this medicine (see list of excipients).
- Do not use *CARDIPASSIVE* without adding sodium bicarbonate.
- *CARDIPASSIVE* is not for intravenous administration.
- Do not use *CARDIPASSIVE* if the solution is not clear or the package is not intact. Discard unused portion.

If these warnings apply or applied to you, please consult your physician before the usage of *CARDIPASSIVE*.

### **USE *CARDIPASSIVE* CAREFULLY under following conditions:**

*CARDIPASSIVE* is intended only for use during cardiopulmonary bypass when the coronary circulation is isolated from the systemic circulation

If large volumes of *CARDIPASSIVE* are infused and allowed to return to the heart lung machine without any venting from the right heart, then plasma magnesium and potassium levels may rise. Development of severe hypotension and metabolic acidosis while on bypass has been reported when large volumes (8 to 10 liters) of solution are instilled and allowed to enter the pump and then the systemic circulation. In case of large volume use of *CARDIPASSIVE* right heart venting is recommended.

It should not be used without adding a suitable buffer such as 8.4% sodium bicarbonate.

After the buffer addition, it should be cooled to 4°C prior to use of *CARDIPASSIVE* and must be used within 24 hours.

Myocardial temperature should be monitored during surgery to maintain hypothermia. Continuous electrocardiogram monitoring is essential to detect changes in myocardial activity during the procedure.

Appropriate equipment to defibrillate the heart following cardioplegia should be readily available.

Inotropic support drugs should be available during postoperative recovery.

*CARDIPASSIVE* bag should not be used in series connection applications.

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

### **Use of *CARDIPASSIVE* with foods and drinks**

No interaction is expected due to the route of administration of *CARDIPASSIVE*

## **Pregnancy**

*Consult your doctor or pharmacist before using this drug.*

Tell your doctor if you are pregnant or if you think you may be pregnant. CARDIPASSIVE should only be given by your doctor if it is necessary.

*In case you realize that you are pregnant during the treatment, immediately consult your doctor or pharmacist.*

## **Lactation**

*Consult your doctor or pharmacist before using this drug.*

## **Driving and using machines**

CARDIPASSIVE has no side effect on the ability for driving and using machines.

## **Important information about some excipients contained in CARDIPASSIVE**

This medicinal product contains 110 mmol sodium per 1000 mL as active ingredient. This should be considered for patients on a controlled sodium diet.

This medicinal product contains 16 mmol potassium per 1000 ml as active ingredient. This should be considered for patients with decreased renal function or patients on a controlled potassium diet.

## **Taking with other medicines**

There may be incompatibility between the drugs used with CARDIPASSIVE. Consult your pharmacist in case of doubt.

When introducing additives, use aseptic technique, mix thoroughly. Do not store the remaining solution.

*If you are currently using any prescribed or unprescribed drug, or if you have used them recently, please inform your doctor or pharmacist.*

## **3. How CARDIPASSIVE will be given?**

- **Instructions for proper use and dosage/administration intervals:**

CARDIPASSIVE should be used only by those trained to perform open heart surgery

- **Route and method of administration:**

Intracardiac use

- **Different age groups:**

### **Children:**

Since the safety and effectiveness of CARDIPASSIVE is not determined in children, it should not be used in this age group.

**Elderly:**

Elderly patient should be started at the low of the dosage in the treatment.

- **Special conditions of use**

**Renal/hepatic impairment:****Renal impairment:**

There is no information available.

**Hepatic impairment:**

There is no information available.

*If you have an impression that the effect of CARDĪPASSĪVE is too strong or too weak, consult your doctor or pharmacist.*

**If you use more CARDĪPASSĪVE than you should:**

Since CARDĪPASSĪVE will be used under the supervision of a doctor, necessary measures will be taken to prevent such a situation. If this is the case, appropriate treatment will be given.

*Consult a doctor or a pharmacist if you used more CARDĪPASSĪVE than you should.*

**If you forget to take CARDĪPASSĪVE:**

Since CARDĪPASSĪVE will be used under the supervision of a doctor, necessary measures will be taken to prevent such a situation.

*Do not take double dosage to balance the skipped dosage.*

**Possible effects related to the termination of the treatment with CARDĪPASSĪVE:**

Since CARDĪPASSĪVE will be used under the supervision of a doctor, necessary measures will be taken to prevent such a situation. If this is the case, appropriate treatment will be given.

**4. Possible side effects**

Like all drugs, CARDĪPASSĪVE also can cause adverse effects in individuals who are hypersensitive against any of the ingredients.

Side effects of CARDĪPASSĪVE are natural conditions for open heart surgery such as heart attack and irregular heart rate.

Spontaneous recovery after cardioplegic cardiac arrest may be delayed or absent when circulation is restored.

It may be necessary to restart the cardiac with a suitable device to restore cardiac functions.

*In case you encounter any adverse effects not mentioned in these PATIENT INFORMATION LEAFLET, please inform your doctor or pharmacists.*

### **5. How to store *CARDİPASSİVE***

*Keep *CARDİPASSİVE* in places out of sight and reach of children and within the original packaging.*

It must be kept in its original packaging at temperatures under 25°C.

The solution prepared by adding 10 mL of 8.4% sodium bicarbonate is stable for 24 hours at 4°C.

### **Use according to the expiry date.**

*Do not use *CARDİPASSİVE* after the expiry date indicated on the package.*

*If you notice any irregularities in the product and/or its packaging, do not use *CARDİPASSİVE*.*

*Do not throw away any expired or unused medicines! For disposal of medical waste, please follow local regulations.*

### ***Marketing Authorization Holder and Manufacturing Site:***

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.

Vakıflar OSB Mahallesi, Sanayi Caddesi, No:22/1, Ergene/Tekirdağ/TURKEY

Tel: +90 282 675 14 04

Fax: +90 282 675 14 05

*This patient leaflet was approved on 21/02/2019.*

**FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY:**

The following information is intended for surgeon or healthcare professional only.  
Do not use CARDIPASSIVE bag in administration connected in series.

Parenteral products should be inspected for particulate matter and discoloration prior to administration.

**To open:**

Tear outer wrap at notch and remove solution bag. To add 10 ml of 8.4% sodium bicarbonate solution and the necessary medicines, follow directions below before preparing for administration.

**To Add Medication:**

1. Prepare additive port for medicine.
2. Using aseptic technique and an appropriate needle, hole diaphragm and inject. Withdraw needle after injection.
3. The additive port may be protected by covering with an additive cap.
4. Mix bag contents thoroughly.

**Preparation for Administration**

1. Close flow control clamp of administration set.
  2. Remove cover from outlet port at bottom of CARDIPASSIVE bag.
  3. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated.
- Note: In case of using a purified administration set, replace the antibacterial filter with the cannula protective cap.
4. Suspend container from hanger.
  5. Squeeze and release drip chamber to establish proper fluid level in chamber.
  6. Attach aortic infusion device to set
  7. Open flow control clamp to expel air from set and aortic infusion device. Close clam
  8. Position aortic infusion device to introduce solution into aortic root.
  9. Regulate rate of administration with flow control clamp