Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

0.15% w/v Potassium Chloride and 5.0% w/v Glucose Intravenous Infusion BP.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride:	1.5 g/L
Glucose (as Monohydrate):	50.0 g/L

mmol/l: K^+: 20, Cl^- : 20

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.
Clear solution, free from visible particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Dosage
The dosage is dependant upon the age, weight and clinical condition of the patients and must be decided on an individual basis.

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.

This 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.

Administration of potassium chloride in glucose solutions may lower the level of serum potassium attained.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

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 paresthesia 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

As with all parenteral solutions incompatibility of the additive medications with the solution must be assessed before addition.

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

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Potassium Chloride 0.15% and Glucose 5% solution by checking for eventual color change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify it is soluble and/or stable in water at the pH of the Potassium Chloride 0.15% w/v and Glucose 5% w/v solution (pH: 3.5 to 6.5). As a guidance, the following medications are incompatible with the Potassium Chloride 0.15 % and Glucose 5 % solution (non-exhaustive listing):

- Amphotericin B
- Dobutamine

Glucose should not be administered through the same infusion equipment as whole blood as hemolysis and clumping can occur.

Those additives known to be incompatible should not be used.

6.3 Shelf Life

Shelf life as packaged: 2 years.

In-use shelf life (Additives):

Chemical and physical stability of any additive medication at the pH of the Potassium Chloride 0.15% and Glucose 5% Solution in the Viaflex container should be established prior to use.

From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place under controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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 1000ml of solution.

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

Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.

Do not remove unit from overwrap until ready for use.

The inner bag maintains the sterility of the product.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Additives may be introduced before infusion or during infusion through the injection site. When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Adding medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.,
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IP24 3SE,
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8 MARKETING AUTHORISATION NUMBER

PA 0167/051/005

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

May 2008