

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% and Glucose 5% Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Name	% (w/v)
Sodium Chloride for Injections	0.9
Glucose Monohydrate for Parenteral Use	5.5
<i>(Equivalent to Anhydrous Glucose)</i>	<i>5.0</i>

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intravenous fluid.

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

pH range 3.5-6.6

Osmolarity approximately 585 mOsmol/L.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the maintenance and treatment of dehydration and 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. It should be determined by a consulting physician experienced in adult or paediatric fluid therapy.

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 (1-2 L of 5% glucose).

The maximum rate of glucose oxidation in adults is approximately 14 mg/kg body weight/min (0.28 ml/kg body weight/min of 5% glucose), but may be only half of this in critically ill patients. To avoid hyperglycaemia and other metabolic complications, the infusion rate of glucose should generally be in the range 2 to 4 mg/kg/min (0.04-0.08 ml/kg/min), with a maximum of 5 mg/kg/min (0.1 ml/kg/min).

Elderly

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

Paediatric population

Adolescents aged >16 years should be managed as adults.

Basic fluid requirements for routine management for infants >28 days of age, toddlers, children and adolescents up to 16 years of age:

Body weight	24-hour fluid requirement
0-10 kg	100 ml/kg body weight
10-20 kg	100 ml/kg body weight \leq 10 kg, + 50 ml/kg body weight for second 10 kg
>20 kg	100 ml/kg body weight \leq 10 kg, + 50 ml/kg body weight for second 10 kg + 20 ml/kg body weight every kg thereafter

Note that in a 24 hour period, males rarely need more than 2500 ml and females rarely need more than 2000 ml of fluids.

Basic fluid requirements for term neonates:

Age	24-hour fluid requirement
Birth to day 1	50-60 ml/kg body weight
Day 2	70-80 ml/kg body weight
Day 3	80-100 ml/kg body weight
Day 4	100-120 ml/kg body weight
Day 5-28	120-150 ml/kg body weight

In term neonates, infants, children, and adolescents up to 16 years of age requiring intravenous fluids for replacement or redistribution, the dosage (in addition to maintenance needs) should be adjusted to account for existing fluid and/or electrolyte deficits or excesses, ongoing losses, or abnormal distribution.

The infusion rate should not exceed the patient's glucose oxidation capacity in order to avoid hyperglycaemia. The maximum rate of oxidation is 13 mg/kg body weight/min for neonates and infants up to 2 years of age, equivalent to 0.26 ml/kg/min of Sodium Chloride 0.9% and Glucose 5%. Maximum glucose oxidation capacity progressively decreases with age to approximately 7 mg/kg/min in adolescents (0.14 ml/kg body weight/min). Critically ill children should have their glucose intake limited to a maximum of 5 mg/kg/min (0.1 ml/kg body weight/min). In pre term infants, glucose should not exceed 4-8 mg/kg body weight/min (0.08-0.16 ml/kg body weight/min).

All patients

The baseline fluid requirements for adults and paediatric patients shown above may need to be adjusted to take account of factors affecting fluid and electrolyte balance such as extreme obesity, non-osmotic secretion of antidiuretic hormone, hypothermia, high ambient humidity, or increased water loss (e.g. pyrexia or burns).

Patients with cardiac and renal impairment

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

Method of administration

Intravenous use.

Monitoring

Clinical monitoring including vital signs, fluid balance, urinary output and electrolytes, laboratory assessments (full blood count, urea, creatinine, and electrolytes), and weight should be performed throughout the course of treatment.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Severe chronic kidney disease, or acute kidney injury associated with oliguria/anuria
- Decompensated heart failure
- Extracellular hyperhydration or hypervolaemia
- Fluid and sodium retention
- Hyperchloraemia
- Gross oedema or ascitic cirrhosis
- Decompensated diabetes mellitus, other known glucose intolerances, hyperosmolar coma, hyperglycaemia
- Hyperlactataemia
- Rehydration in hyperemesis gravidarum

4.4 Special warnings and precautions for use.

Sodium Chloride 0.9% and Glucose 5% Solution for Infusion is a hyperosmolar, isotonic (with reference to the cell membrane), solution with an approximate osmolality of 585 mOsm/l.

When used for routine maintenance, the initial prescription should be restricted to approximately 1 mmol/kg/day of sodium and chloride. Sodium Chloride 0.9% and Glucose 5% Solution for Infusion contains a higher than physiological concentration of chloride (154 vs. 100 mmol/L); patients who develop hyperchloraemia or acidaemia should have their IV fluid prescription reassessed, and their acid base status assessed.

Prolonged administration of Sodium Chloride 0.9% and Glucose 5% Solution for Infusion without adequate potassium provision (1 mmol/kg/day) may cause hypokalaemia. Serum electrolyte concentrations, including sodium, potassium and chloride, and fluid balance should be monitored during use.

Sodium Chloride 0.9% and Glucose 5% Solution should be administered with caution to 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
- 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.

If administered to patients with diabetes mellitus or renal failure, close monitoring of glucose levels is recommended, and insulin and/or potassium requirements may require modification.

Before prescribing Sodium Chloride 0.9% and Glucose 5% Solution to patients with traumatic brain injury and/or raised intracranial pressure, particular attention should be paid to serum glucose concentrations, given the known risks of secondary brain injury associated with hyperglycaemia; hypoglycaemia should also be avoided. Monitoring of serum glucose is recommended. Targeting an intermediate glucose level in the range of 6-10.0 mmol/l has been suggested.

Administration of glucose containing solutions may lead to hyperglycaemia. Solutions containing glucose should not be used routinely after ischaemic stroke, unless specifically indicated, as hyperglycaemia has been implicated in increasing cerebral ischaemic brain damage and impairing recovery.

Paediatric Population

Plasma electrolyte concentrations and blood glucose should be measured before starting IV fluids for routine maintenance and at least every 24 hours thereafter. Subsequent IV fluid prescriptions should be based upon the results of these assessments.

Sodium Chloride 0.9% and Glucose 5% solutions should not be administered rapidly or for prolonged periods, particularly in neonates and infants.

Intravenous fluid should only be prescribed to a premature or term neonates by a consulting physician experienced in paediatric intravenous fluid therapy. Premature or term neonates may retain an excess of sodium due to immature renal function. In premature or term neonates, repeated infusions of sodium chloride should therefore only be given after determination of the current serum sodium and chloride level. No or minimal sodium should be given in term neonates in the critical postnatal adaption phase until postnatal diuresis with weight loss occurs.

Newborns – especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycaemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycaemic control in order to avoid potential long term adverse effects. Hypoglycaemia in the newborn period may have a deleterious effect on the neurodevelopmental outcome; clinical signs of hypoglycaemia include tremors, seizures, respiratory distress, cyanosis, irritability, apnea, and poor feeding. Hyperglycaemia has been associated with intraventricular haemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, prolonged length of hospital stay, and death.

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.

4.5 Interaction with other medicinal products and other forms of interaction

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 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

Concomitant corticosteroid use should be taken into consideration before administering Sodium Chloride 0.9% and Glucose 5%. Medicinal products with mineralocorticoid activity

may cause hypertension, and sodium and water retention. Medicinal products with glucocorticoid activity may increase serum glucose.

4.6 Fertility, pregnancy and lactation

The safety of Sodium Chloride 0.9% and Glucose 5% during pregnancy and lactation has not been assessed.

The solution 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).

Caution should be exercised when prescribing to pregnant women, especially in the presence of (pre-) eclampsia; do not administer for rehydration in hyperemesis gravidarum.

Caution should be exercised to avoid maternal hyperglycaemia during intravenous glucose infusion in the perinatal period in view of the possibility of inducing reflex neonatal hypoglycaemia.

4.7 Effects on ability to drive and use machines

Sodium Chloride 0.9% and Glucose 5% 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

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** 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 infusion is protracted then another vein should be selected after 12 – 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 hypervolaemia or hyponatraemic acidosis.

The frequency of occurrence of each of these events with Sodium Chloride 0.9% and Glucose 5% is not known.

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 imbalance and possibly hyperglycaemia; patients with poorly controlled diabetes mellitus may develop hyperglucosuria, hyperosmolarity, dehydration and osmotic diuresis (as a result of hyperglycaemia).

Hypernatraemia with the potential for oedema is a risk, particularly when there is a defective renal sodium excretion. Hypernatraemia rarely occurs after therapeutic doses of sodium chloride. The most serious effect of hypernatraemia is dehydration of the brain; signs and symptoms depend on severity and include headache, confusion, nausea and vomiting, lethargy, irritability, seizures, nystagmus, myoclonic jerks, loss of consciousness, and coma.

Excessive administration of chloride salts may have an acidifying effect.

In the event of accidental overdose, treatment should be discontinued, the patient should be observed, and the 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 essential 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 0.9% & Glucose 5% 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 0.9% & Glucose 5% solution in animals are not relevant since electrolytes 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 0.9% & Glucose 5% 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 0.9 % & Glucose 5% (non-exhaustive listing):

- amiodarone
- amphotericin B
- ampicillin sodium
- amsacrine
- erythromycin lactobionate (unless the Sodium Chloride 0.9 % and Glucose 5% is buffered)
- sodium nitroprusside

Because of the presence of glucose, Sodium chloride 0.9% and Glucose 5% 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 Steriflex bag (PVC) this solution should not be used as a vehicle for the administration of drugs which may be sorbed on to the bag to varying and significant degrees.

6.3 Shelf life

500 & 1000 ml PVC Bags – 2 years

500 & 1000 ml Polyolefin Bags – 3 years

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and Contents of Container

The container is a flexible 500 or 1000 ml bag made of medical grade PVC.

- a) A hermetically sealed polythene bag.
- b) A rectangular pouch consisting of polyamide/polythene composite
- c) Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite, plugged with a polycarbonate plug with either a bromobutyl (West 4481/45) or gum (West 7006/45) stopper.

Or

A flexible 500 or 1000 ml polyolefin bag sealed in a polyolefin overwrap.

6.6 Special precautions for disposal and other handling

Use only if the solution is clear, without visible particles and if the container is undamaged. Sodium Chloride 0.9% and Glucose 5% solution should be administered with sterile equipment using an aseptic technique.

Compatibility of the medicinal product to be added to Sodium Chloride 0.9% and Glucose 5% 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 0.9% and Glucose 5% solution, the mixture must be administered immediately.

Opening the overwrap:

Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.

Setting up the solution:

Position the roller clamp of the giving-set to just below the drip chamber and close.

Hold the base of the giving set port firmly and grip the wings of the twist off tab. Twist to remove the protective cover. Still holding the base of the giving-set port push the set spike fully into the port to ensure a leak proof connection. Prime the set in accordance with the manufacturer's instructions.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court
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WA7 1NT
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0088

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 June 1989

Date of latest renewal: 10 December 2010

10 DATE OF REVISION OF THE TEXT

29/04/2025