

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.18% and Glucose 4% Intravenous Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Name	% (w/v)	g/l
Sodium Chloride	0.18	1.80
Glucose Monohydrate	4.4	44.00
<i>(Equivalent to Anhydrous Glucose)</i>	<i>4.0</i>	<i>40.00</i>

Each ml contains 1.8 mg sodium chloride and 40 mg glucose (as monohydrate).

Mmol/l (approx.): Na⁺: 30 Cl⁻: 30

Approximately: 668 kJ/l (or 160kcal)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intravenous infusion.

The solution is clear and colourless or faintly straw coloured and practically free from particles.

pH range 3.5-6.6

Osmolarity approximately 283 mOsmol/L.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of dehydration with carbohydrate loss.

4.2 Posology and method of administration

Posology

The dosage of this solution depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, concomitant therapy and in particular the patient's hydration state.

Adults

For routine maintenance, normal daily fluid and electrolyte requirements are 25-30 ml/kg/day water, 1 mmol/kg/day sodium, and 50-100 g/day glucose (1.25 – 2.5 L of 4% glucose). The maximum rate of glucose oxidation is approximately 0.8 g/kg/h (20 ml/kg/h of 4% glucose), but may be only half this in critically ill patients. To avoid hyperglycaemia and other metabolic complications, the infusion rate of glucose should generally be in the range 0.12-0.24 g/kg/h (3-6 ml/kg/h), with a maximum of 0.30 g/kg/h (7.5 ml/kg/h).

Elderly

A reduced volume and rate of infusion may be necessary to avoid circulatory overload.

Patients with cardiac and renal impairment

A reduced volume and rate of infusion may be necessary to avoid circulatory overload.

Paediatric Population

Use of Sodium Chloride 0.18% and Glucose 4% Solution is restricted to specialist paediatric settings such as renal, liver, cardiac, high dependency or intensive care units, where there is expert medical supervision.

The dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, and concomitant therapy and should be determined by the expert. The child must be carefully monitored throughout treatment.

Method of administration

Intravenous use.

Monitoring

Adequate urine flow must be ensured and careful monitoring of fluid balance, plasma and urinary electrolyte concentrations are essential.

Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia. Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. Sodium Chloride 0.18% and Glucose 4% Intravenous Infusion may become extremely hypotonic after administration due to glucose metabolization in the body (see sections 4.4, 4.5 and 4.8).

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Hyperhydration states
- Hyponatraemia
- Acute ischaemic stroke
- Head trauma (first 24 hours)
- Rehydration in hyperemesis gravidarum.

Paediatric Population

This product should not be used in children except in paediatric specialist settings (such as renal, hepatic and cardiac units, high dependency units and intensive care units) under expert medical supervision.

4.4 Special warnings and precautions for use

When used for routine maintenance, a source of potassium to meet daily needs (1 mmol/kg/day) may be required.

Sodium Chloride 0.18% and Glucose 4% should not be administered rapidly or for prolonged periods particularly in infants and the elderly. In potassium deficient patients, administration of Sodium Chloride 0.18% and Glucose 4% will increase potassium loss, potassium supplements should also be administered.

Sodium Chloride 0.18% and Glucose 4% should be administered with caution in patients with conditions associated with sodium retention and/or with complex fluid and/or electrolyte redistribution issues or imbalances, or significant comorbidity, including:

- obesity
- older or frail patients

- gross oedema
- severe sepsis
- hypernatraemia
- renal, liver and/or cardiac impairment
- post-operative fluid retention and redistribution
- malnourished and refeeding issues
- pregnancy, especially in the presence of (pre-) eclampsia
- hypertension

Sodium Chloride 0.18% and Glucose 4% should be administered with caution in patients with diabetic mellitus; the amount of infused glucose should be calculated and insulin requirements modified as appropriate. Serum potassium may also need adjustment.

Patients receiving fluid replacement therapy should be monitored. During the catabolic phase of the response to illness or injury, there is an increase in antidiuretic hormone, cortisol, and aldosterone secretion, especially if there has been any reduction in blood or extracellular fluid volume. These lead to retention of sodium and water and loss of potassium, which should be accounted for when administering a hypotonic solution. Children, the elderly, patients on diuretics and those with Syndrome of Inappropriate Antidiuretic Hormone (SIADH) problems are at particular risk of developing significant hyponatraemia, especially if too much Sodium Chloride 0.18% and Glucose 4% is given or the infusion is given too rapidly. Clinical monitoring should include checks of serum electrolytes (including potassium), glucose level, and the acid-base and water balance. Inadequate monitoring may lead to fluid and electrolyte disturbances such as hyponatraemia. Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death, therefore acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

Paediatric Population

Use of Sodium Chloride 0.18% and Glucose 4% Solution in the paediatric population <16 years of age is restricted to specialist paediatric settings under expert medical supervision. The dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, concomitant therapy and should be determined by the expert.

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism (see section 4.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia:

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain 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, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant corticosteroid use should be taken into consideration before administering Sodium Chloride 0.18% and Glucose 4%. Medicinal products with mineralocorticoid activity may cause hypertension, and sodium and water retention. Medicinal products with glucocorticoid activity may increase serum glucose.

Hypotonic intravenous solutions containing glucose, may cause haemolysis of red cells. Like all solutions for infusion, this product should not be co-administered via an infusion line that is being used for a blood component. Administration through a different lumen of a multi-lumen central venous access device is generally safe. Use of flushing administration sets for the transfusion of blood products is generally not recommended.

Drugs leading to an increased vasopressin effect The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

- Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3,4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide

- Vasopressin analogues, e.g.: Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine

4.6 Fertility, pregnancy and lactation

Sodium Chloride 0.18% and Glucose 4% Intravenous Infusion should be administered with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

The use of Polyfusor T during pregnancy and lactation has not been established, but its use during these periods is not considered to constitute a hazard.

4.7 Effects on ability to drive and use machines

The product has no influence on the ability to drive or use machines.

4.8 Undesirable effects

Tabulated list of adverse reactions		
System Organ Class	Adverse reaction (MedDRA term)	Frequency
Metabolism and nutrition disorders	Hospital Acquired Hyponatraemia**	Not known
Nervous system disorders	Hyponatraemic encephalopathy**	Not known

** Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4). Thrombosis of the chosen vein may occur with intravenous infusion. If the infusion is protracted then another vein should be selected after 12 to 24 hours.

Other adverse reactions related to the potentially low pH (range 3.5-6.6) of Sodium Chloride 0.9% and Glucose 5% include venous irritation and thrombophlebitis.

Unduly rapid, or excessive, administration may lead to pulmonary oedema.

Post Marketing Adverse reactions: Metabolism and nutrition disorders – severe hyponatraemia, which could lead to death, has been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows the continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdosage may lead to fluid overload, electrolyte imbalances, changes in acid-base balance, and possibly hyperglycaemia. The risk of significant hyponatraemia is increased if too much fluid is given or the infusion is given too rapidly; this risk is particularly high in children, the elderly, patients on diuretics, and those with SIADH problems.

Patients with renal impairment or cardiac failure are at increased risk of fluid overload. Hyperglycaemia may occur, especially in patients with diabetes mellitus, which may need to be treated with insulin.

Electrolyte disturbances may need to be treated with either sodium-free or sodium containing intravenous fluids.

In the event of overdose, consideration should be given to discontinuing or temporarily interrupting treatment. The relevant symptomatic and supportive measures should be provided as necessary

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolytes with carbohydrates

ATC code: B05BB02

The pharmacodynamic properties of the solution are those of its components:

- sodium chloride provides a source of sodium and chloride ions to maintain the osmotic tension of the extracellular fluid and tissues.
- glucose is a monosaccharide which provides a source of energy.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of Sodium Chloride 0.18% & Glucose 4% solution are those of its composition (sodium, chloride, glucose).

Intravenous administration of the solution provides an immediate supply of electrolytes to blood.

After injection of radiolabelled sodium (^{24}Na), the half-life is 11 to 13 days for 99% of the injected Na and one year for the remaining 1%. The distribution varies depending on the tissues: it is relatively fast in muscles, liver, kidney, cartilage and skin; slower in erythrocytes and neurons; very slow in bone. Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

Glucose is metabolised via pyruvic or lactic acid to carbon dioxide and water with the release of energy. All body cells are capable of oxidising glucose and it forms the principal source of energy in cellular metabolism.

5.3 Preclinical safety data

Preclinical safety data of Sodium Chloride 0.18% and Glucose 4% solution in animals are not relevant since sodium chloride and glucose are physiological components of the body.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

Hydrochloric acid

Sodium hydroxide

6.2 Incompatibilities

Compatibility of the medicinal product to be added to Sodium Chloride 0.18% and Glucose 4% solution must be assessed before addition.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. Reference should be made to the Summary of Product Characteristics for the additive medicine.

Those additives known to be incompatible should not be used.

As a guidance, the following medications are incompatible with the Sodium Chloride 0.18 % and Glucose 4% Solution (non-exhaustive listing):

- amiodarone
- amphotericin B
- ampicillin sodium
- amsacrine
- erythromycin lactobionate (unless the Sodium Chloride 0.18 % and Glucose 4% solution is buffered)
- sodium nitroprusside.

Because of the presence of glucose, Sodium chloride 0.18% and Glucose 4% solution should not be administered through the same infusion equipment as whole blood, as haemolysis and clumping can occur.

Because of the nature of the plastic material of the bag (PVC), this solution should not be used as a vehicle for the administration of drugs which may be sorbed to the surface of the bag to varying and significant degrees.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Sealed semi-rigid, cylindrical neutral polythene container (500ml) with a Twist-off seal at one end and a ring tab at the opposite end.

6.6 Special precautions for disposal

Do not dilute before use.

Use only if the solution is clear, without visible particles and if the container is undamaged. Sodium Chloride 0.18% and Glucose 4% solution should be administered with sterile equipment using an aseptic technique.

Compatibility of the medicinal product to be added to Sodium Chloride 0.18% and Glucose 4% solution must be assessed before addition. If medications are added, care should be taken to maintain aseptic conditions and ensure complete mixing. Once a medicine is added to Sodium Chloride 0.18% and Glucose 4% solution, the mixture must be administered immediately.

Use standard sterile peritoneal dialysis equipment.

7 MARKETING AUTHORISATION HOLDER

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