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 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. **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.
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Further information available upon request.