

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.15% w/v and Sodium Chloride 0.9% w/v Intravenous Infusion BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Potassium Chloride 0.15% w/v (1.5 g/L) and Sodium Chloride 0.9% w/v (9 g/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 20mmol/L K⁺, 150mmol/L Na⁺ and 170mmol/L Cl⁻

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 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 0167/052/001

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