

Approved Patient Information Leaflet for Cardioplegic Induction Solution Fresenius and Cardioplegic Maintenance Solution Fresenius

SCHEDULING STATUS

S3

Cardioplegic Induction Solution Fresenius 3,757 g/500 ml

Cardioplegic Maintenance Solution Fresenius 1,375 g/500 ml

Solutions for infusion

Potassium chloride

Sugar free.

Read all of this leaflet carefully before you are given Cardioplegic Fresenius solution

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What **Cardioplegic Fresenius** solution is and what it is used for
2. What you need to know before you are given **Cardioplegic Fresenius** solution
3. How to receive **Cardioplegic Fresenius** solution
4. Possible side effects
5. How to store **Cardioplegic Fresenius** solutions
6. Contents of the pack and other information.

1. What Cardioplegic Fresenius solution is and what it is used for

Cardioplegic Fresenius solutions belong to a group of medicines called electrolyte solutions. It is used in heart surgery where the heart is temporarily stopped during surgery while the blood flow is being redirected.

2. What you need to know before you are given Cardioplegic Fresenius solution

Cardioplegic Fresenius solutions should not be given to you:

- if you are hypersensitive (allergic) to potassium chloride or any of the other ingredients of **Cardioplegic Fresenius** solutions (listed in section 6)
- if you have blood abnormalities such as high levels of chloride or potassium
- if you have very poor kidney function with reduced urine production or failure to produce urine
- if you have certain types of heart failure
- if you have Addison's disease (a rare disorder of the adrenal glands which produce specific hormones)
- if you suffer from fluid and sodium retention (swelling)
- if you are having a stroke caused by a blood clot
- if you have head trauma (first 24 hours).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- if you have heart disease or heart failure
- if you have liver disease
- if you have kidney disease or poor kidney function
- if you have problems with your adrenal glands
- if you are dehydrated
- if you have high blood pressure
- if you have high blood pressure in pregnancy
- if you have swelling or any other conditions associated with sodium retention
- if you are suffering from a temporary illness
- if you are in pain

- if you have just had another operation
- if you have an infection
- if you have burn wounds, especially if you have extensive tissue damage
- if you have a central nervous system disease
- if you have been exposed to any of the medicines mentioned under “**Other medicines and Cardioplegic Fresenius solutions**”
- if you have swelling of the brain, as you are more at risk of brain injury
- if you have inflammation, bleeding or bruising of the brain
- if **Cardioplegic Fresenius** solutions are given to children (including babies and older children) because their bodies might have reduced ability to regulate salts and fluids
- if **Cardioplegic Fresenius** solutions are given to the elderly because they are generally more likely to have heart, kidney or liver diseases or be on other medicines.

Children

Children (including babies and older children) are at increased risk of developing low sodium levels and brain damage because their bodies may have reduced ability to regulate salts and fluids. The dosage will therefore be carefully monitored by a doctor experienced in paediatric intravenous fluid therapy.

Other medicines and Cardioplegic Fresenius solutions

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following:

- Lithium – used to treat mood swings and some forms of depression. Administration of **Cardioplegic Fresenius** solutions can result in decreased lithium levels.
- Medicines used to pass more urine, called diuretics, as these medicines increase the risk of having low sodium levels in your blood.

- Medicines that increase the potassium levels in your blood such as potassium sparing diuretics (e.g. amiloride, spironolactone, triamterene).
- Medicines used to treat epilepsy (e.g. carbamazepine, oxcarbazepine).
- Medicines used to treat certain mental conditions, called psychotropics or antipsychotics.
- Chlorpropamide – used to treat high blood sugar (diabetes).
- Clofibrate – used to treat high cholesterol.
- Medicines used to treat certain types of cancer (e.g. vincristine, ifosfamide, cyclophosphamide).
- Medicines used to treat depression, called selective serotonin reuptake inhibitors (SSRIs).
- Medicines used to treat severe pain, called narcotics.
- Medicines used to treat pain and inflammation, called nonsteroidal anti-inflammatory drugs (NSAIDs).
- Desmopressin – used to reduce urine production.
- Oxytocin – used in childbirth.
- Terlipressin – used to treat low blood pressure.
- Medicines used to treat high blood pressure, called angiotensin converting enzyme inhibitors (ACE inhibitors).
- Cyclosporin – used to suppress the immune system e.g. in organ transplants.
- Medicines that contain potassium such as potassium salts of penicillin (an antibiotic used to treat infections).
- Corticosteroids - used to treat rheumatoid arthritis, inflammatory bowel disease (IBD), asthma, allergies and other conditions.

Pregnancy, breastfeeding and fertility

The safety of **Cardioplegic Fresenius** solutions in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving **Cardioplegic Fresenius** solution.

Driving and using machines:

There is no information on the effects of **Cardioplegic Fresenius** solutions on the ability to drive and use machines.

Cardioplegic Fresenius solutions contain sodium.

Cardioplegic Induction Solution Fresenius contains 306 mg sodium (main component of cooking/table salt) in each 500 ml. This is equivalent to 15,3 % of the recommended maximum daily dietary intake of sodium for an adult.

Cardioplegic Maintenance Solution Fresenius contains 289 mg sodium (main component of cooking/table salt) in each 500 ml. This is equivalent to 14,5 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to receive Cardioplegic Fresenius solution

Your doctor will give you **Cardioplegic Fresenius** solution by slow injection into a vein (intravenous injection).

Cardioplegic Fresenius solution will be given to you after it has been mixed with blood and after the addition of glucose injection.

Your doctor will decide which **Cardioplegic Fresenius** solution you should be given and how much you should be given.

You will not be expected to give yourself **Cardioplegic Fresenius** solution. It will be given to you by a person who is qualified to do so.

If you receive more Cardioplegic Fresenius solution than you should:

Since a healthcare provider will administer **Cardioplegic Fresenius** solution, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive Cardioplegic Fresenius solution

Since a healthcare provider will administer **Cardioplegic Fresenius** solution, it is unlikely that the dose will be missed.

4. Possible side effects

Cardioplegic Fresenius solutions can have side effects.

Not all side effects reported for **Cardioplegic Fresenius** solutions are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving **Cardioplegic Fresenius** solution, please consult your healthcare provider for advice.

If any of the following happens, stop receiving Cardioplegic Fresenius solution and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Too much potassium in your blood causing heart rhythm problems, low blood pressure, muscle weakness and/or a heart attack.

- Too little sodium in your blood causing seizures, coma, brain swelling, brain injury and/or death.

These are all very serious side effects. If you have them, you may have had a serious reaction to **Cardioplegic Fresenius** solution. You may need urgent medical attention or further hospitalisation.

Tell your doctor immediately if you notice any of the following:

- Excess water in the body.
- Inflammation of a vein with formation of a blood clot.

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Fever.
- Chills.
- Sweating.
- Inflammation of a vein.
- Leaking of the medicine out of the veins into the surrounding tissue.
- Pain, blistering or infection of the skin surrounding the injection site.

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

Reporting of side effects:

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of **Cardioplegic Fresenius** solutions.

5. How to store Cardioplegic Fresenius solutions

Store at or below 25 °C.

Use immediately after the bag is opened.

Discard any unused portion.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What Cardioplegic Fresenius solutions contain

The active substance is potassium chloride.

Each 500 ml of **Cardioplegic Induction Solution Fresenius** contains 3,757 g potassium chloride.

Each 500 ml of **Cardioplegic Maintenance Solution Fresenius** contains 1,375 g potassium chloride.

The other ingredients are citric acid monohydrate or citric acid anhydrous, hydrochloric acid (for pH-adjustment), sodium chloride, sodium dihydrogen phosphate, sodium citrate dihydrate, tris(hydroxymethyl)aminomethane (tromethamine) and water for injection.
Sugar free.

What Cardioplegic Fresenius solution looks like and contents of the pack:

Cardioplegic Induction Solution Fresenius: A clear, colourless solution.

Cardioplegic Maintenance Solution Fresenius: A clear, colourless to slightly yellow-coloured solution.

1, 18 or 20 x 500 ml freeflex (polyolefine) bags

24 x 500 ml PVC bags.

Not all container types and pack sizes may be marketed.

Holder of Certificate of Registration:

Fresenius Kabi Manufacturing SA (Pty) Ltd

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