Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.15% w/v and Sodium Chloride 0.18% w/v in Glucose 4% w/v Intravenous Infusion BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:

Potassium Chloride	0.15 % w/v
Sodium Chloride	0.18 % w/v
Glucose Monohydrate	4.4 % w/v

(equivalent to anhydrous glucose 4.0%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: 322mOsm/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 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

- Pasma 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 Fertility, 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 arrhythmia’s, 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

As with all parenteral solutions, before adding medications, compatibility of these additives with the solution in Viaflo container must be assessed.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Potassium Chloride 0.15% w/v, Sodium Chloride 0.18% w/v in Glucose 4% solution by checking for eventual colour change and/or eventual precipitate, insoluble complexes or crystal apparition.

The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify it is soluble and stable in water at the pH of Potassium Chloride 0.15%, Sodium Chloride 0.18% and Glucose 4%.
When a compatible medication is added to this formulation, the solution must be administered immediately, unless dilution has taken place in controlled and validated aseptic conditions.

As a guidance, the following medications are incompatible with the Potassium Chloride 0.15%, Sodium Chloride 0.18% and Glucose 4% solution (non-exhaustive listing)
Amphotericin B
Dobutamine

Glucose should not be administered through the same infusion equipment as whole blood as haemolysis and clumping can occur.
Those additives known to be incompatible should not be used.

6.3 Shelf Life

The shelf life is 3 years providing the unit has not been opened.
Once opened, use immediately and discard any remaining contents.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The bags, known as Viaflo, are composed of polyolefin/polyamide co-extruded plastic (PL2442). The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene.

Bag size: 1000ml
Outer carton contents: 10 bags.

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 administration or during administration through the resealable medication port.

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 after preparation, unless preparation has taken place in controlled and validated aseptic conditions.

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

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

1. Opening

a. Remove the Viaflo container from the overpouch just before use.
b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.
c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

Use sterile material for preparation and administration.
a. Suspend container from eyelet support.
b. Remove plastic protector from outlet port at bottom of container:
- grip the small wing on the neck of the port with one hand,
- grip the large wing on the cap with the other hand and twist, the cap will pop off.
c. Use an aseptic method to set up the infusion.
d. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible

To add medicinal product before administration

a. Disinfect medication site.
b. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medicinal product during administration

a. Close clamp on the set.
b. Disinfect medication site.
c. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
d. Remove container from IV pole and/or turn to an upright position.
e. Evacuate both ports by tapping gently while the container is in an upright position.
f. Mix solution and medication thoroughly.
g. Return container to in use position, re-open the clamp and continue administration.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 167/4/7

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 11th April 2008

10 DATE OF REVISION OF THE TEXT

March 2011