Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.3% w/v and Sodium Chloride 0.18% w/v in Glucose 4% w/v Intravenous Infusion BP (Viaflo Container)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:

Potassium Chloride 0.30 % 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 40
Sodium 30
Chloride 70

For the 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: 362 mOsm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prevention and treatment of potassium, sodium and chloride depletion due to a loss of gastrointestinal fluid (vomiting, diarrhoea, surgical drainage, gastric suction, small intestinal bypass procedure, or small bowel fistula), a chronic abuse of laxative, malabsorption syndromes, mucus secreting villous adenoma of the small intestine, or renal salt-losing conditions (renal disorders, overuse of diuretics), particularly in cases (e.g. starvation) where a source of energy is required.

4.2 Posology and method of administration

Posology

Adults, the Elderly and Children

The choice of the specific potassium chloride, sodium chloride, and glucose concentration, dosage, volume, rate and duration of administration depends on the age, weight and clinical condition of the patient and concomitant therapy, and administration should be determined by a physician. For patients with electrolyte and glucose abnormalities and for paediatric patients, consult a physician experienced in intravenous fluid therapy.

Fluid balance, serum glucose, serum sodium and other electrolytes should be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia. Monitoring of serum sodium is particularly important for physiologically hypotonic fluids.

Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution may become extremely hypotonic after administration due to glucose metabolisation in the body (see sections 4.4, 4.5 and 4.8).

Typical doses of potassium for the prevention of hypokalaemia may be up to 50 mmoles daily and similar doses may be adequate in mild potassium deficiency. In severe acute hypokalaemia, up to 20 mmoles of potassium in 500 ml over 2 to 3 hours under ECG control. Patients with renal impairment should receive lower doses.

The maximum recommended dose of potassium is 2 to 3 mmol/kg/24h. The rate should not exceed 10 to 40 mmol/h to avoid hyperkalaemia. For peripheral infusions, potassium concentration should be less than 60 mmol/l to avoid pain.

The recommended dosage for the treatment of carbohydrates and fluid depletion is

- for adults: 500 ml to 3 Litres/24h

Paediatric Population
- 0-10 kg body weight: 100 ml/kg/24h
- 10-20 kg body weight: 1000 ml + (50 ml /kg over 10 kg) /24h
- > 20 kg body weight: 1500 ml + (20 ml/kg over 20 kg)/24h

Method of administration

The administration is performed by intravenous route using sterile and non-pyrogenic equipment.

Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution has an approximate osmolarity of 362 mOsm/L.

Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, any hyperosmolar solutions are recommended to be administered through a large central vein, for thorough and rapid dilution of the hyperosmolar solution.

Intravenous potassium should be administered in a large peripheral or central vein to diminish the risk of causing sclerosis. If infused through a central vein, be sure the catheter is not in the atrium or ventricle to avoid localised hyperkalaemia. Solutions containing potassium should be administered slowly.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact (refer to section 6.6 Special precautions for disposal and other handling).

When introducing additives to Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution, the instructions for use of the medication to be added and other relevant literature must be consulted (refer to section 6.6 Special precautions for disposal and other handling).

Rate of administration

As administered intravenously, potassium should not be given faster than 10 to 40 mmol/h to avoid a dangerous hyperkalaemia. A gradual increase of flow rate should be considered when starting administration of glucose-containing products. Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurologic complications) (4.4 Special warnings and precautions for use).

Monitoring

Adequate urine flow must be ensured and careful monitoring of plasma-potassium and other electrolyte concentrations is essential. High dosage or high speed infusion must be performed under ECG control. Electrolyte supplementation may be indicated according to the clinical needs of the patient.

4.3 Contraindications

The solution is contraindicated in patients presenting with:

- Known hypersensitivity to the product
- Hyperchloremia and hyperkalaemia that are not related to the concentration effect associated to a volume depletion
- Severe renal insufficiency (with oliguria/anuria)
- Uncompensated heart failure and severe congestive heart failure

- Addison's disease

- Fluid and sodium retention

- Acute ischemic stroke

- Head trauma (first 24 hours)

- Uncompensated diabetes
- Hyperosmolar coma

- Hyperglycaemia

- Hyperlactatemia

- Other known glucose intolerances (such as metabolic stress situations)

4.4 Special warnings and precautions for use

Potassium chloride 0.3% w/v, Sodium chloride 0.18% w/v in Glucose 4% w/v is a slightly hypertonic solution. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization (see section 4.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Potassium should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalaemia such as renal or adrenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns. Regular monitoring of clinical status, serum electrolytes and ECG is advisable in patients receiving potassium therapy, particularly those with cardiac or renal impairment.
Sodium salts should be administered with caution to patients with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia, or other conditions associated with sodium retention (see also Section 4.5 Interaction with other medicinal products and other forms of interaction).

In diabetic patients, the amount of infused glucose has to be taken into account and insulin requirements may be modified.

During long term parenteral treatment, a convenient nutritive supply must be given to the patient.

Potassium chloride 0.3%, Sodium chloride 0.18% and Glucose 4% solution contains glucose derived from corn. It should be used with caution in patients with known corn allergies (see section 4.8).

Hyponatraemia

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.
Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.
Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia

Refeeding syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intake while avoiding overfeeding can prevent these complications.

Paediatric Use

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy, and should be determined by a consulting physician experienced in paediatric intravenous fluid therapy.

- Newborns, especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycaemia. Close monitoring during treatment with intravenous glucose solutions is needed to ensure adequate glycemic control, in order to avoid potential long term adverse effects.

- Hypoglycaemia in the newborn can cause, e.g.,

  - prolonged seizures,
  - coma, and
  - cerebral injury.

- Hyperglycaemia has been associated with

  - cerebral injury, including intra-ventricular haemorrhage,
  - late onset bacterial and fungal infection,
  - retinopathy of prematurity,
  - necrotizing enterocolitis,
  - bronchopulmonary dysplasia
  - prolonged length of hospital stay, and
  - death.

- Children (including neonates and older children) are at increased risk of developing hyponatraemia as well as for developing hyponatraemic encephalopathy.
- The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatraemia.
- Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes.
- Rapid correction of hyponatraemia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in paediatric intravenous fluid therapy.

In order to avoid potentially fatal over infusion of intravenous fluids to the neonate, special attention needs to be paid to the method of administration. When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe.
When using an infusion pump all clamps on the intravenous administration set must be closed before removing the administration set from the pump, or switching the pump off. This is required regardless of whether the administration set has an anti free flow device.
The intravenous infusion device and administration equipment must be frequently monitored.

Blood
Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution should not be administered simultaneously with blood through the same administration set because of the possibility of haemolysis.

Geriatric Use
When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

4.5 Interaction with other medicinal products and other forms of interactions

No studies have been conducted by Baxter.

Both the glycaemic effects and its effects on water and electrolyte balance should be taken into account when using Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution and can result in decreased lithium levels.

Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution should be used with caution in patients treated concurrently or recently with agents or products that can cause Hyperkalaemia or increase the risk of hyperkalaemia, such as potassium sparing diuretics (e.g. amiloride, spironolactone, triamterene).

Administration of potassium in patients treated with such agents is associated with an increased risk of severe and potentially fatal hyperkalaemia, in particular in the presence of other risk factors for hyperkalaemia.

Regarding medications (such as certain antiepileptic and psychotropic medications) that increase the risk of hyponatraemia or sodium and fluid retention, see Special Warnings and Precautions for Use.

Drugs leading to an increased vasopressin effect
The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

- Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues, e.g.: Desmopressin, oxytocin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

Solutions containing potassium should be used with caution in patients receiving drugs that increase serum potassium concentrations (potassium-sparing diuretics, ACE inhibitors, cyclosporin, and drugs that contain potassium such as potassium salts of penicillin).

Corticosteroids are associated with the retention of sodium and water, with oedema and hypertension.

4.6 Fertility, pregnancy and lactation

Pregnancy

Intrapartum maternal intravenous glucose infusion may result in foetal hyperglycaemia and metabolic acidosis as well as rebound neonatal hypoglycaemia due to fetal insulin production.

Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see sections 4.4, 4.5 and 4.8).

Fertility
There is no information on the effects of Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution on fertility

Lactation
There is no information on the effects of Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution during breast-feeding.

The potential risks and benefits for each specific patient should be carefully considered before administration.

4.7 Effects on ability to drive and use machines

There is no information on the effects of Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity, where feasible.
Frequencies cannot be estimated from the available data as all listed adverse reactions are based on spontaneous reporting.

Table 1
Tabulated list of adverse reactions

System Organ Class	*Adverse reactions (Preferred terms)*	*Frequency*
Immune system disorders	Anaphylactic reaction Hypersensitivity	Not known
Metabolism and nutrition disorders	Hospital acquired hyponatraemia*** Hyperglycaemia	
Nervous system disorders	Hyponatraemic encephalopathy***	
Vascular disorders	Phlebitis	
Skin and subcutaneous tissue disorders	Rash, Pruritus	
General disorders and administration site conditions	Injection site reactions including, Infusion site pain, Injection site vesicles, Chills, Pyrexia	
Other reaction	Hyperkalaemia Cardiac arrest*	

(*) as a manifestation of rapid intravenous administration and/or of hyperkalaemia
(**)Potential manifestation in patients with allergy to corn, see section 4.4.
(***) Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

Venous thrombosis, extravasation, hypervolaemia, sweating, injection site infection and thrombophlebitis have been reported in the post marketing experience with other solutions of similar composition.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Excess administration of Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution can cause:

- Hyperglycaemia, adverse effects on water and electrolyte balance, and corresponding complications. For example, severe hyperglycaemia and severe dilutional hyponatraemia and their complications, can be fatal.
- Hyponatraemia (which can lead to CNS manifestations including seizures, coma, cerebral edema and death).
- Fluid overload (which can lead to central and/or peripheral edema).
- Hyperkalaemia, if hyperkalaemia is present or suspected, discontinue the infusion immediately and institute close ECG, laboratory and other monitoring and, as necessary, corrective therapy to reduce serum potassium levels. Manifestations of hyperkalaemia may include:

    - disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation
    - hypotension
    - muscle weakness up to and including muscular and respiratory paralysis, paresthesia of extremities gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain)

- Arrhythmias and conduction disorders, in addition to arrhythmias and conduction disorders, the ECG shows progressive changes that occur with increasing potassium levels. Possible changes include:

    - peaking of T waves,
    - loss of P waves, and
    - QRS widening

However, the correlation between potassium levels and ECG changes is not precise, and whether or at which potassium level certain ECG signs develop depends on factors such as patient sensitivity, the presence of other electrolyte disorders, and the rapidity of the development of hyperkalaemia. The presence of any ECG findings that are suspected to be caused by hyperkalaemia should be considered a medical emergency.

- See also section 4.4 and 4.8

    - When assessing an overdose, any additives in the solution must also be considered.
    - Clinically significant overdose of Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution may, therefore, constitute a medical emergency.
    - Interventions include discontinuation of Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolytes with Carbohydrates
ATC code: B05BB02.

Potassium Chloride 0.3% w/v, Sodium Chloride 0.18% w/v and Glucose 4% w/v is a slightly hypertonic solution. Once administered, the solution becomes hypotonic due to its low sodium content.

The pharmacodynamic properties of this solution are those of its components (glucose, sodium, potassium, and chloride) in maintaining fluid, electrolyte and energy balance.

Potassium is essential for numerous metabolic and physiological processes including nerve conduction, muscle contraction, and acid-base regulation. A normal concentration of potassium in plasma is about 3.5 to 5.0 mmol per litre. Potassium is predominantly an intracellular action.

The passage of potassium into the cells and retention against the concentration gradient requires active transport via the Na^+/K^+ ATPase enzyme.

Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

Glucose is the principal source of energy in cellular metabolism.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of this solution are those of its components (glucose, sodium, potassium, and chloride).

Intravenous administration of the solution provides an immediate supply of electrolytes and glucose to blood.

Factors influencing potassium transfer between intracellular and extracellular fluid such as acid base disturbances can distort the relationship between plasma concentrations and total body stores. Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules in exchange of sodium or hydrogen ions. The capacity of the kidneys to conserve potassium is poor and some urinary excretion of potassium continues even when there is severe depletion. Some potassium is excreted in the faeces and small amounts may also be excreted in sweat.

After injection of radiosodium (^{24}Na), the half life is 11 to 13 days for 99% of the injected Na and one year for the remaining 1%. The distribution varies according to tissues: it is fast in muscles, liver, kidney, cartilage and skin; it is slow in erythrocytes and neurones; it is very slow in the bone. Sodium is predominantly excreted by the kidney, but (as described earlier) there is extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

The two main metabolic pathways of glucose are gluconeogenesis (energy storage) and glycogenolysis (energy release). Glucose metabolism is regulated by insulin.

5.3 Preclinical safety data

The preclinical safety assessment of Potassium Chloride 0.3% w/v, Sodium Chloride 0.18% w/v and Glucose 4% w/v solution for infusion in animals is not relevant as electrolytes and glucose are physiological constituents of the body and are covered by appropriate pharmacopoeial references.

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 0.3% w/v, Sodium Chloride 0.18% w/v in Glucose 4% w/v 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 0.3% w/v, Sodium Chloride 0.18% w/v in Glucose 4% w/v solution.

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 guide, the following medications are incompatible with the Potassium Chloride 0.3% w/v, Sodium Chloride 0.18% w/v in Glucose 4% w/v 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.

In-use shelf-life (Additives)

Chemical and physical stability of any additive medication at the pH of the Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution in the Viaflo 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 in 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

No special precautions for storage.

6.5 Nature and contents of container

The bags, known as Viaflo, contain 500ml of solution for infusion and are composed of polyolefin/polyamide co-extruded plastic (PL2442). The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene.

6.6 Special precautions for disposal and other handling

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.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.
Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

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 or during administration through the resealable medication port.
Additives known or determined to be incompatible should not be used.
Before adding a substance or medication, verify that it is soluble and/or stable in Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% solution and that the pH range of the solution is appropriate.

The instructions for use of the medication to be added and other relevant literature must be consulted.

After addition, if there is a colour change and/or the appearance of precipitates, insoluble complexes or crystals, do not use.

Mix the solution thoroughly when additives have been introduced.
Do not store solutions containing additives.
For single use only.

When additive is used, verify tonicity 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

Baxter Holding B.V.
Kobaltweg 49
3542CE Utrecht
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA2299/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th April 2008
Date of last renewal: 11th April 2013

10 DATE OF REVISION OF THE TEXT

August 2020