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 & PA2299/002/001
UK: Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE.
Ireland: Baxter Holding B.V., Kobaltweg 49, 3542CE Utrecht, Netherlands
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