

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

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

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of concentrate contains 163mg Magnesium Chloride Hexahydrate, 60mg Potassium Chloride and 14mg Procaine Hydrochloride

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

Excipients with known effect: Sodium

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Concentrate for solution for Infusion

A clear colourless solution

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic 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.

#### 4.2 Posology and method of administration

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

#### 4.3 Contraindications

Hypersensitivity to procaine

#### 4.4 Special warnings and precautions for use

The contents of an ampoule must be diluted with Compound Sodium Chloride Injection BPC, immediately before use.

This medicinal product contains less than 0.005mg sodium per ml, essentially 'sodium free'.

#### 4.5 Interaction with other medicinal products and other forms of interaction

None stated.

## 4.6 Fertility, 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. 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 pre-clinical safety data that would be significant to the prescriber.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Disodium Edetate  
Sodium Hydroxide  
Water for Injections

## 6.2 Incompatibilities

This medicinal product must not be mixed with any other medicinal products except those mentioned in *section 6.6, Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product.*

## 6.3 Shelf life

Unopened: 3 years

After dilution:

Chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would not normally be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.

## 6.4 Special precautions for storage

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

## 6.5 Nature and contents of container

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

## 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any remaining contents after use.

The contents of the 20ml ampoule must be diluted with 1 litre of cold (2-8°C) Compound Sodium Chloride Injection BPC and the contents of the 10ml ampoule must be diluted with 500ml of Compound Sodium Chloride Injection BPC.

## 7 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd.,  
Bampton Road,  
Romford RM3 8UG,  
England

## 8 MARKETING AUTHORISATION NUMBER

PA0361/014/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 September 2001

Date of last renewal: 07 September 2006

**10 DATE OF REVISION OF THE TEXT**

November 2013