

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.15 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4% w/v, Solution for Infusion.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 1.5 g/l  
Sodium Chloride: 1.8 g/l  
Glucose 40.0 g/l  
(equivalent to Glucose monohydrate 44 g/l)

	K <sup>+</sup>	Na <sup>+</sup>	Cl <sup>-</sup>
mmol/l	20	31	51
mEq/l	20	31	51

For the full list of excipients: see Section 6.1.

## 3 PHARMACEUTICAL FORM

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

Osmolarity: 322 mOsm/L

pH: 3.5 - 4.5

## 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

The choice of the specific sodium chloride and glucose concentration, dosage, volume, rate and duration of administration depends on the age, weight, clinical condition of the patient and concomitant therapy. It 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 may need to 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. Sodium Chloride 0.18 % w/v and Glucose 4% w/v solution may become extremely hypotonic after administration due to glucose metabolism in the body (see sections 4.4, 4.5 and 4.8).

Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurologic complications).

Electrolyte supplementation may be indicated according to the clinical needs of the patient.

***Adults, older patients and adolescents (age 12 years and over):***

The Recommended dosage is 500 ml to 3 L/24h

**Administration rate**

The infusion rate is usually 40 ml/kg/24h and should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore the maximum acute administration rate is 5 mg/kg/min.

***Paediatric Population***

Use of 0.18% sodium chloride and 4% glucose should be restricted to specialist paediatric settings such as renal, hepatic and cardiac units, high dependency units and intensive care units.

The dosage varies with weight:

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.

The administration rate varies with weight:

0-10 kg body weight: 6-8 ml/kg/h

10-20 kg body weight: 4-6 ml/kg/h

> 20 kg body weight: 2-4 ml/kg/h

The infusion rate should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore the maximum acute administration rate is 10-18 mg/kg/min, depending on the total body mass.

For all patients, a gradual increase of flow rate should be considered when starting administration of glucose containing products.

### ***Method of administration***

The administration is performed by intravenous infusion.

Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution is hypotonic and hyperosmolar, due to the glucose content.

### ***Precautions to be taken before manipulating or administering the product***

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear and the seal is intact. 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.

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.

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.

Additives may be introduced before or during infusion through the resealable medication port. When additive is used, verify tonicity prior to parenteral administration. Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, any hyperosmolar solution is recommended to be administered through a large central vein, for rapid dilution of the hyperosmotic solution.

For further information on the product with additives, please see sections 6.2, 6.3 and 6.6.

### 4.3 Contraindications

The solution is contraindicated in patients presenting with:

- Known hypersensitivity to the product
- Hyperchloremia and hyperkalemia 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

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism (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.

#### ***Hyponatraemia***

The infusion of solutions with sodium concentrations <0.9% may result in hyponatraemia. Close clinical monitoring may be warranted.

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

### ***Sodium retention, fluid overload and oedema***

Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution should be used with particular caution, in:

- Patients with conditions that may cause sodium retention, fluid overload and oedema (central and peripheral), such as
  - Primary hyperaldosteronism,
  - Secondary hyperaldosteronism associated with, for example,
    - hypertension,
    - congestive heart failure,
    - liver disease (including cirrhosis),
    - renal disease (including renal artery stenosis, nephrosclerosis)
  - Pre-eclampsia.
- Patients taking medications that may increase the risk of sodium and fluid retention, such as corticosteroids

### ***Hypokalaemia***

The infusion of Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution may result in hypokalaemia. This medicine should be used with particular caution in patients with or at risk for hypokalemia. Close clinical monitoring may be warranted in, for example:

- persons with metabolic alkalosis
- persons with thyrotoxic periodic paralysis, administration of intravenous glucose has been associated in aggravating hypokalaemia
- persons with increased gastrointestinal losses (e.g., diarrhea, vomiting)
- prolonged low potassium diet
- persons with primary hyperaldosteronism
- patients treated with medications that increase the risk of hypokalaemia (e.g. diuretics, beta-2 agonist, or insulin)

### ***Hypo- and hyperosmolality, serum electrolytes and water imbalance***

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution can cause:

- Hypo-osmolality
- Hyperosmolality, osmotic diuresis and dehydration
- Electrolyte disturbances such as
  - hyponatraemia (see above),
  - hypokalaemia (see above),
  - hypophosphataemia,
  - hypomagnesaemia,

- Overhydration/hypervolaemia and, for example, congested states, including central (e.g., pulmonary congestion) and peripheral oedema.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

### ***Hyperglycaemia***

Rapid administration of glucose solutions may produce substantial hyperglycaemia and a hyperosmolar syndrome. In order to avoid hyperglycaemia the infusion rate should not exceed the patient's ability to utilize glucose.

To reduce the risk of hyperglycaemia-associated complications, the infusion rate must be adjusted and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

Intravenous glucose should be administered with caution in patients with, for example:

- impaired glucose tolerance (such as in diabetes mellitus, renal impairment, or in the presence of sepsis, trauma or shock),
- severe malnutrition (risk of precipitating a refeeding syndrome, see below),
- thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due to impaired oxidative metabolism of pyruvate),
- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load

Other groups of patients in whom Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution should be used with caution include:

- patients with ischemic stroke. hyperglycaemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes.
- patients with severe traumatic brain injury (in particular during the first 24 hours following the trauma). Early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury.
- Newborns (see Paediatric glycaemia-related issues).

Prolonged intravenous administration of glucose and associated hyperglycaemia may result in decreased rates of glucose-stimulated insulin secretion.

### ***Hypersensitivity Reactions***

- Hypersensitivity/infusion reactions, including anaphylaxis, have been reported (see section 4.8).
- Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.
- Solutions containing glucose should be used with caution in patients with known allergy to corn or corn products

### ***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.

### ***Severe renal impairment***

Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution should be administered with particular caution to patients at risk of (severe) renal impairment. In such patients, administration may result in sodium retention and/or fluid overload.

### ***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 physician experienced in paediatric intravenous fluid therapy.

### ***Paediatric Population***

Intravenous fluid therapy should be closely monitored in the paediatric populations as they may have impaired ability to regulate fluids and electrolytes. Adequate urine flow must be ensured and careful monitoring of fluid balance, plasma and urinary electrolyte concentrations are essential.

### ***Paediatric glycaemia-related issues***

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 glycaemic 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 intraventricular haemorrhage,
- late onset bacterial and fungal infection,
- retinopathy of prematurity,
- necrotizing enterocolitis,
- increased oxygen requirements,
- prolonged length of hospital stay and
- death.

### ***Paediatric hyponatraemia-related issues***

- 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.
- Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death; therefore, acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.
- Plasma electrolyte concentrations should be closely monitored in the paediatric population.
- 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.

### ***Blood***

Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or haemolysis.

### ***Geriatric use***

When selecting the type of infusion 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 interaction**

No studies have been conducted by Baxter.

Both the glycaemic and effects on water and electrolyte balance should be taken into account when administering Sodium Chloride 0.18% w/v and Glucose 4% w/v solution to patients treated with other substances that affect glycaemic control or fluid and/or electrolyte balance.

### ***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, vasopressin, terlipressin

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

Caution is advised in patients treated with

- lithium. Renal sodium and lithium clearance may be increased during administration and can result in decreased lithium levels.
- corticosteroids, which are associated with the retention of sodium and water (with oedema and hypertension).
- diuretics, beta-2 agonist, or insulin, whom increase the risk of hypokalemia
- certain antiepileptic and psychotropic medications that increase the risk of hyponatraemia.

#### **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 foetal insulin production.

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

##### ***Fertility***

There is no information on the effects of Sodium Chloride 0.18% w/v and Glucose 4% w/v solution on fertility

##### ***Lactation***

Sodium Chloride 0.18% w/v and Glucose 4% w/v solution can be used 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 0.15%, 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 post-marketing experience, listed by MedDRA System Organ Class (SOC), then where feasible, by Preferred Term in order of severity.

Frequencies cannot be estimated from the available data as all listed adverse reactions are based on spontaneous reporting

<b>System Organ Class</b>	<b>Adverse reactions (Preferred terms)</b>	<b>Frequency</b>
Metabolism and nutrition disorders	Hypervolaemia	Not known
	Electrolyte imbalance	Not known
	hospital acquired hyponatraemia*	Not known
	Hyponatraemia*	Not known
Nervous system disorders	hyponatraemic encephalopathy**	Not known
Cardiac disorders	Cardiac failure	Not known
Renal and urinary disorders	Polyuria	Not known
Immune system disorders	Hypersensitivity	Not known
	Anaphylactic reaction	Not known

\*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).

*Adverse reactions may be associated to the medicinal product(s) added to the solution; the nature of the additive will determine the likelihood of any other adverse reactions.*

<b>System Organ Class</b>	<b>Adverse reactions (Preferred Terms)</b>	<b>Frequency</b>
Metabolism and nutrition disorders	Hypervolaemia	Not known
Vascular disorders	Vein injury	Not known
	Thrombophlebitis superficial	Not known
General disorders and administration site conditions	Chills	Not known
	Pyrexia	Not known
	Application site infection	Not known
	Application site pain	Not known
	Application site reaction	Not known
	Injection site phlebitis	Not known
	Injection site extravasation	Not known

### ***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 the Yellow Card Scheme.

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

## 4.9 Overdose

Excess administration of Potassium Chloride 0.15%, 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 0.15%, Sodium Chloride 0.18% and Glucose 4% solution may, therefore, constitute a medical emergency.

- Interventions include discontinuation of Potassium Chloride 0.15%, 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 0.15%, Sodium Chloride 0.18% and Glucose 4% 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 mmoles 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  $\text{Na}^+/\text{K}^+$  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 ( $^{24}\text{Na}$ ), 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 0.15%, Sodium Chloride 0.18% and Glucose 4% 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 0.15%, Sodium Chloride 0.18% and Glucose 4% solution by checking for eventual colour 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 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**

Shelf life as packaged:

500 and 1000ml containers: 3 years

#### In-use shelf-life (Additives)

Chemical and physical stability of any additive medication at the pH of the Potassium Chloride 0.15%, 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 are composed of polyolefin /polyamide co-extruded plastic (PL 2442).

The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene.

The bag size is either 500 or 1000 ml.

Outer carton contents: - 20 bags of 500 ml  
or - 10 or 12 bags of 1000ml.

Not all pack sizes may be marketed

## **6.6 Special precautions for disposal**

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 0.15%, 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 color 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
  - a. Use sterile material for preparation and administration.
  - b. 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 Healthcare Ltd  
Caxton Way  
Thetford  
Norfolk  
IP24 3SE  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

PL 00116/0340

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

25 April 2002

**10. DATE OF REVISION OF THE TEXT**

08/05/2024