Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

0.15% w/v Potassium Chloride, 0.18% w/v Sodium Chloride and 4% w/v Glucose Intravenous Infusion BP, Viaflex Container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Potassium Chloride	0.15 % w/v
Sodium Chloride	0.18 % w/v
Anhydrous Glucose	4.0 % w/v
(as Glucose Monohydrate)	4.4 % w/v

Equivalent to:	mmol/L
Potassium	20
Sodium	30
Chloride	50

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

pH: 3.5 - 5.5
Osmolarity: 322 mOsm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the restoration and maintenance of fluid, calorie and sodium, potassium and chloride balance where the oral route of administration is not feasible.

4.2 Posology and method of administration

Dosage
Dosage of product is dependent upon the age, weight, clinical state and degree of deficiency of the patient and must be determined on an individual basis.

Administration
Intravenous.

4.3 Contraindications

- Use of a solution which is cloudy, contains sediment or is in any way unusual.
- Use in patients with fluid and sodium retention, congestive heart failure, or severe impairment of renal function.
- Use in the presence of dehydration without fluid replacement.
- Use in hyperkalaemia such as is associated with adrenal insufficiency or severe renal insufficiency.

4.4 Special warnings and precautions for use

- Plasma electrolyte levels should be carefully monitored during use, especially in patients with pre-existing imbalances, in renal failure or in hepatic disease.
- This fluid should be administered with great care to patients with diabetes mellitus.
- Potassium replacement therapy is critical and must be guided by electrocardiography. Plasma levels may not be directly related to tissue levels.
- Potassium replacement should be used with extreme caution in patients with cardiac disease, renal dysfunction, digitalisation or hepatic insufficiency.
- The rate of administration of this solution should be slow to avoid cardiotoxicity.
- Administration of potassium chloride in glucose solutions will lower the levels of serum potassium attained.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

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 unborn 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

In the event of adverse reactions discontinue infusion.

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.

6.2 Incompatibilities

Compatibilities should be checked when additives are used.

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

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

6.3 Shelf Life

The shelf life is 2 years providing the unit has not been opened.
Once opened, use immediately and discard any remaining contents.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

The product will be presented in 500 ml or 1000 ml Viaflex plastic containers.

The plastic used to manufacture the containers is a Viaflex PVC plastic designated PL-146.

The containers will be sealed in a plastic over pouch.

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.
For single use only. Discard any unused portion.
Do not reconnect partially used bags.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd
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Thetford
Norfolk
IP24 3SE
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8 MARKETING AUTHORISATION NUMBER

PA 0167/004/001A

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 November 1977

Date of last renewal: 02 November 2007

10 DATE OF REVISION OF THE TEXT

May 2008