Baxter

Equilibria

FLUID OPTIMIZATION

Many adult hospital inpatients require **IV fluid therapy**[1]

The fluid needs of critical (rescue and optimisation) and non-critical (stabilisation and de-escalation) patients vary.[2–4]

The composition of various fluids used throughout the patient journey are highlighted below.

Based on a 70 kg patient	mmol/2L*								g/2L*	mL
	Cations				Anions					
	Na^+	K^+	Ca^{2+}	Mg^{2+}	Cl^-	Acetate	Lactate	Gluconate	Glucose	Water
0.9% sodium chloride[5†]	308	-	-	-	308	-	-	-	-	2000
Hartmann's solution[6]	262	10	4	-	222	-	58	-	-	2000
Plasma-Lyte 148 (pH 7.4)[7]	280	10	-	3	196	54	-	46	-	2000
Potassium chloride 0.3%, sodium chloride 0.18% & glucose 4%[8‡]	62	80	-	-	142	-	-	-	80	2000
Maintelyte[9]	80	40	-	3	80	46	-	-	100	2000
	mmol/day								g/day	mL/day
NICE daily requirements[1]	70	70	-	-	70	-	-	-	50–100	1750–2100

Select the *right* fluid for the *right* patients to help avoid complications due to fluid overload and electrolyte imbalances.

*A 70 kg patient will require two bags of IV fluid per day; therefore, levels of components have been adjusted accordingly.
†Approximate values. Please refer to the Summary of Product Characteristics for full details.
‡Approximate mmol given please see Summary of Product Characteristics for full details.

References: 1. National Institute for Health and Care Excellence CG 174 Intravenous fluid therapy in adults in hospital. Clinical guideline CG174, 2013. **2.** Malbrain M *et al. Ann Intensive Care*. 2018;8:66. **3.** Benes J *et al. BioMed Res Int*. 2015;2015:729075. **4.** Hoste *EA et al. Br J Anaesth*. 2014;113:740–7. **5.** Baxter Sodium Chloride 0.9% Intravenous Infusion B.P. UK SmPC. December 2018. **6.** Baxter Compound Sodium Lactate Solution for Infusion. UK SmPC. December 2018. **7.** Baxter Plasma-Lyte 148 (pH 7.4). UK SmPC. December 2018. **8.** Baxter Potassium Chloride 0.3%, Sodium Chloride 0.18% and Glucose 4% Solution for Infusion BP. UK SmPC. October 2019. **9.** Baxter Maintelyte 50mg/mL Solution for Infusion. UK SmPC. March 2020.

Prescribing information for 0.9% sodium chloride

Sodium Chloride 0.9% Intravenous Infusion BP Viaflo - PRESCRIBING INFORMATION

Name and composition: Sodium Chloride 0.9% Intravenous Infusion BP

Indications: Isotonic extracellular dehydration, sodium depletion, or vehicle or diluent of compatible drugs for parenteral administration

Dosage and Route: Fluid balance, serum electrolytes and acid-base balance may need to should be monitored before and during administration with particular attention to serum sodium in patients with increased non-osmotic vasopressin release and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia. Infusion rate/volume depend on the age, weight, clinical condition (e.g. burns, surgery, head-injury, infections), and concomitant therapy & should be determined by a physician experienced in paediatric intravenous fluid therapy. Recommended dose for isotonic extracellular dehydration and sodium depletion: adults 500 - 3000 ml/24h. Babies and children: 20 to 100 ml / 24 h / per kg body weight, depending on age and body mass. Dose when used as a vehicle / diluent between 50 to 250 ml per dose of medicinal product. The dose and infusion rate shall be dictated by admixed prescribed drug for administration. Administer by intravenous infusion through a sterile, non-pyrogenic administration set using aseptic technique. Prime the line with solution to prevent air entering the system. Only use if product is free from particulate matter, no discolouration and seal intact. Do not remove unit from overwrap until ready to use. Administer immediately following insertion of infusion set. To prevent air embolism do not connect bags in series, remove residual air from the container prior to pressurising, do not use vented administration set with the vent open **Side effects:** *See Summary of Product Characteristics for detail. Nervous system disorders:* tremor, acute hyponatraemic encephalopathy. *Metabolism and nutrition disorders:* Hospital acquired hyponatraemia, which may cause irreversible brain injury and death, due to development of acute hyponatraemic encephalopathy. *Vascular disorders:* Hypotension. *Skin and subcutaneous tissue disorders:* urticaria, rash, pruritus. *General disorders and administration site conditions*: Infusion site reactions, such as infusion site erythema, vein irritation, Injection site streaking, burning sensation, local pain or reaction, infusion site urticaria, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia, pyrexia, chills. The following adverse reactions have not been reported with this product but may occur: hypernatraemia (eg. when administered to patients with nephrogenic diabetes insipidus or high nasogastric output), hyperchloraemic metabolic acidosis, hyponatraemia, which may be symptomatic. Hyponatraemia may occur when normal free water excretion is impaired. (eg SIADH or postoperative). **Precautions:** The inner bag maintains the sterility of the product. Discard after single use. Discard any unused portion. Do not reconnect partially used bags. Particular caution in patients with (severe) renal impairment. Inappropriate volume and rate may lead to fluid overload and/or solute overload, clinically relevant electrolyte and acid-base disturbances. High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure and in patients with non-osmotic vasopressin release, due to the risk of hospital-acquired hyponatraemia. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral 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, cerebral contusion and brain oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia. Clinical monitoring is required at the beginning of any intravenous infusion. During prolonged therapy or when the patient's condition dictates, periodic clinical and laboratory monitoring may be necessary. Caution in patients with pre-eclampsia. Particular caution in patients with or at risk for hypernatraemia, hyperchloraemia, metabolic acidosis, hypervolaemia, iatrogenic hyperchloraemic metabolic acidosis. Particular caution in patients with primary hyperaldosteronism or conditions that may cause sodium retention, fluid overload and oedema or use with medications that may increase the risk of sodium and fluid retention. Symptoms of unknown aetiology which can appear to be hypersensitivity reactions have been reported very rarely, if symptoms develop (hypotension, pyrexia, tremor, chills, urticaria, rash, pruritus) stop the infusion immediately. A rapid change in sodium concentration is potentially dangerous. Paediatric patients may have impaired ability to regulate fluid and electrolyte levels. Repeated infusions should only be given after serum sodium concentration has been determined. Geriatric patients are more likely to have cardiac, renal, hepatic and other diseases or drug therapy that may affect volume/rate of infusion. This medicine should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin. **Contraindications:** Hypernatraemia, hyperchloraemia. Consider contraindications of drug added when used as a diluent. **Interactions:** The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids: Drugs stimulating vasopressin release include: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics; drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs, cyclophosphamide; Vasopressin analogues include: Desmopressin, oxytocin, vasopressin, terlipressin. Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine. Caution in patients receiving lithium. Corticosteriods/steriods and carbenoxolone are associated with retention of sodium and water (with odema and hypertension). **Overdose:** Nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma, and death. Hypernatraemia to be treated by a specialised physician. May cause a loss of bicarbonate with an acidifying effect. When used as a diluent, signs / symptoms of overdose will be related to the additives used. Discontinue treatment, monitor for signs / symptoms related to the medicinal product administered. Relevant supportive measures should be provided.
Legal category: POM
Basic NHS price:

Bag volume	Code	Hospital List Price (£ ex VAT)
50 ml	FE1306G	£1.63
100 ml	FE1307G	£1.66
250 ml	FKE1322	£1.66
500 ml	FKE1323	£1.66
1000 ml	FKE1324	£1.84

Marketing Authorisation Number and Holder: PL 0116/0334 and **PA 2299/002/001**
UK: Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE.
Ireland: Baxter Holding B.V., Kobaltweg 49, 3542CE Utrecht, Netherlands
Date of preparation: September 2020

Adverse Events should be reported. For the UK reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland report to the Health Products Regulatory Authority (HPRA) using a Yellow Card obtained from the HPRA via the online system (www.hpra.ie) or by telephone on +353 (0)1-6764971.

Adverse Events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on +44 (0)1635 206360, or by email to vigilanceuk@baxter.com

Prescribing information Hartmann's solution

PRESCRIBING INFORMATION – Compound Sodium Lactate Solution for Infusion B.P. (Viaflo). Synonyms – Ringer Lactate Solution for Infusion, Hartmann's Solution for Infusion. **Name and composition:** Each 1000ml contains: Sodium Chloride 6.00g, Potassium Chloride 0.40g, Calcium Chloride dihydrate 0.27g, Sodium Lactate 3.20g. pH 5.0-7.0. **Indications:** Restoration of extracellular fluid and electrolyte balances, replacement of extracellular fluid loss where isotonic concentrations of electrolytes are sufficient, short term volume replacement in hypovolemia or hypotension, regulation or maintenance of metabolic acidosis balance and/or treatment of mild to moderate metabolic acidosis (except lactic acidosis). **Dosage and Route:** Adults 500ml – 3L per 24 hours. Infants, toddlers and children 20ml – 100ml/kg body weight/24 hours. Fluid balance, serum electrolytes and acid-base balance may need to should be monitored before and during administration with particular attention to serum sodium in patients with increased non-osmotic vasopressin release and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia. Infusion rate/volume depend on the age, weight, clinical condition (e.g. burns, surgery, head-injury, infections), and concomitant therapy & should be determined by a physician experienced in paediatric intravenous fluid therapy. Safety and efficacy in paediatric patients has not been established by adequate and well controlled trials. Lactate-containing solutions should be administered with caution to neonates and infants less than 6 months of age. Consider geriatric patients more likely to have cardiac, renal, hepatic and other diseases or concomitant drug therapy. For intravenous infusion through a sterile non-pyrogenic administration set using aseptic technique. Set should be primed with solution to prevent air entering the system. Do not administer unless solution is clear, free from visible particulate matter and the seal is intact. Do not remove from overwrap until ready for use. Administer immediately following insertion of infusion set. Do not connect containers in series to avoid air embolism. Remove residual air from the container before pressurizing. Vented administration sets with the vent open should not be used with flexible plastic containers due to risk of air embolism. When making additions aseptic technique must be used, mix solution thoroughly. Do not store solutions containing additives. **Side effects:** ***See Summary of Product Characteristics for detail***. *Immune System Disorders:* Hypersensitivity/Infusion reactions including Anaphylactic/Anaphylactoid reaction, possibly manifested by one or more of the following symptoms: Angioedema, Chest pain, Chest discomfort, Decreased heart rate, Tachycardia, Blood pressure decreased, Respiratory distress, Bronchospasm, Dyspnea, Cough, Urticaria, Rash, Pruritus, Erythema, Flushing, Throat irritation, Paresthesias, Hypoesthesia oral, Dysgeusia, Nausea, Anxiety, Pyrexia, Headache. Metabolism and Nutrition Disorders: Hyperkalaemia, Hospital acquired hyponatraemia (which may cause irreversible brain injury and death, due to development of acute hyponatraemic encephalopathy). *Nervous system disorders:* Acute hyponatraemic encephalopathy. *General Disorders and Administration Site Conditions:* Infusion Site Reactions manifested by one or more of the following symptoms: Phlebitis, Infusion site inflammation, Infusion site swelling, Infusion site rash, Infusion site pruritus, Infusion site erythema, Infusion site pain, Infusion site burning. *The following adverse reactions have been reported during the use of other sodium-lactate containing solutions:* hypersensitivity: Laryngeal oedema (Quincke's oedema), skin swelling, Nasal congestion, Sneezing, electrolyte disturbances, Hypervolaemia, Panic Attack, infection at the site of injection, extravasation, Infusion site anaesthesia (numbness). **Precautions:** Stop the infusion immediately if signs or symptoms of suspected hypersensitivity reaction occur. Ceftriaxone must not be administered simultaneously with compound sodium lactate, through the same line. Flush line thoroughly between infusions – see contra-indications section for patients below 28 days old. Only use compound sodium lactate in patients with hypernatraemia or hyperchloraemia after careful consideration of alternative intravenous fluids. Caution in patients predisposing to hypernatraemia, hyperchloraemia or hypercalcaemia. Compound sodium lactate should not be used in an attempt to correct potassium insufficiency. Particular caution in patients predisposed to hyperkalaemia and patients with cardiac disease. Care should be taken to prevent extravasation (calcium chloride is irritant) and intramuscular injection must be avoided. Caution in patients with renal impairment, may result in sodium and/or potassium retention. Risk of fluid and/or solute overload and electrolyte disturbances. Caution if administered to patients with hypervolaemia, overhydration or conditions causing sodium retention, fluid overload and oedema. Caution in patients at risk of alkalosis. High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure and in patients with non-osmotic vasopressin release, due to the risk of hospital-acquired hyponatraemia. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral 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, cerebral contusion and brain oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia. This medicine should not be added to or administered simultaneously through the same line as citrate anticoagulated/preserved blood due to risk of coagulation. Monitor glucose levels in patients with type 2 diabetes. During long term parenteral treatment nutritive supply must be given. This medicine should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin. **Contraindications:** Concomitant administration of ceftriaxone and compound sodium lactate is contra-indicated in newborns (≤28 days of age) even if separate infusion lines are used due to risk of fatal ceftriaxone-calcium salt precipitation. Contra-indicated in patients with known hypersensitivity to sodium lactate, extracellular hyperhydration or hypervolemia, severe renal insufficiency (with oliguria/anuria), uncompensated cardiac failure, hyperkalaemia, hypercalcaemia, metabolic alkalosis, ascitic cirrhosis, severe metabolic acidosis, conditions associated with increased lactate levels, including lactic acidosis, or impaired lactate utilization, such as severe hepatic insufficiency. Conditions associated with concomitant digitalis therapy. **Interactions:** See precautions and contra-indication for use with ceftriaxone. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids: Drugs stimulating vasopressin release include: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics; drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs, cyclophosphamide; Vasopressin analogues include: Desmopressin, oxytocin, vasopressin, terlipressin. Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine. *Presence of sodium:* Caution with drugs that may increase retention of sodium and fluid retention. *Presence of potassium:* Caution with drugs that may cause or increase the risk of hyperkalaemia - Potassium-sparing diuretics (amiloride, spironolactone, triamterene, alone or in association), angiotensin converting enzyme inhibitors (ACEi) and angiotensin II receptor antagonists, tacrolimus, cyclosporin; may lead to potentially fatal hyperkalemia (particularly in patients with severe renal insufficiency). *Presence of calcium:* digitalis glycosides (digitalis cardiotonic); effects enhanced, may lead to serious or fatal cardiac arrhythmia. Thiazide diuretics or vitamin D; can lead to hypercalcaemia. Bisphosphonates, fluoride, some fluoroquinolones and tetracyclines; less absorbed. *Presence of lactate:* Caution in patients treated with drugs for which renal elimination is pH dependent. Renal clearance of acidic drugs, such as salicylates, barbiturates, lithium; renal clearance increased – alkalinisation of urine by bicarbonate (from lactate metabolism). Renal clearance of alkaline drugs, such as sympathomimetics (e.g. ephedrine, pseudoephedrine) and stimulants (e.g. dexamphetamine sulphate, phenfluramine hydrochloride) may be decreased. **Overdose:** Fluid and sodium overload (with risk of oedema), hyperkalaemia, hypercalcemia, hypokalemia, metabolic alkalosis. If overdose related to medication added to the solution signs and symptoms will relate to the nature of the additive.

Legal category: POM

Basic NHS price:

Bag volume	Code	Hospital List Price (£ ex VAT)
500ml	FKE2323	2.53
1000ml	FKE2324	3.25

Marketing Authorisation Number and Holder: PL 00116/0330 and **PA2299/012/001**

UK: Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE.

Ireland: Baxter Holding B.V., Kobaltweg 49, 3542CE Utrecht, Netherlands

Date of preparation: March 2019

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Prescribing information for Plasma-Lyte solution

Plasma-Lyte 148 (pH 7.4) Solution for infusion - PRESCRIBING INFORMATION

Name and composition: Plasma-Lyte® 148 (pH 7.4) solution for infusion. Sodium chloride 5.26g/L, potassium chloride 0.37g/L, magnesium chloride hexahydrate 0.30g/L, sodium acetate trihydrate 3.68g/L, sodium gluconate 5.02g/L. **Indications:** Fluid replacement (e.g. after burns, head injury, fracture, infection, peritoneal irritation), intraoperative fluid replacement, haemorrhagic shock and clinical situations requiring rapid blood transfusion, mild to moderate metabolic acidosis, also in case of lactate metabolism impairment. **Dosage and Route:** Fluid balance, serum electrolytes and acid-base balance should be monitored before and during administration with particular attention to serum sodium in patients with increased non-osmotic vasopressin release and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia. Infusion rate/volume depend on the age, weight, clinical condition (e.g. burns, surgery, head-injury, infections), and concomitant therapy & should be determined by a physician experienced in paediatric intravenous fluid therapy. Intravenous only. Can be administered peripherally or centrally. Safety and efficacy in children has not been established in adequate, well controlled trials. Treatment of paediatric patients is described in literature. Consider that geriatric patients are generally more likely to have cardiac, renal, hepatic and other diseases or concomitant drug therapy. Dose and rate depends on age, weight, clinical and biological condition of the patient and concomitant therapy. Infusion rate usually 40 ml/kg/24h in adults, elderly and adolescents. Intraoperative administration rate is about 15 ml/kg/h. Recommended dose 500ml to 3 litres/24h. Dose varies with weight. 0-10kg b.w. up to 100ml/kg/24h: 10-20 kg b.w. 1000ml+(50ml/kg over 10kg)/24h: >20 kg b.w. 1500ml+(20ml/kg over 20kg)/24h. Rate varies with weight 0-10kg b.w. 6-8ml/kg/h: 10-20 kg b.w. 4-6ml/kg/h: >20kg b.w. 2-4ml/kg/h. Do not administer solution unless it is clear, particulate free, no discolouration and seal intact. Air embolism possible if containers are connected in series. Remove residual air prior to pressure infusion. Open vented sets should not be used with these bags. **Side effects:** *See Summary of Product Characteristics (SmPC) for detail. Immune system disorders:* Hypersensitivity/infusion reaction: including Anaphylactoid reaction, and the following manifestations Tachycardia, Palpitations, Chest pain, Chest discomfort, Dyspnea, Respiratory rate increased, Flushing, Hyperaemia, Asthenia, Feeling abnormal, Piloerection, Oedema peripheral, Pyrexia, Urticaria (Hypotension, Wheezing, Cold sweat, Chills, Hyperkalaemia). *Metabolism and nutrition disorders:* Hypervolaemia, Hospital acquired hyponatraemia, which may cause irreversible brain injury and death, due to development of acute hyponatraemic encephalopathy. *Nervous system disorders*: Seizures Acute hyponatraemic encephalopathy. *Vascular disorders*: Thrombophlebitis, Venous thrombosis. *Skin and subcutaneous tissue disorders:* Urticaria. *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). *Investigations*: False positive laboratory results (Bio-Rad Laboratories' Platelia Aspergillus EIA test). **Precautions:** Not indicated for treatment of hypochloraemic hypokalaemic alkalosis nor for primary treatment of severe metabolic acidosis or treatment of hypomagnesaemia. Contains insufficient potassium to produce useful effect in severe potassium deficiency. Caution in patients with or at risk of hypermagnaesemia, monitor for excess magnesium particularly in eclampsia. Caution in patients with hypocalcaemia. Caution in patients with or at risk of hyperkalaemia and in patients with cardiac disease, severe renal impairment, or predisposed to hyperkalaemia, potassium levels should be closely monitored. Monitor patient's clinical status and laboratory parameters to mitigate risk of fluid and/or solute overload and electrolyte disturbances. High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure and in patients with non-osmotic vasopressin release, due to the risk of hospital-acquired hyponatraemia. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral 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, cerebral contusion and brain oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia. Caution in hypervolaemia, over hydration or conditions that cause sodium retention and oedema. Particular caution in patients with or at risk of alkalosis. Hypersensitivity/infusion reactions including anaphylactoid reactions have been reported, appropriate therapeutic countermeasures must be instituted as clinically indicated. Caution following neuromuscular block, magnesium salts can lead to recurarisation effect. Take into account electrolyte supply in parenteral nutrition. Possible false positive test for Aspergillus infection using Bio-Rad Laboratories Platelia Aspergillus EIA test, confirm by other diagnostic methods. No adequate data for use in pregnancy or lactation, carefully consider potential risks and benefits for each patient, although this medicine should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin. **Contraindications:** Hyperkalaemia, renal failure, heart block, metabolic or respiratory alkalosis, hypochlorhydria, hypersensitivity to active substances or excipients. **Interactions:** The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids: Drugs stimulating vasopressin release include: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics; drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs, cyclophosphamide; Vasopressin analogues include: Desmopressin, oxytocin, vasopressin, terlipressin. Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine. *Presence of sodium* – corticoids/steroids and carbenoxolone associated with sodium retention and water. *Presence of potassium* – The following combinations increase plasma potassium and may lead to potentially fatal hyperkalaemia, notably in renal failure: potassium sparing diuretics, angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists, tacrolimus, cyclosporine. *Presence of magnesium* – neuromuscular blockers enhanced effect. Acetylcholine reduced effect. Aminoglycoside antibacterials and nifedipine enhanced effect. *Presence of acetate and gluconate* – renal clearance of acidic drugs may be increased, such as salicylates, barbiturates and lithium. Renal clearance of alkaline drugs may be decreased, such as ephedrine, pseudoephedrine, dexamphetamine, phenfluramine. **Overdose:** Water and sodium overload (oedema), hyperkalaemia, hypermagnesemia, acidosis, hypokalaemia and metabolic alkalosis. If overdose related to medication added to the solution signs and symptoms will relate to the nature of the additive. **Legal category:** POM

Basic NHS price:

Bag volume	Code	Hospital List Price (£ ex VAT)
500ml	FKE0323	1.46
1000ml	FKE0324	1.83

Marketing Authorisation Number and Holder: PL 00116/0332 and **PA2299/032/001**
UK: Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE.
Ireland: Baxter Holding B.V., Kobaltweg 49, 3542CE Utrecht, Netherlands
Date of preparation: March 2019

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Prescribing information for KCl 0.3% + NaCl 0.18% + glucose 4%

Potassium chloride 0.3% w/v, sodium chloride 0.18% w/v, glucose 4% w/v, Solution for infusion PRESCRIBING INFORMATION – UK

Name and composition: Potassium chloride 0.3% w/v, sodium chloride 0.18% w/v, glucose 4% w/v solution for infusion. Each 1L contains 40 mmol K^+, 31 mmol Na^+, 71 mmol Cl^-. **Indications:** Prevention & treatment of potassium, sodium and chloride depletion due to a loss of gastrointestinal fluid (vomiting, diarrhoea, surgical drainage, gastric suction, small intestinal bypass procedure, or small bowel fistula), chronic abuse of laxative, malabsorption syndromes, mucus secreting villous adenoma of the small intestine, or renal salt-losing conditions (renal disorders, overuse of diuretics), particularly in cases where a source of energy is required. **Posology and Method of Administration:** Dosage, concentration, volume & rate of administration depends on the age, weight, clinical condition of the patient and concomitant therapy. In the case of electrolyte/glucose abnormalities or paediatric patients, consult a physician experienced in IV therapy. For prevention of hypokalaemia up to 50 mmol/d K^+ similar doses may be adequate for mild potassium deficiency. For acute hypokalaemia, up to 20 mmol K^+ in 500ml over 2-3 hours under ECG control. Patients with renal impairment should receive lower doses. Maximum recommended dose of potassium is 2-3 mmol/kg/24h. Rate should not exceed 10-40 mmol/h. Peripheral infusions should be less than 60 mmol/L K^+ to avoid pain. Maximum rate of glucose is 500 – 800 mg/kg/h. Administration to be performed intravenously into a large peripheral or central vein using sterile, non-pyrogenic equipment. Hyperosmolar solutions may cause venous irritation and phlebitis and are recommended to be administered through a large central vein. Rate should not exceed 10-40 mmol/h K^+ to avoid dangerous hyperkalaemia. When introducing additives, consult other relevant literature. Increase flow gradually; rapid correction of hyponatraemia and hypernatraemia is potentially dangerous. 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 and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia. **Side effects:** *See Summary of Product Characteristics for detail.* Anaphylactic reaction (for example, with patients allergic to corn), hypersensitivity, hospital acquired hyponatraemia (may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy), hyperglycaemia, phlebitis, rash, pruritus, injection site reactions including, infusion site pain, injection site vesicles, chills, pyrexia. Hyperkalaemia cardiac arrest (as a manifestation of rapid intravenous administration and/or of hyperkalaemia). Venous thrombosis, extravasation, hypervolaemia, sweating, injection site infection and thrombophlebitis have been reported in the post marketing experience with other solutions of similar composition. **Precautions:** *See Summary of Product Characteristics for detail.* In the body, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization. Intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia. Potassium should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalaemia such as renal or adrenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns. Regular monitoring of clinical status, serum electrolytes and ECG is advisable. Sodium salts should be administered with caution to patients with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia, or other conditions associated with sodium retention. This product should be used with caution in patients with known corn allergies. Patients with non-osmotic vasopressin release, patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy. 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 are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia. Refeeding severely undernourished patients may result in the refeeding syndrome; careful monitoring and slowly increasing nutrient intake while avoiding overfeeding can prevent complications. Newborns, especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycaemia. Rapid correction of hyponatraemia is potentially dangerous. 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. This product should not be administered simultaneously with blood through the same administration set because of the possibility of haemolysis. Consider that geriatric patients are generally more likely to have other diseases or concomitant drug therapy. Intrapartum maternal intravenous glucose infusion may result in foetal hyperglycaemia and metabolic acidosis as well as rebound neonatal hypoglycaemia due to fetal insulin production. This 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. **Contraindications:** Known hypersensitivity to the product, hyperchloremia and hyperkalaemia that are not related to the concentration effect/associated to a volume depletion. Severe renal insufficiency (with oliguria/anuria), uncompensated heart failure and severe congestive heart failure, Addison's disease, Fluid and sodium retention, acute ischemic stroke, head trauma (first 24 hours), uncompensated diabetes, hyperosmolar coma, hyperglycaemia, hyperlactatemia, other known glucose intolerances (such as metabolic stress situations). **Interactions:** Both the glycaemic effects and its effects on water and electrolyte balance should be taken into account. Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased. 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) to do association with an increased risk of severe and potentially fatal hyperkalaemia, in particular in the presence of other risk factors for hyperkalaemia. Regarding medications (such as certain antiepileptic and psychotropic medications) that increase the risk of hyponatraemia or sodium and fluid retention. Solutions containing potassium should be used with caution in patients receiving drugs that increase serum potassium concentrations (potassium-sparing diuretics, ACE inhibitors, cyclosporin, and drugs that contain potassium such as potassium salts of penicillin). Corticosteroids are associated with the retention of sodium and water, with oedema and hypertension. As a guidance, the following medications are incompatible: Amphotericin B, Dobutamine, Glucose should not be administered through the same infusion equipment as whole blood as haemolysis and clumping can occur. See section 4.5 for the list of drugs that 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. **Overdose:** 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. Correlation between potassium levels and ECG changes is not precise, the presence of any ECG findings that are suspected to be caused by hyperkalaemia should be considered a medical emergency. Clinically significant overdose may constitute a medical emergency. **Legal category:** POM **Marketing Authorisation Number and Holder:** PL 00116/0341 Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk. IP24 3SE. UK **Basic NHS Price** Code FE1724 £2.40 **Date of preparation:** Sept 2019

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Prescribing information for KCl 0.3% + NaCl 0.18% + glucose 4%

Potassium chloride 0.3%, sodium chloride 0.18% w/v, glucose 4% w/v, Solution for infusion BP PRESCRIBING INFORMATION – ROI

Name and composition: Potassium Chloride 0.3% w/v and Sodium Chloride 0.18% w/v in 4% w/v Glucose Intravenous Infusion BP (Viaflo Container). Potassium chloride 3.0 g/L, sodium chloride 1.8 g/L, glucose monohydrate 44.0g/L equivalent to 40 mmol/L potassium, 30 mmol/L sodium, 70 mmol/L chloride, 160 kCal/L glucose. **Indications**: Prevention and treatment of potassium, sodium and chloride depletion due to a loss of gastrointestinal fluid a chronic abuse of laxative, malabsorption syndromes, mucus secreting villous adenoma of the small intestine, or renal salt-losing conditions, particularly in cases where a source of energy is required. **Dosage and Route:** The dosage, volume, rate and duration of administration depends on the age, weight, and clinical and biological conditions condition of the patient and concomitant therapy. Administration should be guided by a physician experienced in intravenous fluid therapy. To prevent or treat mild hypokalaemia, typical doses are up to 50 mmol daily. In severe acute hypokalaemia, up to 20 mmol of potassium in 500 ml over 2 to 3 hours under ECG control. In renal impairment, lower the dose. The maximum recommended dose of potassium is 2 to 3 mmol/kg/24h. The rate should not exceed 10 to 40 mmol/h to avoid hyperkalaemia. The recommended dosage for the treatment of carbohydrates and fluid depletion is - for adults: 500ml to 3 litres/24h – *Paediatrics* 0-10 kg body weight; 100ml/kg/24h; 10-20kg body weight: 1000ml + (50ml/kg over 10kg)/24h; 20kg body weight: 1500ml + (20ml/kg over 20kg)/24h. Administer slowly via the intravenous route, preferably through a large central vein, using sterile and non-pyrogenic equipment. Ensure central catheter is not in the atrium or ventricle to avoid localised hyperkalaemia. Do not administer unless the solution is clear, free from particulate matter and the seal is intact. When introducing additives relevant literature must be consulted. *Rate of administration* Should not be given faster than 10 to 40 mmol/h to avoid a dangerous hyperkalaemia. A gradual increase of flow rate should be considered. Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous. Monitor for adequate urine output. Monitoring plasma-potassium and other electrolyte concentrations is essential. High dosage or rapid infusion must be performed under ECG control. **Side effects:** frequency unknown: anaphylactic reaction, hypersensitivity, hyponatraemia, hyperglycaemia, phlebitis, rash, pruritus, injection site reactions including: infusion site pain, injection site vesicles, chills, pyrexia. Other side effects include hyperkalaemia and cardiac arrest. Venous thrombosis, extravasation, hypervolaemia, sweating, injection site infection and thrombophlebitis have been reported in the post marketing experience with other solutions of similar composition. **Precautions**: Once administered, the solution becomes hypotonic. Potassium should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalaemia. Regular monitoring of clinical status, serum electrolytes and ECG is advisable. Sodium salts should be administered with caution to patients with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia, or other conditions associated with sodium retention. In diabetic patients, modify insulin requirements. During long term parenteral treatment, a convenient nutritive supply must be given to the patient. Use with caution in patients with known corn allergies. Administration may result in hyponatraemia, which can lead to headache, nausea, seizures, lethargy, coma, cerebral edema, and death. There is increased risk of hyponatraemia in children, elderly patients, women, postoperatively, patients with psychogenic polydipsia, patients treated with medications that increase the risk of hyponatraemia Acute symptomatic hyponatraemic encephalopathy is considered a medical emergency. The risk of hyponatraemic encephalopathy is increased in paediatric patients, women, patients with hypoxaemia, patients with underlying central nervous system disease. Administration to severely undernourished patients may result in the refeeding syndrome. Thiamine deficiency and fluid retention may also develop. Monitoring and a slow increase of nutrient intake prevent these complications. *Paediatric Use:* The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy, and should be determined by a consulting physician experienced in paediatric intravenous fluid therapy. Newborns, premature and with low birth weight, are at increased risk of developing hypo- or hyperglycaemia. Ensure adequate glycemic control by monitoring. Hypoglycaemia in the newborn can cause, e.g., prolonged seizures, coma, and cerebral injury. Hyperglycaemia has been associated with cerebral injury, including intra-ventricular haemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death. Neonates and all children are at increased risk of developing hyponatraemia and hyponatraemic encephalopathy. The non-osmotic secretion of ADH may result in hyponatraemia. Plasma electrolyte levels should be closely monitored due to impaired ability to regulate fluids and electrolytes. Rapid correction of hyponatraemia is potentially dangerous When using a syringe pump a bag of fluid should not be left connected to the syringe. When using an infusion pump all clamps must be closed before removing the administration set from the pump, or switching the pump off regardless of any anti-free flow device in the set. Intravenous infusion devices and administration equipment must be frequently monitored. *Blood:* Simultaneous administration of blood through the same set may cause haemolysis. *Geriatric Use:* Take into account geriatric patients are generally more likely to have compromised organ function, comorbidities and concomitant drug therapy. **Contraindications** Known hypersensitivity to the product or the excipients, Hyperchloraemia and hyperkalemia not related to volume depletion, Severe renal insufficiency (with oliguria/anuria), Uncompensated heart failure and severe congestive heart failure, Addison's disease, Fluid and sodium retention, Acute ischemic stroke, Head trauma (first 24 hours), Uncompensated diabetes, Hyperosmolar coma, Hyperglycaemia, Hyperlactatemia, Other known glucose intolerances. **Interactions:** No studies have been conducted by Baxter. The glycaemic effects and its effects on water and electrolyte balance should be taken into account in patients treated with substances that affect glycaemic control, or fluid and/or electrolyte balance. Caution in patients treated with lithium. An increase in renal sodium and lithium clearance may occur. Caution in patients treated with other agents that may cause hyperkalaemia. 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, see Special Warnings and Precautions for Use. Corticosteroids are associated with the retention of sodium and water, with oedema and hypertension. **Overdose**: Excess administration may cause hyperglycaemia and severe dilutional hyponatraemia which may be fatal, Fluid overload, 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, 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. The presence of any ECG findings that are suspected to be caused by hyperkalaemia should be considered a medical emergency. **Legal category:** POM **Marketing Authorisation Number and Holder Ireland:** PA2299/001/001 Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands. **Date of preparation:** September 2020.

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Prescribing information for Maintelyte solution

Maintelyte Solution for infusion PRESCRIBING INFORMATION – UK & ROI

Name & composition: Glucose (as monohydrate) 50.00g, sodium chloride 1.00g, sodium acetate trihydrate 3.13g, potassium chloride 1.50g, magnesium chloride hexahydrate 0.30g equivalent to Na^+ 40 mmol/L, K^+ 20 mmol/L, Mg^{2+} 1.5 mmol/L, CH_3COO^- 23 mmol/L, Cl^- 40 mmol/L, 200 kCal/L. **Indications**: Supplement of water, carbohydrates & electolytes to patients where normal intake is insufficient or when there is a deficiency. **Posology & Method of Administration**: Dosage, rate & duration of administration are to be individualized, depending upon the indication, age, weight, clinical/ biological condition of the patient, concomitant treatment & the patients clinical/ laboratory parameters. Fluid balance, blood glucose & electrolyte concentrations should be monitored throughout treatment. Recommended adult dose is 2-3 litres per day; (based on 70kg patient): 1000 ml administered intravenously during 4 -12 hours at a rate of 1.2 to 3.5 ml/kg/ hour. Infusion rate must not exceed the patient's glucose oxidation capacity (typically 5mg/kg/min). There are no dosing recommendations for use in children. Administer intravenously only. The use of pressurized IV solutions in flexible plastic containers increases the risk of air embolism if the residual air is not fully evacuated prior to use. Vented administration sets with the vent open can result in air embolism. The solution should not be administered through the same equipment as wholeblood. **Side effects:** Frequency not known. Hypersensitivity/ infusion reactions including anaphylactoid reaction (potential manifestation in patients with allergy to corn). Hyperkalaemia, hyperglycaemia, hypervolaemia, hyponatraemia, seizures, hyponatraemic encephalopathy, thrombophlebitis, venous thrombosis, electrolyte disturbance & Infusion site reactions. **Precautions**: Risk of hyponatraemia in patients with reduced cerebral compliance, non-osmotic vasopressin release & patients exposed to vasopressin agonists & other drugs that can lower sodium. Acute hyponatraemia can lead to acute brain odema & life-threatening brain injury. Caution in patients at risk of fluid & electrolyte disturbances, hypervolaemia or overhydration (or conditions that cause sodium retention & oedema), severe renal impairment. Maintelyte does not contain adequate magnesium to treat hypomagnesemia. Administer with caution & monitor for patients at risk of hyperkalaemia, hypocalcaemia or alkalosis. Maintelyte is not suitable to treat severe metabolic or respiratory acidosis. Stop the infusion immediately at any signs of hypersensitivity reactions. Caution in patients with known allergy to corn or corn products. In severely malnourished patients, caution should be exercised initially when administering glucose. Caution in patients with impaired glucose tolerance or diabetes mellitus. Take into account the glucose content of Maintelyte when calculating insulin requirements. Maintelyte is contra-indicated in the first 24 hours following head trauma. Hyperglycemia has been implicated in increasing cerebral ischemic brain damage & impairing recovery after acute ischemic strokes. Administration of hypertonic solutions may cause venous irritation (phlebitis). Safety & effectiveness in children have not been established by adequate & well-controlled trials; newborns are at increased risk of developing hypo- or hyperglycemia. Hypoglycemia in newborns can cause prolonged seizures, coma & brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial & fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, & death. Acute symptomatic hyponatremic encephalopathy is considered a medical emergency. Consider elderly patients are more likely to have cardiac, renal, hepatic or other insufficiencies &/or concomitant drug therapy. **Contraindications**: Contraindicated in patients with hyperkalaemia, severe renal insufficiency (with oliguria/anuria), uncompensated cardiac or pulmonary failure, uncontrolled diabetes or other known glucose intolerances, hyperosmolar coma, hyperglycemia or hyperlactatemia. Hypersensitivity to the active substance or excipients. **Interactions:** Interactions with sodium: Corticoids/ Steroids & carbenoxolone may cause sodium & water retention. Interactions with potassium: Potassium sparring diuretics, angiotensin converting enzyme inhibitors & angiotensin II receptor antagonists. Tacrolimus & cyclosporine increase plasma potassium which may lead to fatal hyperkalaemia. Interactions with acetate: Maintelyte may interfere in the elimination of drugs for which renal elimination is pH dependent. Interactions with magnesium may potentiate the effect of depolarising neuromuscular blockers; combination of these substances is not recommended. Caution in patients receiving drugs that can increase the risk of hypocalcaemia (e.g. diuretics, NSADs, antipsychotics, selective serotonin reuptake inhibitors, opioids, antiepileptics, oxytocin & chemotherapy). **Overdose**: Rapid infusion may lead to water & sodium overload with odema. Renal dialysis may be necessary. Excessive administration may lead to hyperglycaemia, hyperkalaemia (paresthesia, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest & mental confusion), hypermagnesemia (see SPC for signs), hypokalaemia & metabolic alkalosis (mood changes, tiredness, shortness of breath, muscle weakness, irregular heartbeat), hypocalcaemia (muscle hypertonicity, twitching, tatany). Excessive administration of chloride salts may cause a loss of bicarbonate with an acidifying effect. Acute treatment: Stop the infusion immediately. Administer diuretics & monitor serum electrolytes, correct electrolyte &/or acid-base imbalances. Consider any additives when assessing overdose, may require immediate medical attention & treatment. A patient with supralethal hypermagnesaemia was successfully treated using assisted ventilation, calcium chloride, administered intravenously, and forced diuresis with mannitol infusions. **Legal category:** POM **Marketing Authorisation Number & Holder: UK -** PL 00116/0666 Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk. IP24 3SE. Ireland - PA2299/045/001 Baxter Holding B.V.Kobaltweg 49, 3542CE Utrecht, Netherlands. **Basic NHS Price** Produce code FE2604 Bag Size 1000ml £1.83 **Date of preparation:** May 2020. Further information available upon request.

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