SUMMARY OF PRODUCT CHARACTERISTICS

Sodium Chloride (0.9% w/v) and Glucose (5.0% w/v) Intravenous Infusion BP

1. NAME OF THE MEDICINAL PRODUCT

Sodium Chloride (0.9% w/v) and Glucose (5.0% w/v) Intravenous Infusion BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml of solution contains:

Sodium chloride BP …… 0.9 g

Anhydrous glucose BP …… 5.0 g

Electrolyte content per litre: Na^+ 154 mmol/l, Cl^- 154 mmol/l. Caloric content: 200 kcal/litre. Approximate osmolarity: 585 mOsmol/l.

Excipients with known effect:

Each litre contains 154 mmol sodium (approximately 3,541 mg). For warnings regarding sodium content, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.

Colourless or faintly straw-coloured, clear solution. Isotonic and hyperosmolar.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Chloride (0.9% w/v) and Glucose (5.0% w/v) Intravenous Infusion BP is indicated for:

- Treatment of sodium depletion, extracellular dehydration or hypovolaemia in cases where supply of water and carbohydrates is required due to restriction of fluid and electrolyte intake by normal routes.

4.2 Posology and method of administration

The choice of concentration, dosage, volume, rate and duration of administration depends on the patient's age, weight, clinical condition and concomitant therapy, and should be determined by a physician. Fluid balance, serum glucose, serum sodium and other electrolytes should be monitored before and during administration.

Adults, older patients and adolescents (≥12 years)

Recommended dosage: 500 ml to 3 litres/24 hours. Administration rate: usually 40 ml/kg/24 hours. Maximum acute administration rate: 5 mg/kg/minute (to avoid hyperglycaemia).

Paediatric population

Dosage varies with weight: 0–10 kg: 100 ml/kg/24 h; 10–20 kg: 1,000 ml + (50 ml/kg over 10 kg)/24 h; >20 kg: 1,500 ml + (20 ml/kg over 20 kg)/24 h. Administration rate: 0–10 kg: 6–8 ml/kg/h; 10–20 kg: 4–6 ml/kg/h; >20 kg: 2–4 ml/kg/h. Maximum: 10–18 mg/kg/min depending on total body mass.

Method of administration

Intravenous infusion only. Administer with sterile equipment using aseptic technique. Inspect visually for particulate matter and discoloration before administration. Do not administer if solution is not clear or seal is not intact. Do not administer blood simultaneously through the same administration set.

4.3 Contraindications

- Known hypersensitivity to any component of the solution.
- Extracellular hyperhydration or hypervolaemia.
- Fluid and sodium retention.
- Severe renal insufficiency (with oliguria/anuria).

- Uncompensated cardiac failure.
- Hypernatraemia or hyperchloraemia.
- General oedema and ascitic cirrhosis.
- Clinically significant hyperglycaemia.
- Uncompensated diabetes mellitus or other glucose intolerance (including metabolic stress, hyperosmolar coma or hyperlactataemia).

4.4 Special warnings and precautions for use

Hypokalaemia

Infusion may result in hypokalaemia. Close clinical monitoring is warranted in patients at risk: metabolic alkalosis, thyrotoxic periodic paralysis, increased GI losses, prolonged low-potassium diet, primary hyperaldosteronism, and patients treated with diuretics, beta-2 agonists or insulin.

Sodium retention, fluid overload and oedema

Use with particular caution in patients with metabolic acidosis, hypernatraemia, hyperchloraemia, hypervolaemia, primary or secondary hyperaldosteronism (hypertension, congestive heart failure, liver disease, renal disease, pre-eclampsia), and patients taking corticosteroids.

Hyponatraemia

Patients with non-osmotic vasopressin release, and those with heart, liver and kidney disease are at particular risk of acute hyponatraemia. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (headache, nausea, seizures, lethargy, vomiting), which may be life-threatening. Children, women of fertile age and patients with reduced cerebral compliance are at particular risk.

Hyperglycaemia

Rapid administration may produce substantial hyperglycaemia and hyperosmolar syndrome. The infusion rate should not exceed the patient's ability to utilise glucose. Monitor blood glucose and administer insulin if levels exceed acceptable limits. Use with caution in impaired glucose tolerance, severe malnutrition, thiamine deficiency, ischaemic stroke and severe traumatic brain injury.

Sodium content

Each litre contains 154 mmol sodium. Patients on a strict low-sodium diet should take this into account.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs that increase vasopressin effect (chlorpropamide, clofibrate, carbamazepine, SSRIs, antipsychotics, desmopressin, oxytocin, terlipressin, NSAIDs, cyclophosphamide) increase the risk of hyponatraemia following treatment with i.v. fluids. Diuretics and antiepileptics (oxcarbazepine) also increase the risk of hyponatraemia. Lithium: renal sodium and lithium clearance may be increased, resulting in decreased lithium levels. Corticosteroids: associated with sodium and water retention. Diuretics, beta-2 agonists and insulin increase the risk of hypokalaemia.

4.6 Fertility, pregnancy and lactation

Pregnancy

Intrapartum maternal intravenous glucose infusion may result in foetal hyperglycaemia, metabolic acidosis and rebound neonatal hypoglycaemia. Special caution is required in pregnant women during labour, particularly if administered in combination with oxytocin, due to the risk of hyponatraemia.

Breast-feeding

Can be used during breast-feeding. The potential risks and benefits should be carefully considered for each patient.

Fertility

No information available on effects on fertility.

4.7 Effects on ability to drive and use machines

Not applicable. This product is administered by intravenous infusion in clinical settings.

4.8 Undesirable effects

Summary of the safety profile

All adverse reactions are based on spontaneous post-marketing reporting; frequencies are categorised as Not known.

System Organ Class	Adverse Reaction	Frequency
Immune system disorders	Anaphylactic reaction, hypersensitivity (potential manifestation in patients allergic to corn)	Not known
Metabolism and nutrition disorders	Hypernatraemia, hyperglycaemia, hospital-acquired hyponatraemia (may cause irreversible brain injury and death)	Not known
Nervous system disorders	Hyponatraemic encephalopathy	Not known
Vascular disorders	Phlebitis	Not known
Skin and subcutaneous tissue disorders	Rash, pruritus	Not known
General disorders and administration site conditions	Pyrexia, chills, infusion site pain, infusion site vesicles	Not known

Other adverse reactions reported include hyponatraemia (which may be symptomatic) and hyperchloraemic acidosis.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose
Excess administration can cause hyperglycaemia, hyponatraemia, hypernatraemia and fluid overload, all of which may be fatal. Interventions include discontinuing the infusion, dose reduction, administration of insulin and other clinically indicated measures. Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous due to risk of serious neurological complications.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Electrolytes with carbohydrates. ATC code: B05BB02.

Sodium chloride 0.9% w/v and glucose 5% w/v is an isotonic and hyperosmolar solution. The pharmacodynamic properties are those of its components: sodium, chloride and glucose. Sodium plays an important role in neurotransmission, cardiac electrophysiology and renal metabolism. Chloride is the main extracellular anion. Glucose is the principal source of energy in cellular metabolism, providing 200 kcal/litre.

5.2 Pharmacokinetic properties
The pharmacokinetic properties are those of the components (glucose, sodium and chloride). After injection of radiosodium (24Na), the half-life is 11–13 days for 99% of the injected Na. Distribution is rapid in muscles, liver, kidney, cartilage and skin. Sodium is predominantly excreted by the kidneys with extensive renal reabsorption. The two main metabolic pathways of glucose are gluconeogenesis (energy storage) and glycogenolysis (energy release). Glucose metabolism is regulated by insulin.

5.3 Preclinical safety data
Preclinical safety data in animals are not relevant since the constituents are physiological components of animal and human plasma. Toxic effects are not expected under the conditions of clinical application.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Water for Injection BP

6.2 Incompatibilities
Not applicable. Additives may be incompatible; tonicity must be verified before parenteral administration of any additive.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
No special precautions for storage. Keep out of the reach and sight of children.

6.5 Nature and contents of container
500 ml LDPE plastic containers packed in BOPP film wrapping. Pack size: 500 ml.

6.6 Special precautions for disposal and other handling
For single use only. Discard after single use. Discard any unused portion. Do not reconnect partially used bags. Preparation: Remove from overwrap just before use. Check for leaks, clarity and absence of foreign matter. Use aseptic technique.

7. MARKETING AUTHORISATION HOLDER
GOODMED HEALTHCARE LIMITED

P.O. Box 76337, Nairobi, Kenya.

office@goodmed.co.uk

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