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 difficulty in swallowing or start to feel very unwell. These allergic reactions are rare but do need urgent medical treatment.

Reporting of side effects

If you or your doctor think you are having side effects, please tell your doctor or nurse. 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 25oC.

The doctor or nurse will check that the 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 diisodium 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 20 ml of Sterile Concentrate for Cardioplegia Infusion 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, RM8 8UG, United Kingdom.

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

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INFORMATION FOR THE USER

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

Sterile Concentrate for Cardioplegia Infusion is used during heart surgery to prevent the heart from beating. It is an anaesthetic. This medicine contains a combination of drugs.

2. Before Sterile Concentrate for Cardioplegia Infusion is given

Sterile Concentrate for Cardioplegia Infusion will be given as an infusion. It will be given to you by a medically competent person named 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

How Sterile Concentrate for Cardioplegia Infusion will be given

Sterile Concentrate for Cardioplegia Infusion will be given as an infusion into the coronary arteries during cardiopulmonary bypass to induce cardioplegia. 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 and then infused into the coronary arteries.

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

Continued overleaf