Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.3 % w/v and Glucose 5% w/v Solution for Infusion BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride: 3.0 g/L
Glucose (as monohydrate): 50.0 g/L

mmol/l : K^+: 40 Cl^-: 40

For the full list of excipients : see 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.
Clear solution, free from visible particles.
Osmolarity: 358 mOsm/L
pH: 3.5 - 6.5

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of potassium depletion and/or hypokalemia in cases where supply of water and carbohydrates is required, due to restriction of the intake of fluids and electrolytes by normal routes.

4.2 Posology and method of administration

Posology
Adults, the Elderly and Children
The choice of specific potassium chloride and glucose concentration, dosage, volume, rate and duration of administration depends on the age, weight, and clinical conditions of the patient, 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.
Doses may be expressed in terms of mEq or mmol of potassium, mass of potassium, or mass of potassium salt:
1 g KCl = 525 mg of K^+ or 13.4 mEq or 13.4 mmol of K^+ and Cl^-.
1 mmol K^+ = 39.1 mg K^+

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

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

Use in 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

The infusion rate should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore, the maximum dose ranges from 5mg/kg/min for adults to 10-18 mg/kg/min for babies and children depending on the age and the total body mass.

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in paediatric intravenous fluid therapy (see Section 4.4).

Posology for prevention and treatment of potassium depletion
Typical dose of potassium for the prevention of hypokalaemia may be up to 50 mmols daily and similar doses may be adequate in mild potassium deficiency. The maximal recommended dose of potassium is 2 to 3 mmol/kg/24H.
When used for the treatment of hypokalaemia, the recommended dosage is 20 mmols of potassium over 2 to 3 hours (i.e. 7-10 mmol/h) under ECG control.
The maximum recommended administration rate should not exceed 15-20 mmol/h.
Patient with renal impairment should receive lower doses.
In any case, the dosage given under "General Posology" should not be exceeded.

Method of administration
The administration is performed by intravenous route using sterile and non-pyrogenic equipment.
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 central vein, be sure the catheter is not in the atrium or ventricle to avoid localized hyperkalaemia.
Solutions containing potassium should be administered slowly.
Do not administer unless the solution is clear and the seal is intact (see section 6.6).
When introducing additives, compatibility must be confirmed before use (see section 6.2 and 6.6).
Rate of administration
As administered intravenously, potassium should not be given faster than 15 to 20 millimoles/h to avoid dangerous hyperkalaemia. A gradual increase of flow rate should be considered when starting administration of glucose-containing products.
Monitoring
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 % w/v and Glucose 5% w/v Solution may become extremely hypotonic after administration due to glucose metabolisation in the body (see sections 4.4, 4.5 and 4.8).
Adequate urine flow must be ensured and careful monitoring of plasma-potassium and other electrolyte concentrations is essential. Higher 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 contra-indicated in patients presenting with:

- Known hypersensitivity to the product
- Hyperkalaemia
- Clinically significant hyperglycaemia
- Hyperchloremia that is not related to the concentration effect associated to a volume depletion
- Severe renal insufficiency (with oliguria/anuria)
- Uncompensated cardiac failure
- Addison's diseaseThe solution is also contraindicated in case of uncompensated diabetes, other known glucose intolerances (such as metabolic stress situations), hyperosmolar coma and hyperlactatemia.

4.4 Special warnings and precautions for use

Potassium Chloride 0.3% and Glucose 5% solution is a hypertonic solution, with an approximate osmolarity of 358 mOsm/l.

Glucose intravenous infusions are usually isotonic solutions. 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.

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
Rapid correction of hyponatremia may cause serious neurologic complications, in particular in paediatric patients (see Paediatric Use).

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 Potassium Chloride 0.3% w/v and Glucose 5% w/v solution may cause:

- Hypo-osmolality
- Hyperosmolality, osmotic diuresis and dehydration
- Electrolyte disturbances such as
    - Hyponatraemia (see Hyponatraemia),
    - Hypophosphatemia,
    - Hypomagnesemia,
- Acid-base imbalance
- Overhydration/hypervolemia and, for example, congested states, including central (e.g., pulmonary congestion) and peripheral edema. Particular caution should be taken in patients with conditions that may cause sodium retention, fluid overload, and edema (central and peripheral).
- Hyponatremia and a decrease in extracellular sodium concentrations related to hyperglycaemia causing a transcellular shift of water.
- Infusion of Potassium Chloride 0.3% w/v and Glucose 5% w/v solution corresponds to the increasing body's load of free water, possibly leading to hypoosmotic hyponatremia.

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.
Particular caution is advised in patients at increased risk of and from water and electrolyte disturbances that could be aggravated by increased free water load.

Hyperglycaemia
Rapid administration of glucose solutions may produce substantial hyperglycaemia and 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),
- 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 Potassium Chloride 0.3% w/v and Glucose 5% 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.

Infusion of solutions containing glucose could be contraindicated in the first 24 hours following head trauma and blood glucose concentration should be closely monitored during intracranial hypertension episodes.

Administration of glucose containing solutions may lead to hyperglycemia. In this case, it is recommended not to use this solution after acute ischemic strokes as hyperglycaemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery.

Hyperkalaemia
Caution should be taken to patients with conditions predisposing to hyperkalaemia and/or associated with increased sensitivity to potassium, such as patients with:

- acute dehydration,
- extensive tissue injury or burns,
- certain cardiac disorders such as congestive heart failure or atrioventricular (AV) block (especially if they receive digitalis), myocardial infarction
- potassium-aggravated skeletal muscle channelopathies (e.g., Hyperkalaemic periodic paralysis, paramyotonia congenita, and potassium-aggravated myotonia/paramyotonia).
- Renal or adrenocortical insufficiency

Caution should be taken to patients who are at risk of experiencing hyperosmolality, acidosis, or undergoing correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space) and patients treated concurrently or recently with agents or products that can cause hyperkalaemia (see Interactions with Other Medicinal Products and Other Forms of Interaction, Section 4.5).

Caution should be taken for patients with cardiac arrhythmia. Arrhythmias can develop at any time during hyperkalaemia. Frequently, mild or moderate hyperkalaemia is asymptomatic and may be manifested only by increased serum potassium concentrations and, possibly, characteristic ECG changes.

Regular monitoring of clinical status, blood glucose level, plasma electrolyte concentrations, plasma creatinine levels, BUN level, acid-base balance and ECG is essential in patients receiving potassium therapy, particularly those with cardiac or renal impairment.

Hypokalaemia
The infusion Potassium Chloride 0.3% w/v and Glucose 5% w/v solution may result in reduction in potassium level worsening hypokalaemia. Monitor patient for signs of arrhythmias, muscle weakness, paralysis, heart block, and rhabdomyolysis, particularly:

- in persons with metabolic alkalosis,
- in persons with thyrotoxic or hypokalemic periodic paralysis,
- in persons with increased gastrointestinal losses (e.g., diarrhoea, vomiting),
- in persons on prolonged low potassium diet (e.g., undernourished or cachectic patients),
- in persons with primary hyperaldosteronism,

- in patients treated with medications that increase the risk of hypokalaemia (e.g. hydrochlorothiazide, loop diuretics, beta-2 agonists, or insulin).

Hypersensitivity Reactions

- Hypersensitivity/infusion reactions, including anaphylaxis, have been reported with Potassium Chloride 0.3% w/v and Glucose 5% w/v Solution (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.

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.

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 (see section 4.6).
- 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,
- increased oxygen requirements,
- prolonged length of hospital stay
- 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.
- Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain edema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life threatening brain injury.
- 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.

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% w/v and Glucose 5% w/v Solution should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or haemolysis.

Due to the risk of pseudo-agglutination precipitated by its glucose content, Potassium Chloride 0.3% and Glucose 5% solution must not be added to or administered simultaneously through the same tubing with citrate anticoagulated/preserved blood.

Elderly Use
When selecting the type of infusion solution and the volume/rate of infusion for an elderly geriatric patient, consider that elderly 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 effects and its effects on water and electrolyte balance should be taken into account when using Potassium Chloride 0.3% w/v and Glucose 5% w/v Solution in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.

Potassium Chloride 0.3% w/v and Glucose 5% w/v 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) corticosteroids, ACE inhibitors, ciclosporin, tacrolimus and drugs that contain potassium.

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 that increase the risk of hyponatraemia or sodium and fluid retention, such as corticosteroids, see Special Warnings and Precautions for Use.Glucose should not be administered through the same infusion equipment as whole blood as haemolysis and clumping can occur (see section 4.4).
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

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 (see paediatric use).

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

Fertility
There is no information on the effects of Potassium Chloride 0.3% w/v and Glucose 5% w/v Solution on fertility.

Lactation
There is no information on the effects of Potassium Chloride 0.3% w/v and Glucose 5% w/v Solution on lactation.

Hyperkalemic and hypokalemic serum levels lead to impaired cardiac function of the maternal and foetal hearts. Therefore, the maternal electrolyte levels are to be controlled regularly.
As long as the maternal electrolyte serum levels are kept within the physiological range, there are no potential concerns regarding administration of Potassium Chloride 0.3% and Glucose 5% solution during pregnancy and lactation.
Potassium Chloride 0.3 % w/v and Glucose 5% w/v 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 section 4.4, 4.5 and 4.8).

4.7 Effects on ability to drive and use machines

There is no information on the effects of Potassium Chloride 0.3% w/v and Glucose 5% w/v 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	Hypokalaemia hospital acquired Hyponatraemia***	
Nervous system disorders	Hyponatraemic encephalopathy***	
General disorders and administration site conditions	Infusion site reactions including, Infusion site pain, Infusion site vesicles, Infusion site pruritus, Infusion site phlebitis, Chills, Pyrexia	
Cardiac disorders	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, thrombophlebitis, vein irritation and hyperkalaemia 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:

Ireland
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% w/v and Glucose 5% w/v 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% w/v and Glucose 5% w/v Solution may, therefore, constitute a medical emergency.

Interventions include discontinuation of Potassium Chloride 0.3% w/v and Glucose 5% w/v 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 (ATC code) : "electrolytes with carbohydrates" (B05BB02)
Potassium chloride 0.3% and Glucose 5% solution is a hypertonic solution of electrolytes and glucose, with an approximate osmolarity of 358 mOsm/l.
The pharmacodynamic properties of this solution are those of its components (potassium, chloride and glucose).

Potassium is predominantly an intracellular cation, primarily found in muscle; only about 2% is present in the extracellular fluid. It is essential for numerous metabolic and physiological processes including nerve conduction, muscle contraction, and acid-base regulation.
Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa.
Glucose is the principal source of energy in cellular metabolism.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of Potassium Chloride 0.3% and Glucose 5% are those of its components (potassium, chloride and glucose).
Intravenous administration of this 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 feces and small amounts may also be excreted in 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

Preclinical safety data of Potassium Chloride 0.3% and Glucose 5% solution in animals are not relevant since potassium chloride and glucose are physiological components of the body. Toxic effects are not to be expected if serum electrolytes are kept within physiological range.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid, concentrated
Water for Injections

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 this 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/or stable in water at the pH of Potassium Chloride 0.3% 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 0.3 % and Glucose 5 % 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 (see section 4.4).
Those additives known to be incompatible should not be used.

6.3 Shelf life

Shelf life as packaged:
500 ml: 24 months
1000 ml: 36 months

In-use shelf life
Chemical and physical stability of any additive medication at the pH of the Potassium Chloride 0.3% and Glucose 5% 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 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

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 overpouch 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 1000 mL

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 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.

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% and Glucose 5% 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.

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.

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 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 medication 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 medication 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 and continue administration.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA2299/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 April 2003

Date of last renewal: 30 October 2006

10 DATE OF REVISION OF THE TEXT

April 2024