

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Compound Sodium Lactate & Glucose 5% w/v Solution for Infusion.
(Synonym: “Ringer Lactate & Glucose 5% w/v solution for infusion”)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose (as monohydrate)	50.0 g/l
Sodium Chloride:	6.00 g/l
Potassium Chloride:	0.40 g/l
Calcium Chloride dihydrate:	0.27 g/l
Sodium Lactate:	3.20 g/l

	Na ⁺	K ⁺	Ca ⁺⁺	Cl ⁻	C ₃ H ₅ O ₃ ⁻ (lactate)
mmol/l	131	5	2	111	29
mEq/l	131	5	4	111	29

200 kcal/L (840 kJ/L)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for infusion.

Clear solution, free from visible particles.

555 mOsm/l (approx.) pH: 4.0 – 6.5

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Compound Sodium Lactate & Glucose 5% w/v solution (Ringer Lactate & Glucose 5% w/v solution) is used in the following indications when a source of carbohydrate is required:

- Restoration of extracellular fluid and electrolyte balance or replacement of extracellular fluid loss where isotonic concentrations of electrolytes are sufficient

- Short term volume replacement (alone or in association with colloid) in case of hypovolemia or hypotension.
- Regulation or maintenance of metabolic acidosis balance and/or treatment of mild to moderate metabolic acidosis (except lactic acidosis)

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

As for other calcium-containing infusion solutions, concomitant administration of ceftriaxone and Compound Sodium Lactate & Glucose 5% solution is contraindicated in newborns (≤ 28 days of age), even if separate infusion lines are used (risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream). For patients over 28 days of age please see section 4.4.

Compound Sodium Lactate & Glucose 5% solution is also contraindicated in patients with

- A known hypersensitivity to sodium lactate.
- Extracellular hyperhydration or hypervolemia
- Severe renal insufficiency (with oliguria/anuria)
- Uncompensated cardiac failure
- Hyperkalemia
- Hypercalcaemia
- Metabolic alkalosis
- Ascitic cirrhosis
- Severe metabolic acidosis
- Conditions associated with increased lactate levels (hyperlactatemia) including lactic acidosis, or impaired lactate utilization, such as severe hepatic insufficiency.
- Concomitant digitalis therapy (see section 4.5 Interactions with other medicinal products and other forms of interaction)

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

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 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

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 hypokalaemia. 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

No studies have been conducted on the influence of Compound Sodium Lactate & Glucose 5% 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

System Organ Class	Adverse reactions (Preferred terms)	Frequency
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.

System Organ Class	Adverse reactions (Preferred Terms)	Frequency
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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

4.9 Overdose

An excessive volume or too high a rate of administration of Compound Sodium Lactate & Glucose 5% solution may lead to fluid and sodium overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired. 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.

Excessive administration of calcium salts may lead to hypercalcemia. Symptoms of hypercalcemia may include anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, polydipsia, polyuria, nephrocalcinosis, renal calculi, and, in severe cases, cardiac arrhythmias and coma. Too rapid intravenous injection of calcium salts may also lead to many of the symptoms of hypercalcemia as well as to chalky taste, hot flushes, and peripheral vasodilatation. Mild asymptomatic hypercalcemia will usually resolve on stopping administration of calcium and other contributory drugs such as vitamin D. If hypercalcemia is severe, urgent treatment (such as loop diuretics, hemodialysis, calcitonin, bisphosphonates, trisodium edetate) is required.

Excessive administration of lactate may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalemia. 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 due to bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride, and potassium may be of particular importance.

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

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 (ATC code): B05BB02 “Electrolytes with Carbohydrates”.

Compound Sodium Lactate & Glucose 5% w/v solution (Ringer Lactate & Glucose 5% w/v solution) is an hypertonic solution of electrolytes and glucose.

The pharmacological properties of the Compound Sodium Lactate & Glucose 5% w/v solution (Ringer Lactate & Glucose 5% w/v solution) are those of its components (glucose, sodium, potassium, calcium, chloride and lactate).

Glucose is the main source of energy, and this solution provides 200 kcal/L.

The main effect of Compound Sodium Lactate & Glucose 5% w/v (Ringer Lactate & Glucose 5% w/v) is the expansion of the extracellular compartment including both the interstitial fluid and the intravascular fluid.

The lactate is metabolised into bicarbonate, mainly in the liver, and produces an alkalinising effect on the plasma.

In healthy volunteers receiving Compound Sodium Lactate (Ringer Lactate), central venous pressure changes were associated with a secretion of atrial natriuretic peptide.

There is no significant changes in glucagon, norepinephrine, epinephrine, blood glucose and insulin levels in aortic surgery patients receiving Compound Sodium Lactate & Glucose 5% w/v (Ringer Lactate & Glucose 5% w/v).

When medication is added to Compound Sodium Lactate & Glucose 5% w/v (Ringer Lactate & 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 Compound Sodium Lactate & Glucose 5% w/v solution (Ringer Lactate & Glucose 5% w/v solution) are those of its components (glucose, sodium, potassium, calcium, chloride and lactate).

Infusion of Compound Sodium Lactate & Glucose 5% w/v (Ringer Lactate & Glucose 5% w/v) in normal hemodynamically stable adults does not increase circulating lactate concentrations.

The pharmacokinetics of D-lactate and L-lactate are similar.

The lactate in Compound Sodium Lactate & Glucose 5% w/v solution (Ringer Lactate & Glucose 5% w/v solution) is metabolized by both oxidation and gluconeogenesis, predominantly in the liver, and bicarbonate is generated by both processes over 1-2 h.

When medication is added to Compound Sodium Lactate & Glucose 5% w/v (Ringer Lactate & 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 Compound Sodium Lactate & Glucose 5% w/v (Ringer Lactate & Glucose 5% w/v) solution 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. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

Ceftriaxone must not be mixed with calcium-containing solutions including Compound Sodium Lactate & Glucose 5% solution. See also sections 4.3 and 4.4.

As with all parenteral solutions additives may be incompatible. Compatibility of the additives with the Compound Sodium Lactate & Glucose 5% solution and Viaflo container must be assessed before addition. After addition of an additive, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

The Instructions for Use of the medication to be added and other relevant literature must be consulted.

Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Compound Sodium Lactate & Glucose 5% solution is appropriate.(pH 4.0 to 6.5)..

When making additions to Compound Sodium Lactate & Glucose 5% solution, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

As guidance the following medications are incompatible with the Compound Sodium Lactate & Glucose 5% solution (*non-exhaustive listing*):

Medications incompatible with Compound Sodium Lactate & Glucose 5% solution

- Aminocaproic acid
- Amphotericin B
- Ceftriaxone
- Cortisone acetate
- Diethylstilbestrol
- Etamivan
- Ethyl alcohol
- Phosphate and carbonate solutions
- Oxytetracycline
- Thiopental sodium
- Versenate disodium

Medications with partial incompatibility with Compound Sodium Lactate & Glucose 5% solution:

- Tetracycline stable for 12 hours
- Ampicillin sodium
 - concentration of 2%-3% stable for 4 hours
 - concentration >3% must be given within 1 hour
- Minocycline stable for 12 hours
- Doxycycline stable for 6 hours

Additives known or determined to be incompatible should not be used.

6.3. Shelf life

Shelf life (Unopened): 30 months for 1000 ml container.

2 years for 250 ml and 500 ml container.

In-use shelf life: Additives

Chemical and Physical stability of any additive at the pH of Compound Sodium Lactate & Glucose 5% w/v solution (Ringer Lactate 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 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.

Bag sizes: 250ml, 500ml and 1000ml.

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

Outer carton contents:	30	bags of	250ml
	20	bags of	500ml
	10	bags of	1000ml
	12	bags of	1000ml

Not all pack sizes may be marketed

6.6 Special precautions for disposal

After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

Opening

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

Preparation for administration

Use sterile material for preparation and administration.

- Suspend container from eyelet support.
- 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.
- Use an aseptic method to set up the infusion.
- Attach administration set. Refer to directions accompanying set for connection, priming of the set and administration of the solution.

Techniques for injection of additive medications

Warning: Some additives may be incompatible. Check additive compatibility with both the solution and container prior to use. 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.

To add medication before administration

- Disinfect medication site.
- Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
- 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

- Close clamp on the set
- Disinfect medication site.
- Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
- Remove container from IV pole and/or turn to an upright position.
- Evacuate both ports by tapping gently while the container is in an upright position.
- Mix solution and medication thoroughly.
- 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 00116/0331

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

19/03/2006

10 DATE OF REVISION OF THE TEXT

18/03/2024