SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Plasma-Lyte® 148 & Glucose 5% w/v solution for infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose monohydrate	55.00 g/l
Sodium Chloride:	5.26 g/l
Potassium Chloride:	0.37 g/l
Magnesium Chloride hexahydrate:	0.30 g/l
Sodium Acetate trihydrate:	3.68 g/l
Sodium Gluconate:	5.02 g/l

	Na^+	K^+	Mg^{++}	Cl^-	CH_3COO^- (Acetate)	$C_6H_{11}O_7^-$ (Gluconate)
mmol/l	140	5.0	1.5	98	27	23
mEq/l	140	5.0	3.0	98	27	23

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.
Clear solution, free from visible particles

Osmolarity: 572 mOsm/l (approx.)
pH: 4.0 to 6.0

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Plasma-Lyte 148 & Glucose 5% w/v is indicated:

- for fluid replacement with carbohydrate supply (e.g. after burns, head injury, fracture, infection, and peritoneal irritation),
- as intraoperative fluid replacement,

- in mild to moderate metabolic acidosis, also in case of lactate metabolism impairment.

4.2 Posology and method of administration

Adults, the Elderly, Adolescents and Children:

The dosage and rate of administration depend on the age, weight, clinical and biological conditions of the patient and concomitant therapy.

Fluid balance, blood glucose, and serum electrolytes should be monitored before and during administration (see sections 4.4, 4.5, 4.6 and 4.8).

Recommended dosage:

The recommended dosage is:
- for adults, the elderly and adolescents: 500 ml to 3 litres / 24h
- for infants, toddlers and children:
  - 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

Administration rate:The infusion rate is usually 40 mL/kg/24h in adults, the elderly and adolescents.

When used for intraoperative fluid replacement, normal rate can be higher and is about 15 mL/kg/h.

In paediatric patients the infusion rate is 5 ml/kg/h in average but the value varies with age: 6-8 mL/kg/h for infants, 4-6 mL/kg/h for toddlers, and 2-4 mL/kg/h for children.

The infusion rate should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore the maximum acute administration rate 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.

Note:

- infants and toddlers: aged from 28 days to 23 months (a toddler is an infant who can walk)
- Children: aged from 2 to 11 years.

Use in Paediatric Patients

Safety and effectiveness of Plasma-Lyte 148 & Glucose 5% w/v solution in children have not been established by adequate and well controlled trials.

Use in Geriatric Patients

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.

Method of administration:

The administration is performed by intravenous route.

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.

Glucose solutions should NOT be administered through the same infusion equipment as whole blood, as hemolysis and clumping can occur.

Due to its hyper-osmolality, this solution should NOT be administered through a peripheral vein.
The solution 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.

Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the solution. Administer immediately following the insertion of infusion set.

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 infusion or during infusion through the injection site.

4.3 Contraindications

The solution is contra-indicated in patients presenting:

- Hyperkalaemia
- Renal failure
- Heart block
- Metabolic or respiratory alkalosis
- Hypochlorhydria
- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

The solution is also contraindicated in case of uncompensated diabetes, other known glucose intolerances (such as metabolic stress situations), hyperosmolar coma, hyperglycaemia, hyperlactataemia

4.4 Special warnings and precautions for use

Electrolyte balance

Plasma-Lyte 148 & Glucose 5% w/v solution is not indicated for the treatment of hypochloraemic hypokalaemic alkalosis.

Plasma-Lyte 148 & Glucose 5% w/v solution is not indicated for the primary treatment of severe metabolic acidosis neither for the treatment of hypomagnesemia.

Hyponatraemia:
Treatment with intravenous fluids having a lower sodium concentration than the patient's serum sodium may cause hyponatremia (see section 4.2). Children, patients with reduced cerebral compliance, patients with non-osmotic vasopressin release (e.g. in acute illness, trauma, post-operative stress, central nervous system diseases), and patients exposed to vasopressin agonists and other drugs that can lower serum sodium (see section 4.5) are at particular risk of acute hyponatraemia. Acute hyponatraemia can lead to acute brain oedema and life-threatening brain injury.

Use in Patients with or at Risk for and from Hypermagnesemia
Parenteral magnesium salts should be used with caution in less severe degrees of renal impairment and in patients with myasthenia gravis. Patients should be monitored for clinical signs of excess magnesium, particularly when being treated for eclampsia (see also Section **Error! Reference source not found. - Error! Reference source not found.**).

Use in patients with Hypocalcaemia
Plasma-Lyte 148 & Glucose 5% w/v solution contains no calcium, and an increase in plasma pH due to its alkalinizing effect may lower the concentration of ionized (not protein-bound) calcium. Plasma-Lyte 148 & Glucose 5% w/v solution should be administered with particular caution to patients with hypocalcaemia.

Use in Patients with or at Risk for Hyperkalemia
Solutions containing potassium salts should be administered with caution 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 (see also Section 4.5). The plasma potassium level of the patient should be particularly closely monitored in patients at risk of hyperkalaemia.

The following combinations are not recommended; they increase the concentration of potassium in the plasma and may lead to potentially fatal hyperkalaemia notably in case of renal failure increasing the hyperkalaemic effects (see 4.5):

- Angiotensin converting enzyme inhibitors (ACEi) and, by extrapolation, angiotensin II receptor antagonists: hyperkalaemia potentially lethal

- Tacrolimus, cyclosporine

Use in patients with potassium deficiency
Although Plasma-Lyte 148 & Glucose 5% w/v solution has a potassium concentration similar to the concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium deficiency and therefore it should not be used for this purpose.

Fluid balance/renal function

Risk of Fluid and/or Solute Overload and Electrolyte Disturbances

The patient's clinical status and laboratory parameters (fluid balance, blood and urine electrolytes as well as acid-base balance) must be monitored during use of this solution.

Depending on the volume and rate of infusion, intravenous administration of Plasma-Lyte 148 & Glucose 5% w/v solution can cause
− fluid and/or solute overload resulting in overhydration/hypervolemia therefore high volume infusion must be used under specific monitoring in patients with cardiac, pulmonary or renal failure.

Use in Patients with Hypervolaemia or Overhydration, or Conditions that Cause Sodium Retention and Oedema

Plasma-Lyte 148 & Glucose 5% w/v solution should be administered with particular caution to hypervolaemic or overhydrated patients.

Solutions containing sodium chloride should be carefully administered to patients with hypertension, heart failure, peripheral or pulmonary edema, impaired renal function, pre-eclampsia, aldosteronism, or other conditions associated with sodium retention (see also Section **Error! Reference source not found.** - **Error! Reference source not found.**).

Use in Patients with Severe Renal Impairment
Plasma-Lyte 148 & Glucose 5% w/v solution should be administered with particular caution to patients with severe renal impairment. In such patients administration of Plasma-Lyte 148 & Glucose 5% w/v solution may result in sodium and/or potassium or magnesium retention.

Acid-base balance

Use in Patients with or at Risk for Alkalosis

Plasma-Lyte 148 & Glucose 5% w/v solution should be administered with particular caution to patients with alkalosis or at risk for alkalosis. Excess administration of Plasma-Lyte 148 & Glucose 5% w/v solution can result in metabolic alkalosis because of the presence of acetate and gluconate ions.

Other warnings

Hypersensitivity Reactions

Hypersensitivity/infusion reactions, including anaphylactoid reactions, have been reported with Plasma-Lyte 148 & Glucose 5% w/v solution.

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction 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.

Administration

Administration in the postoperative period shortly after recovery from neuromuscular block should be used with caution since magnesium salts can lead to recurarisation effect.

Administration of glucose containing solutions may lead to hyperglycaemia. In this case, it is recommended not to use this solution after acute ischaemic strokes as hyperglycaemia has been implicated in increasing cerebral ischaemic brain damage and impairing recovery. During long term parenteral treatment, a convenient nutritive

supply must be given to the patient, electrolyte supply should be taken into account and adjusted accordingly.

Use in patients with diabetes

If administered to diabetics or patients with renal insufficiency, close monitoring of glucose levels is required, and insulin and/or potassium requirements may be modified.

Use in Patients with or at Risk for Hyperglycaemia

Solutions containing glucose should be used with caution in patients with impaired glucose tolerance or diabetes mellitus.

Because Plasma-Lyte 148 & Glucose 5% w/v solution contains glucose as well as gluconate (a portion of which may be metabolized to glucose), administration of Plasma-Lyte 148 & Glucose 5% w/v solution that exceeds the metabolic capacity for glucose may lead to hyperglycaemia.

In order to avoid hyperglycaemia the infusion rate should not exceed the patient's ability to utilise glucose.

Due to glucose presence, Plasma-Lyte 148 & Glucose 5% w/v should not be infused concomitantly to massive blood transfusion (risk of pseudo-agglutination).

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

Early hyperglycemia has been associated with poor outcomes in patients with severe traumatic brain injury.

Glucose-containing solutions should, therefore, be used with caution in patients with head injury, in particular during the first 24 hours following the trauma.

Newborns – especially those born premature and with low birth weight -(Please refer below section - Paediatric population)

If hyperglycaemia occurs, the rate of glucose administration should be reduced and/or insulin administered, or the insulin dose adjusted.

Paediatric population

Newborns – especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitits, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

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.

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.

Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes.

Osmolarity

Plasma-Lyte 148 & Glucose 5% w/v solution is a hyper-osmotic solution, having an osmolarity of 572 mOsmol/L. The normal physiologic serum osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of hyper-osmotic solutions may cause venous irritation, including phlebitis.

Hyperosmolar solutions should be administered with caution to patients with hyperosmolar states.

Interference with laboratory tests for gluconate containing solutions
There have been reports of false-positive test results using the Bio-Rad Laboratories Platelia Aspergillus EIA test in patients receiving Baxter gluconate containing Plasmalyte solutions. These patients were subsequently found to be free of Aspergillus infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing Plasmalyte solutions should be interpreted cautiously and confirmed by other diagnostic methods.

Administration

Adding other medications 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.

For information on incompatibilities and preparation of the product and additives, please see section 6.2 and 6.6.

4.5 Interaction with other medicinal products and other forms of interaction

Hyperglycaemic effect of this solution could modify the insulin needs of diabetic patients.

Drugs that can increase the risk for hyponatremia

Drugs that can lower serum sodium may increase the risk of acquired hyponatraemia following treatment with intravenous fluids inappropriately balanced to the need of the patient in terms of fluid volume and sodium content (see sections 4.2, 4.4, 4.6 and

4.8). Examples are diuretics, non-steroid anti-inflammatory drugs (NSAIDs), antipsychotics, selective serotonin reuptake inhibitors, opioids, antiepileptics, oxytocin, and chemotherapy.

Interaction related to the presence of sodium:

Corticoids/Steroids and carbenoxolone, which are associated with the retention of sodium and water (with oedema and hypertension).

Interaction related to the presence of potassium:

The following combinations increase the concentration of potassium in the plasma and may lead to potentially fatal hyperkalaemia notably in case of renal failure increasing the hyperkalaemic effects:

Combination not recommended

- Potassium-sparing diuretics (amiloride, potassium canreonate, spironolactone, triamterene, alone or in combination) (see 4.4),
- Angiotensin converting enzyme inhibitors (ACEi) and, by extrapolation, angiotensin II receptor antagonists: hyperkalaemia potentially lethal (see 4.4),
- Tacrolimus, cyclosporin (see 4.4)

Administration of potassium in patients treated with such medications can produce severe and potentially fatal hyperkalaemia, particularly in patients with severe renal insufficiency.

Interaction related to the presence of magnesium:

- Neuromuscular blockers such as tubocurarine, suxamethonium, and vecuronium whose effects are enhanced by the presence of magnesium.
- Acetylcholine whose release and effects are reduced by magnesium salts what may contribute to neuromuscular blockade.
- Aminoglycoside antibacterials and nifedipine that have additive effects with parenteral magnesium and enhanced the neuromuscular blocking.

Interaction related to the presence of acetate and gluconate (which are metabolised into bicarbonate):

- Caution is advised when administering Plasma-Lyte 148 & Glucose 5% w/v solution to patients treated with drugs for which renal elimination is pH

dependent. Due to its alkalinizing effect (formation of bicarbonate), Plasma-Lyte 148 & Glucose 5% w/v solution may interfere with the elimination of such drugs.

- Renal clearance of acidic drugs such as salicylates, barbiturates and lithium may be increased because of the alkalinisation of urine by the bicarbonate resulting from acetate and gluconate metabolism.
- Renal clearance of alkaline drugs, such as sympathomimetics (e.g. ephedrine, pseudoephedrine) and stimulants (e.g. dexamphetamine sulphate, phenfluramine hydrochloride) may be decreased.

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of Plasma-Lyte 148 & Glucose 5% w/v solution in pregnant or lactating women. The potential risks and benefits for each specific patient should be carefully considered before using Plasma-Lyte 148 & Glucose 5% w/v solution in pregnancy or lactating woman.

If Plasma-Lyte 148 & Glucose 5% w/v solution is administrated to pregnant women during labour, particularly if administered in combination with oxytocin, there may be an increased risk for hyponatraemia (see section 4.4, 4.5 and 4.8).

4.7 Effects on ability to drive and use machines

There is no information of the effects of Plasma-Lyte 148 & Glucose 5% w/v solution on the ability to drive and use machines

4.8 Undesirable effects

The following adverse reactions have been reported in the postmarketing experience, with unspecified Plasma-lyte products and Plasma-lyte products with Glucose, listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity, where feasible.
Frequency is defined as very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100): rare (≥ 1/10,000 to < 1/1000); very rare (< 1/10,000); and not known (cannot be estimated from the available data).

System Organ Class (SOC)	MedDRA Preferred Term	Frequency

Immune system disorders	Hypersensitivity /infusion reaction (including Anaphylactoid reaction, and the following manifestations: Hypotension, Chest discomfort, Dyspnea, Wheezing, Flushing, Hyperaemia, Asthenia, Urticaria, Cold sweat, Pyrexia, Chills *Tachycardia, Palpitations, Chest pain, Respiratory rate increased, Feeling abnormal, Piloerection, Oedema Peripheral)	Not known
Metabolism and nutrition disorders	Hyperkalaemia, Hyperglycaemia Hypervolemia Hyponatraemia	Not known Not known
Nervous system disorders	Seizures Hyponatraemic encephalopathy	Not known
Vascular disorders	Thrombophlebitis Venous thrombosis	Not known Not known
Skin and subcutaneous tissue disorders	Urticaria	Not known
General disorders and administration site conditions	Infusion site reactions (e.g., Burning sensation Fever Injection site pain Injection site reaction Injection site phlebitis Injection site irritation Injection site infection Extravasation)	Not known
Investigations	False positive laboratory results (Bio-Rad Laboratories' Platelia Aspergillus EIA test) (see Section 4.4)	Not known

* The adverse reactions highlighted in italic are reported for other similar products

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

4.9 Overdose

Excessive administration of a glucose-containing solution may lead to hyperglycemia, hyperosmolarity, osmotic diuresis, and dehydration.

Overuse or too fast administration may lead to water and sodium overload with a risk of oedema, particularly when there is a defective renal sodium excretion. In this case extra renal dialysis may be necessary.

Excessive administration of potassium may lead to the development of hyperkalemia, especially in patients with renal impairment. Symptoms include paresthesia of the extremities, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion. Treatment of hyperkalemia involves the administration of calcium, insulin (with glucose) sodium bicarbonate, exchange resins or dialysis.

Excessive parenteral administration of magnesium salts leads to the developments of hypermagnesemia, important signs of which are loss of deep tendon reflexes and respiratory depression, both due to neuromuscular blockade. Other symptoms of hypermagnesemia may include nausea, vomiting, flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, muscle weakness, bradycardia, coma, and cardiac arrest. A patient with supralethal hypermagnesemia was successfully treated using assisted ventilation, calcium chloride, administered intravenously, and forced diuresis with mannitol infusions.

Excessive administration of chloride salts may cause a loss of bicarbonate with an acidifying effect.

Excessive administration of compounds, such as sodium acetate and sodium gluconate, which are metabolized to form the bicarbonate anion may lead to hypokalemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include mood changes, tiredness, shortness of breath, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop especially in hypocalcemic patients. Treatment of metabolic alkalosis associated with bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance.

Prolonged administration or rapid infusion of large volumes of glucose containing solutions may lead to hyperosmolarity, dehydration, hyperglycaemia, hyperglucosuria and osmotic diuresis (due to hyperglycaemia).

When overdose is related to medications added to the solution infused, the signs and symptoms of over infusion will be related to the nature of the additive being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant symptomatic and supportive measures should be provided as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: “Electrolytes with Carbohydrates” - ATC code: “B05BB02”

- B05: blood substitutes and perfusion solutions

- B05B: I.V. solutions
- B05BB: Solutions affecting the electrolyte balance

Plasma-Lyte 148 & Glucose 5% w/v is an hyper-osmotic solution of electrolytes in 5% glucose, with an approximate osmolarity of 572 mOsm/l. The electrolytes constituents of Plasma-Lyte 148 & Glucose 5% w/v solution and their concentrations are designed to match those of plasma.

The pharmacological properties of Plasma-Lyte 148 & Glucose 5% w/v solution are those of its components (water, glucose, sodium, potassium, magnesium, chloride, acetate and gluconate).

The main effect of Plasma-Lyte 148 & Glucose 5% w/v is the expansion of the extracellular compartment including both the interstitial fluid and the intravascular fluid, with a source of energy.

Sodium acetate and gluconate are bicarbonate-producing salts and as such are alkalinizing agents.

Glucose is the principal source of energy in cellular metabolism.

When medication is added to Plasma-Lyte 148 & Glucose 5% w/v, the overall pharmacodynamics of the solution will depend on the nature of the drug used.

5.2. Pharmacokinetic Properties

The pharmacokinetic properties of the Plasma-Lyte 148 & Glucose 5% w/v solution are those of the ions its composition includes (glucose, sodium, potassium, magnesium, chloride, acetate and gluconate).

Acetates are metabolised by muscle and peripheral tissues to bicarbonate, without solicitation of the liver.

The two main metabolic pathways of glucose are gluconeogenesis (energy storage) and glycogenolysis (energy release).

When medication is added to Plasma-Lyte 148 & Glucose 5% w/v, the overall pharmacokinetics of the solution will depend on the nature of the drug used.

5.3. Preclinical Safety Data

Preclinical safety data of Plasma-Lyte 148 & Glucose 5% w/v solution for infusion in animals are not relevant since its constituents are physiological components in animal and human plasma.
Toxic effects are not to be expected under the condition of clinical application.
The safety of potential additives should be considered separately.

6. PHARMACEUTICALS PARTICULARS

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

Hydrochloric acid concentrated (for pH adjustment)

6.2 Incompatibilities

Additives

When introducing additives to Plasmalyte 148 and Glucose 5% w/v solution, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

Incompatibility of the medicinal product to be added with the solution in Viaflo container must be assessed before addition.

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

Before adding a substance or medication, verify it is soluble and/or stable in water and that the pH range of Plasma-Lyte 148 & Glucose 5% w/v is appropriate(pH 4.0 - 6.0) After addition, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

Glucose 5% solutions are not compatible with blood or red blood cells, as haemolysis and clumping have been described.

Those additives known to be incompatible should not be used.

6.3 Shelf life

Unopened: 2 years for the 250 ml and 500 ml containers

3 years for the 1000 ml container

In-use shelf-life: Additives

Chemical and Physical stability of any additive at the pH of Plasmalyte 148 and Glucose 5% w/v solution in the Viaflo container should be established prior to use.

From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer

than 24 hours at 2 to 8°C unless reconstitution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

The bags are composed of polyolefin/polyamide co-extruded plastic (PL 2442). The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene which serves only to provide physical protection to the bags.

The bag size is either 250, 500 or 1000mL.

Outer carton contents:

1	bag of	250ml
30	bags of	250ml
1	bag of	500ml
20	bags of	500ml
1	bag of	500ml
10	bags of	1000ml
12	bags of	1000ml

6.6 Special precautions for disposal and other handling

After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion. The solution may appear as a clear, colourless to faintly straw-coloured solution, free from visible particles.

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 broken.

c. Check the solution for clarity 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: Some additives may be incompatible.

When additive is used, verify osmolarity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

To add medication before administration

a. Disinfect medication port.
b. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) 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 port.
c. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) 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 00116/0333

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/10/2009

10 DATE OF REVISION OF THE TEXT

13/05/2026