SUMMARY OF PRODUCT CHARACTERISTICS

NS — Sodium Chloride Intravenous Infusion BP (0.9% w/v)

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium chloride BP 0.9% w/v (9 g/L; approximately 154 mmol/L Na^+ and 154 mmol/L Cl^-).

Tonicity: approximately 308 mOsm/L.

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3. PHARMACEUTICAL FORM

Solution for infusion.

Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Chloride 0.9% Intravenous Infusion is indicated for:

- Treatment of isotonic extracellular dehydration.
- Treatment of sodium depletion.
- Vehicle or diluent for compatible drugs for parenteral administration.

4.2 Posology and method of administration

Adults, elderly and children

Fluid balance, serum electrolytes and acid-base balance should be monitored before and during administration, with particular attention to serum sodium in patients with non-osmotic vasopressin release (SIADH) or those co-medicated with vasopressin agonists, due to the risk of hospital-acquired hyponatraemia.

The infusion rate and volume depend on age, weight, clinical condition and concomitant therapy, and should be determined by a physician experienced in intravenous fluid therapy.

Treatment of isotonic extracellular dehydration and sodium depletion:

Adults: 500 ml to 3 litres per 24 hours. Infants and children: 20–100 ml per kg per 24 hours, depending on age and body mass.

As a vehicle or diluent: 50–250 ml per dose of the medicinal product to be administered. When used as a diluent for injectable preparations, the dosage and infusion rate are also dictated by the prescribed drug.

Method of administration

Intravenous infusion through a sterile, non-pyrogenic administration set, using aseptic technique. The equipment should be primed with the solution to prevent air from entering the system. Inspect visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear, free from visible particles and the seal is intact. Do not remove unit from overwrap until ready for use. Administer immediately following insertion of the infusion set.

Do not connect flexible plastic containers in series. Do not use vented administration sets with the vent in the open position with flexible plastic containers (risk of air embolism). Additives may be introduced before or during infusion through the injection site — see section 6.6 for guidance.

4.3 Contraindications

- Hypernatraemia.
- Hyperchloraemia.
- Contraindications related to any added medicinal product should also be considered.

4.4 Special warnings and precautions for use

Fluid balance and renal function

Use with particular caution in patients with or at risk of severe renal impairment; administration may result in sodium retention. Depending on volume and rate of infusion, Sodium Chloride 0.9% can cause fluid and/or solute overload resulting in hypervolaemia (including central and peripheral oedema) and clinically relevant electrolyte disturbances and acid-base imbalance.

Hyponatraemia

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, CNS diseases), and patients with cardiac, hepatic or renal diseases or those exposed to vasopressin agonists, are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterised by headache, nausea, seizures, lethargy and vomiting; this can be severe, irreversible and life-threatening. Children, women in the fertile age and patients with reduced cerebral compliance are at particular risk.

Risk of sodium retention, fluid overload and oedema

Use with particular caution in patients with or at risk of: hypernatraemia; hyperchloraemia; metabolic acidosis (may be worsened by prolonged use, especially in renal impairment); hypervolaemia (congestive heart failure, pulmonary oedema); iatrogenic hyperchloraemic metabolic acidosis; primary or secondary hyperaldosteronism; pre-eclampsia; patients on corticosteroids.

Infusion reactions

Symptoms of unknown aetiology resembling hypersensitivity reactions (hypotension, pyrexia, tremor, chills, urticaria, rash, pruritus) have been reported very rarely. Stop the infusion immediately if signs or symptoms of such reactions develop and institute appropriate therapeutic countermeasures.

Paediatric population

Plasma electrolyte concentrations should be closely monitored as children may have impaired ability to regulate fluids and electrolytes. Repeated infusions should only be given after determination of the serum sodium level.

Geriatric population

Geriatric patients are generally more likely to have cardiac, renal, hepatic and other diseases or concomitant drug therapy; select the type of infusion solution and the volume/rate of infusion accordingly.

Correction of hypernatraemia and hyponatraemia

Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurological complications). Rapidly correcting hypernatraemia once adaptation has occurred may lead to cerebral oedema, potentially resulting in seizures, permanent brain damage or death.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs increasing the vasopressin effect (risk of hospital-acquired hyponatraemia):

Drugs stimulating vasopressin release include: chlorpropamide, clofibrate, carbamazepine, vincristine, SSRIs, MDMA (ecstasy), ifosfamide, antipsychotics, narcotics. Drugs potentiating vasopressin action include: chlorpropamide, NSAIDs, cyclophosphamide. Vasopressin analogues: desmopressin, oxytocin, terlipressin. Diuretics in general and antiepileptics such as oxcarbazepine also increase the risk of hyponatraemia.

Lithium:

Caution is advised; renal sodium and lithium clearance may be increased, resulting in decreased lithium levels. Monitor lithium levels.

Corticosteroids/steroids and carbenoxolone:

Associated with retention of sodium and water (with oedema and hypertension).

Additives:

When used as a diluent for injectable preparations, the nature of additives will determine potential interactions. Verify that any additive is soluble and stable in water at the pH of Sodium Chloride 0.9% Intravenous Infusion. Check for colour change, precipitate or crystallisation. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately.

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of Sodium Chloride 0.9% in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each patient. Administer with special caution in pregnant women during labour, particularly regarding serum sodium if administered with oxytocin. Caution is advised in patients with pre-eclampsia.

4.7 Effects on ability to drive and use machines

No studies have been conducted on the influence of Sodium Chloride 0.9% on the ability to drive or operate machinery.

4.8 Undesirable effects

Summary of the safety profile

The following adverse reactions have been reported in post-marketing experience. Frequency cannot be estimated from available data.

System Organ Class	Adverse Reaction	Frequency
Nervous system disorders	Tremor; acute hyponatraemic encephalopathy*	Not known
Metabolism and nutrition	Hospital-acquired hyponatraemia*	Not known
Vascular disorders	Hypotension	Not known
Skin and subcutaneous tissue	Urticaria, rash, pruritus	Not known
General disorders and administration site conditions	Infusion site erythema, vein irritation, injection site streaking, burning sensation, local pain, infusion site urticaria, infection at injection site, venous thrombosis or phlebitis, extravasation, hypervolaemia, pyrexia, chills	Not known

** Hospital-acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy.*

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

Excessive infusion may lead to hypernatraemia (CNS manifestations including seizures, coma, cerebral oedema and death) and sodium overload (central and/or peripheral oedema). Treatment should be provided by an attending specialised physician. Excess chloride may cause loss of bicarbonate with an acidifying effect. When used as a diluent for injectable preparations, the signs and symptoms of over-infusion will be related to the nature of the additives.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other IV solution additives. ATC code: B05XX.

Sodium Chloride 0.9% Intravenous Infusion is an isotonic solution with an approximate osmolarity of 308 mOsm/L. The pharmacodynamic properties are those of the sodium and chloride ions in maintaining fluid and electrolyte balance. Sodium circulates through cell membranes using various mechanisms including the sodium pump (Na-K-ATPase). Sodium plays important roles in neurotransmission, cardiac electrophysiology and renal metabolism.

5.2 Pharmacokinetic properties

Sodium is predominantly excreted by the kidney with extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

5.3 Preclinical safety data

The safety of sodium chloride in animals is not relevant in view of its presence as a normal component in animal and human plasma.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections BP.

6.2 Incompatibilities
Nil.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30°C in a dry place. Protect from light. Keep out of the reach and sight of children.

6.5 Nature and contents of container
500 ml LDPE plastic containers packed in BOPP wrapping pouch.

6.6 Special precautions for disposal and other handling
Before adding a drug, verify it is soluble and stable in water at the pH range of Sodium Chloride 0.9% Intravenous Infusion. Additives may be introduced before or during infusion through the injection site.

To add medication before administration: Disinfect the medication site; inject using a syringe with 19–22 gauge needle. Mix solution and medication thoroughly. Do not store bags containing added medications.

To add medication during administration: Close the clamp on the set; disinfect the medication site; inject medication; remove from IV pole and turn upright; evacuate both ports; mix thoroughly; return to use position.

Verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately. Discard after single use; discard any unused portion; do not reconnect partially used bags.

7. MARKETING AUTHORISATION HOLDER
GOODMED HEALTHCARE LIMITED (Marketed by)

P.O. Box 76337, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
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