

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.3% w/v and sodium Chloride 0.9% w/v Intravenous Infusion BP

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active substance

Potassium Chloride 0.3% w/v (3g/L) and Sodium Chloride 0.9% w/v (9g/L)

*For a full list of excipients, see section 6.1.*

#### 3 PHARMACEUTICAL FORM

Solution for infusion.

Sterile, non-pyrogenic, clear, colourless, aqueous solution which provides 40 mmol/L K<sup>+</sup>, 150mmol/L Na<sup>+</sup> and 190 mmol/L Cl<sup>-</sup>

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For prophylactic and replacement therapy requiring the use of sodium chloride and potassium.

##### 4.2 Posology and method of administration

###### Dosage

The dosage is dependant upon the age, weight and clinical condition of the patient.

###### Administration

Intravenous.

##### 4.3 Contraindications

Use in patients with severe impairment of renal function.

Use in hyperkalaemia such as is associated with adrenal insufficiency or severe renal insufficiency.

##### 4.4 Special warnings and precautions for use

Administration should be carried out only under specialist surveillance. Plasma electrolyte levels should be carefully monitored during use, especially in patients with pre-existing imbalances, in renal failure or in hepatic disease.

Venous irritation and thrombophlebitis may occur at the injection site.

The fluid should be administered with great care to patients with diabetes mellitus or renal insufficiency.

Potassium replacement therapy is critical and must be guided by measurement of plasma levels and ECG.

Potassium replacement should be used with extreme caution in patients with cardiac disease, renal dysfunction, digitalisation or hepatic insufficiency.

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

None stated.

#### **4.6 Pregnancy and lactation**

This product has been used in pregnant women and no harmful effects are known with respect to the course of pregnancy and the health of the mother and the neonate.

#### **4.7 Effects on ability to drive and use machines**

Not applicable.

#### **4.8 Undesirable effects**

Adverse reactions to potassium containing solutions include paraesthesia of the extremities, flaccid paralysis, mental confusion, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest.

#### **4.9 Overdose**

Discontinue infusion if adverse reaction occurs.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Not applicable.

#### **5.2 Pharmacokinetic properties**

Not applicable.

#### **5.3 Preclinical safety data**

Not applicable.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Water for Injections  
Concentrated Hydrochloric Acid (for pH adjustment)

#### **6.2 Incompatibilities**

In the absence of compatibility studies, this product must not be mixed with other medicinal products.

### **6.3 Shelf Life**

Unopened: 2 years

Once opened: Use immediately. Discard any unused portion.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

A clear, collapsible Viaflex infusion bag, composed of plasticised poly (vinyl chloride) (PVC), effectively sealed in a High Density Polyethylene or Polypropylene overpouch and containing 500 or 1000ml of solution.

Not all pack sizes may be marketed.

### **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**

Do not use unless solution is clear and the container is undamaged.

Discard any unused portion.

Do not reconnect partially used bags.

## **7 MARKETING AUTHORISATION HOLDER**

Baxter Healthcare Ltd.,  
Caxton Way,  
Thetford,  
Norfolk,  
IP24 3SE,  
United Kingdom.

## **8 MARKETING AUTHORISATION NUMBER**

PA 0167/052/009

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

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

## **10 DATE OF REVISION OF THE TEXT**

August 2008