

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sterile Concentrate for Cardioplegia Infusion

2 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.

3 PHARMACEUTICAL FORM

Sterile aqueous solution

4 CLINICAL PARTICULARS

4.1 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.

4.2. 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.

4.3. Contra-indications

Hypersensitivity to procaine

4.4. 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.

4.5. Interactions with other Medicaments and other forms of Interaction

None stated.

4.6. Pregnancy and Lactation

None stated

4.7. Effects on Ability to Drive and Use Machines

None stated.

4.8. Undesirable Effects

None stated.

4.9. 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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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. The 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.

5.2. Pharmacokinetic Properties

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

5.3. Preclinical Safety Data

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 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Edetate BP

Sodium Hydroxide

Water for Injections BP

6.2. Incompatibilities

None stated.

6.3. Shelf Life

3 years (36 month)

6.4. Special Precautions for Storage

Do not store above 25°C.

Protect from light

6.5. 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.

6.6. Instruction for Use/Handling

None stated

7 MARKETING AUTHORISATION HOLDER

Macarthy's Laboratories Ltd

T/a Martindale Pharmaceuticals

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Romford

RM3 8UG

8. Marketing Authorisation Number

PL 01883/0012

9. Date of First Authorisation/Renewal of Authorisation

6 April 1982

10 DATE OF REVISION OF THE TEXT

24/06/2013