Baxter
Equilibria
FLUID OPTIMIZATION

11

Essentials of adult IV fluid management

Prescribing and administering IV fluids to adult patients

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1
Think drink!

IV fluids should **ONLY** be provided for patients whose needs CANNOT be met by **oral** or **enteral** routes…

...and should be **STOPPED** as soon as possible[1]

2

Assess fluid and electrolyte status

What are the patient's likely fluid and electrolyte needs?[1]

- History
- Clinical examination
- Current medications
- Clinical monitoring
- Laboratory investigations

Are they:

Euvolaemic?[2]

- Normal blood pressure
- Normal pulse rate
- Normal central venous pressure

Hypovolaemic?[1,2]

- Cold peripheries
- Hypotension
- Tachycardia
- Impaired capillary refill time
- Respiratory rate >20 breaths per minute

Hypervolaemic?[2,3]

- Oedema
- Inspiratory crackles
- Raised jugular venous pressure
- Fluid overload

Think again!

3

Follow IV fluid management guidelines

IV fluids should be prescribed as part of a protocol, following current IV fluid management guidelines for:[1]

Routine maintenance

Replacement & redistribution

Resuscitation

Routine maintenance

For patients who are euvolaemic[1]

Do not have fluid excess or abnormal losses but **cannot** meet their daily needs of fluids and electrolytes through **oral** or **enteral** routes

Replacement & redistribution

For patients who need IV fluids to address:[1]

- Existing deficits or excesses
- On-going abnormal losses or abnormal fluid distribution

Resuscitation

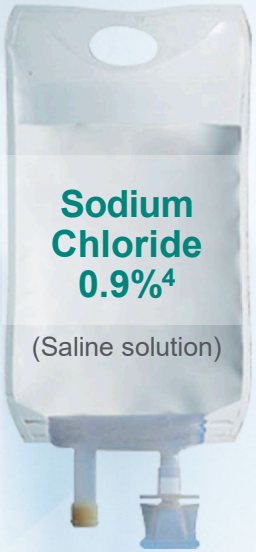
For patients who are hypovolaemic[1]

For example, due to dehydration or sepsis

4

Know the basics

What's in the bag?



Sodium Chloride 0.9%[4]

(Saline solution)

Sodium	154 mmol/L
Chloride	154 mmol/L

Maintelyte solution[5]

Sodium	40 mmol/L
Potassium	20 mmol/L
Magnesium	1.5 mmol/L
Chloride	40 mmol/L
Acetate	23 mmol/L
Glucose	50 g/L

Plasma-Lyte 148[6]

Sodium	140 mmol/L
Potassium	5 mmol/L
Magnesium	1.5 mmol/L
Chloride	98 mmol/L
Acetate	27 mmol/L
Gluconate	23 mmol/L

Hartmann's solution[7]

Sodium	131 mmol/L
Potassium	5 mmol/L
Calcium	2 mmol/L
Chloride	111 mmol/L
Lactate	29 mmol/L

5

Understand how to prescribe IV fluids for routine maintenance

Do you know what the normal daily requirements for routine maintenance are?

What's required?

Normal daily fluid and electrolyte requirements[1]	
Water	25–30 mL/kg
Sodium	1 mmol/kg
Potassium	1 mmol/kg
Chloride	1 mmol/kg
Glucose	50–100 g

Don’t forget the **potassium**

- For **routine maintenance,** consider administering **IV fluid with potassium,** otherwise there’s a potential risk of **hypokalaemia**[1]
- **BUT potassium <u>should not</u> be added to IV solutions on the ward**[8]

Use a commercially prepared solution with potassium supplementation where possible

For routine maintenance, a 60 kg man requires:[1]

- 1,500-1,800 mL of water
- 60 mmol sodium
- 60 mmol potassium
- 60 mmol chloride
- 50-100 g glucose

Per day

What should you consider prescribing him?

Glucose saline with potassium?

Suitable… **BUT** excess glucose saline may lead to **hyponatraemia** in certain situations[9]

Other regimens are available that could also meet his requirements

6

Understand how to prescribe fluids for replacement & redistribution

Adjust the IV prescription

Add to or subtract from maintenance must account for:[1]

- Existing fluid and/or electrolyte deficits or excesses
- On-going losses
- Abnormal distribution

Ask a specialist

Seek specialist help if patients have:[1]

- A complex fluid and/or electrolyte redistribution issue or imbalance
- Significant comorbidity

7

Understand how to prescribe fluids for resuscitation

Give a **fluid bolus of 500 mL crystalloid** containing **130 - 154 mmol/L sodium**, **over 15 minutes**[1]

Reassess
the patient's fluid needs[1]

Patient **still hypovolaemic** and **hasn't had >2 L?**

Further boluses of **250–500 mL crystalloid** may be given[1]

Patient has **signs of shock** or **has had >2 L?**

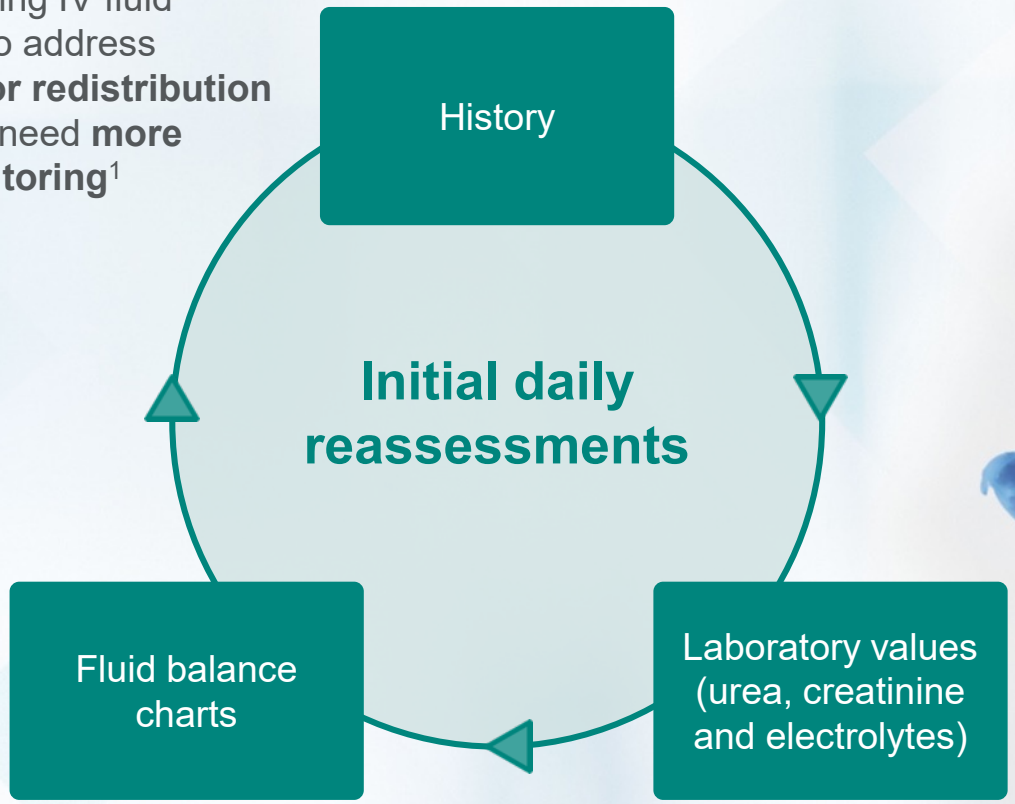
Get specialist help[1]

8

Reassess, reassess, reassess!

All patients continuing to receive IV fluids need regular reassessment

- Measure **weight twice weekly**[1]
- Patients receiving IV fluid management to address **replacement or redistribution** problems may need **more frequent monitoring**[1]



9

Know the consequences of getting it wrong

Consequences of IV fluid mismanagement:[1]

- Pulmonary oedema
- Peripheral oedema
- Volume depletion
- Shock

Excess
sodium and water → **Fluid overload[1]**

Insufficient
sodium and water → **Volume depletion & acute kidney injury[1]**

10

Report it

It is recommended that incidents of fluid mismanagement should be reported*

(for example, unnecessarily prolonged dehydration or inadvertent fluid overload)

through standard critical incident reporting

to encourage improved training and practice[1]

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

*To report an incident, see the Adverse Event Reporting information in the black box on this slide.

11

Complete the chart

Patients should have an

IV fluid management plan,

detailing their fluid and electrolyte prescription over the next 24 hours

Fluid balance charts should **always** be completed to inform the patient's management plan and enable accurate reassessment and prescription

Prescribing and giving IV fluids to adults

The 11 essentials

1. Think drink!
2. Assess fluid and electrolyte status
3. Follow fluid management guidelines
4. Know the basics
5. Understand how to prescribe for routine maintenance
6. Understand how to prescribe for replacement & redistribution
7. Understand how to prescribe for resuscitation
8. Reassess, reassess, reassess!
9. Know the consequences of getting it wrong
10. Report it
11. Complete the chart

PRESCRIBING INFORMATION – UK & ROI
Sodium Chloride 0.9% Intravenous Infusion BP Viaflo

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 (e.g. 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. (e.g. 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 & PA2299/002/001
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.

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PRESCRIBING INFORMATION – UK & ROI

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)
500 ml	FKE2323	£2.53
1000 ml	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 – UK & ROI
Plasma-Lyte 148 (pH 7.4) Solution for infusion

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)
500 ml	FKE0323	£1.46
1000 ml	FKE0324	£1.83

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 – UK & ROI
Maintelyte Solution for infusion

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 whole blood.
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.
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