PACKAGE LEAFLET: INFORMATION FOR THE USER

Cardioplegia Concentrate for Solution for Infusion

Magnesium Chloride Hexahydrate 163mg/ml
Potassium Chloride 60mg/ml
Procaine Hydrochloride 14mg/ml
(referred to as Cardioplegia Concentrate in this leaflet)

Read this leaflet carefully before you are given Cardioplegia Concentrate.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or nurse.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:

1. What Cardioplegia Concentrate is and what it is used for
2. Before Cardioplegia Concentrate is given
3. How Cardioplegia Concentrate will be given
4. Possible side effects
5. Storing Cardioplegia Concentrate
6. Further information

1. What Cardioplegia Concentrate is and what it is used for

Cardioplegia Concentrate for Solution for Infusion is used during heart surgery to prevent the heart from beating (i.e. to induce cardioplegia). Cardioplegia Concentrate may be used if you are having a heart valve replaced or a heart transplant.

This medicine contains a combination of drugs; Magnesium Chloride, Potassium Chloride and Procaine Hydrochloride. The Magnesium Chloride and Potassium Chloride are used to stop the heart from beating, whilst the Procaine Hydrochloride acts as a local anaesthetic.

2. Before Cardioplegia Concentrate is given

Do NOT use Cardioplegia Concentrate if:
- You are allergic (hypersensitive) to Magnesium Chloride, Potassium Chloride or Procaine Hydrochloride, or any of the other ingredients of this medicine listed in Section 6 (Further Information).

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

Driving and using machines
After being given Cardioplegia Concentrate you should not drive or use machines until your doctor has told you that it is safe to do so.

Excipient with known effect: Sodium
This medicinal product contains less than 0.005mg sodium per ml, i.e. essentially 'sodium- free'.

3. How Cardioplegia Concentrate will be given

Cardioplegia Concentrate will be given as an infusion (drip) during surgery by a medically competent person trained in open heart surgery. Before it is given to you, it will be diluted by adding 20ml Cardioplegia Concentrate to 1 litre of Compound Sodium Chloride Injection immediately before use.

If you are given too much Cardioplegia Concentrate
As Cardioplegia Concentrate is given to you in hospital under the supervision of your doctor, it is unlikely that you will receive too much. Your doctor has information on how to recognise and treat an overdose.

If you have any questions on this product, ask your doctor or nurse.

Continued overleaf

TECHNICAL PRESCRIBING INFORMATION

Cardioplegia Concentrate for Solution for Infusion (163mg/60mg/14mg per ml)

Indications:

Solution for infusion into the coronary arteries during cardiopulmonary bypass to induce cardioplegia. This includes aortic valve replacement and the paralysis and preservation of the harvested donor heart during transplantation.

Dose:

A sterile aqueous solution for infusion after dilution. The contents of an ampoule are diluted with cold (2 - 8°C) Compound Sodium Chloride Injection BPC, prior to use.

The dilute solution is stored at 2-8°C and should be used within 24 hours of preparation.

Dilute 10ml with 500ml of Compound Sodium Chloride Injection BPC

Dilute 20ml with 1000ml of Compound Sodium Chloride Injection BPC

Total dose is patient specific, recommended infusion rate 2-4ml/g myocardium for not less than 30seconds.

Contra-indications:

Hypersensitivity to procaine

Warnings:

The contents of an ampoule must be diluted under aseptic conditions with cold (2-8°C) Compound Sodium Chloride Injection BPC, and if not used immediately then stored at 2-8°C and used within 24 hours of preparation.

Interactions:

None stated.

Pregnancy:

None stated.

Side effects:

None stated.

Overdose:

Appropriate supportive measures should be taken.

Apnoea: It may be necessary to apply artificial respiration.

For circulatory depression: Give a vasopressor and intravenous fluids.

For seizures: Give oxygen and intravenous diazepam.

For methaemoglobinaemia: Give oxygen and methylene blue.

Continued overleaf

4. Possible side effects

Like all medicines Cardioplegia Concentrate can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have difficulty in breathing or swallowing, experience swelling to your face, lips, throat or tongue. These allergic reactions are rare but do need urgent medical treatment.

5. Storing Cardioplegia Concentrate

- Keep out of the sight and reach of children
- Cardioplegia Concentrate should be kept in the original carton in order to protect from light and stored below 25°C
- The doctor or nurse will check that this product is not used after the expiry date. The expiry date refers to the last day of that month. The doctor or nurse will also check that the product does not show signs of visible damage or discoloration

6. Further Information

What Cardioplegia Concentrate contains
The active ingredients are Magnesium Chloride Hexahydrate 163mg/ml, Potassium Chloride 60mg/ml and Procaine Hydrochloride 14mg/ml.

Each 10ml ampoule contains 1626mg Magnesium Chloride Hexahydrate, 596mg Potassium Chloride and 136mg Procaine Hydrochloride.

Each 20ml ampoule contains 3253mg Magnesium Chloride Hexahydrate, 1193mg Potassium Chloride and 273mg Procaine Hydrochloride.

When diluted as directed, the solution contains 3.19mg/ml Magnesium Chloride Hexahydrate, 1.17mg/ml Potassium Chloride and 0.27mg/ml Procaine Hydrochloride.

The other ingredients are Disodium Edetate, Sodium Hydroxide and Water for Injections.

What Cardioplegia Concentrate looks like and contents of the pack
Cardioplegia Concentrate is a clear, colourless concentrate for solution for infusion supplied in glass ampoules. Each ampoule contains either 10ml or 20ml of Cardioplegia Concentrate and is available in packs of ten ampoules. Each pack of ten ampoules comes in a cardboard carton that contains a patient information leaflet.

Marketing Authorisation Holder and Manufacturer:
Martindale Pharmaceuticals Ltd.,
Bampton Road, Romford, RM3 8UG, United Kingdom.

If this leaflet is difficult to see or read, please contact the marketing authorisation holder for help.

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Pharmacodynamics:

At the concentration produced after diluting the product, magnesium chloride increases conduction time and the PR and QRS intervals are lengthened. Elevated potassium levels have significant effects on electrical activity in the heart. The T waves become increased in height, the PR interval lengthens and the P wave disappears as potassium concentration increases. Procaine hydrochloride acts as a local anaesthetic. The primary site of action for procaine is the myocardium, resulting in a decrease in electrical excitability, conduction rate and force of contraction.

Pharmacokinetics:

Procaine hydrochloride is almost completely metabolised with only about 2% excreted unchanged in the urine. The half life is less than one minute.

Incompatibilities:

None stated.

Shelf life:

36 months unopened
Store below 25°C and protect from light
The dilute solution should be stored at 2-8°C and used within 24 hours of preparation

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