

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:

1. What Sterile Concentrate for Cardioplegia Infusion is and what it is used for
2. Before Sterile Concentrate for Cardioplegia Infusion is given
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1. 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.

Continued overleaf

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

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

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