PACKAGE LEAFLET: INFORMATION FOR THE USER

Sterile Concentrate for Cardioplegia Infusion

Magnesium Chloride Hexahydrate 163mg/ml Potassium Chloride 60mg/ml Procaine Hydrochloride 14mg/ml

Read this leaflet carefully before you are given Sterile Concentrate for Cardioplegia Infusion.

- 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:

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

What Sterile Concentrate for Cardioplegia infusion is and what it is used for

Sterile Concentrate for Cardioplegia Infusion is used during heart surgery to prevent the heart from beating (i.e. to induce cardioplegia). 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 Sterile Concentrate for Cardioplegia Infusion is given

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

Taking with 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.

3. How Sterile Concentrate for Cardioplegia Infusion will be given

Sterile Concentrate for Cardioplegia Infusion 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 Sterile Concentrate for Cardioplegia Infusion to 1 litre of Compound Sodium Chloride Injection immediately before use.

If you are given too much Sterile Concentrate for Cardioplegia Infusion

As Sterile Concentrate for Cardioplegia Infusion 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.

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less than one minute.

List of Excipients

Disodium Edetate BP Sodium Hydroxide

Water for Injections BP

Preclinical Safety Data

Sterile Concentrate for Cardioplegia Infusion Pharmacodynamic Properties At the concentration produced after diluting the product,

Magnesium Chloride Hexahydrate 163mg/ml Potassium Chloride 60mg/ml Procaine Hydrochloride 14mg/ml

Trade Name of the Medicinal Product

Sterile Concentrate for Cardioplegia Infusion

TECHNICAL PRESCRIBING INFORMATION

Qualitative and Quantitative Composition

Each ml of solution contains 0.163g Magnesium Chloride Hexahydrate Ph Eur, 0.060g Potassium Chloride Ph Eur and 0.014g Procaine Hydrochloride Ph Eur.

Pharmaceutical Form

Sterile aqueous solution

Therapeutic Indications

Sterile Concentrate for Cardioplegia Infusion is used during heart surgery to induce cardioplegia.

Solution for infusion into the coronary arteries during cardiopulmonary bypass to induce cardioplegia.

Posology and Method of Administration

A sterile aqueous solution for dilution. 20 ml are diluted with 1 litre of Compound Sodium Chloride Injection BPC, immediately before use.

Contra-indications

Hypersensitivity to procain

Special Warnings and Precautions for Use

The contents of one (20 ml) ampoule must be diluted with 1 litre of Compound Sodium Chloride Injection BPC, immediately before use.

Interactions with other Medicaments and other forms of Interaction

None stated.

Pregnancy and Lactation

None stated.

Effects on Ability to Drive and Use Machines

None stated.

Undesirable 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

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4. Possible side effects

Like all medicines Sterile Concentrate for Cardioplegia Infusion 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing Sterile Concentrate for Cardioplegia Infusion

- Keep out of the sight and reach of children
- Sterile Concentrate for Cardioplegia Infusion 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

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. The Procaine hydrochloride acts as a

myocardium, resulting in a decrease in electrical excitability, conduction rate and force of contraction.

local anaesthetic. The primary site of action for procaine is the

Pharmacokinetic Properties
Procaine hydrochloride is almost completely metabolised with

only about 2% excreted unchanged in the urine. The half life is

Acute toxicity data for procaine hydrochloride indicates an LD50 of 200 mg/kg following oral administration in the Rat.

There are no other additional preclinical safety data that

would be of significance to the prescriber.

6. Further Information

What Sterile Concentrate for Cardioplegia Infusion contains The active ingredients are magnesium chloride hexahydrate 163mg/ml, potassium chloride 60mg/ml and procaine hydrochloride 14mg/ml. The other ingredients are disodium

edetate, sodium hydroxide and water for injections.

What Sterile Concentrate for Cardioplegia Infusion looks like and contents of the pack

Sterile Concentrate for Cardioplegia Infusion is a clear, colourless solution supplied in glass ampoules. Each ampoule contains 20ml of Sterile Concentrate for Cardioplegia 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, Bampton Road, Romford, RM3 8UG, United Kingdom.

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

Product licence number: PL 01883/0012 Date of last revision: June 2013





Incompatibilities

None stated.

Shelf Life

3 years (36 month)

Special Precautions for Storage

Do not store above 25°C. Protect from light

Nature and Contents of Container

Clear colourless Ph Eur type I glass ampoules containing 20 ml of solution.
The ampoules are packed in cartons of 10.

Instruction for Use/Handling

None stated

Product licence number: PL 01883/0012



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