

NEW ZEALAND DATA SHEET

1 GLUCOSE AND SODIUM CHLORIDE (solution for infusion)

Glucose 2.5% Sodium Chloride 0.45%

Glucose 4% Sodium Chloride 0.18%

Glucose 5% Sodium Chloride 0.45%

Glucose 5% Sodium Chloride 0.9%.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The concentrations of the active ingredients dissolved in a litre of Water for Injection are as follows:

Glucose 2.5% Sodium Chloride 0.45% Infusion solution

Glucose 4% Sodium Chloride 0.18% Infusion solution

Glucose 5% Sodium Chloride 0.45% Infusion solution

Glucose 5% Sodium Chloride 0.9% Infusion solution.

Glucose and Sodium Chloride infusion solutions do not contain an antimicrobial agent or added buffer.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Appearance

Glucose and Sodium Chloride infusion solution is a clear, colourless to faintly straw-coloured solution, practically free from visible particles.

Glucose and Sodium Chloride infusion solutions are sterile, nonpyrogenic solutions.

Glucose and Sodium Chloride infusion solutions are for intravenous infusion and are for single use in one patient on one occasion only.

They are iso-osmotic as indicated by their osmolarity shown in the following table, except

Glucose 5% Sodium Chloride 0.9% and **Glucose 5% Sodium 0.45%** which are hypertonic solutions.

Glucose and Sodium Chloride infusion solutions have a pH of 3.5 - 6.5.

| Glucose and Sodium Chloride infusion solution preparations | |
|--|------------------------------------|
| Product | Osmolarity ^a (mOsmol/L) |
| Glucose 2.5% Sodium Chloride 0.45% Infusion solution (500mL) | 294 |
| Glucose 4% Sodium Chloride 0.18% Infusion solution (500mL) | 282 |
| Glucose 4% Sodium Chloride 0.18% Infusion solution (1000mL) | 284 |
| Glucose 5% Sodium Chloride 0.45% Infusion solution (1000mL) | 432 |
| Glucose 5% Sodium Chloride 0.9% Infusion solution (1000mL) | 586 |

Note: Osmolarities^a (mOsmol/L) are calculated figures which equate to the approximate Osmolalities (mOsmol/kg); **Glucose 5% Sodium Chloride 0.9%** Infusion solution (1000mL) and **Glucose 5% Sodium Chloride 0.45%** Infusion solution (1000mL) are hypertonic solutions as indicated by the osmolarities of 586mOsmol/L and 432mOsmol/L, respectively.

NEW ZEALAND DATA SHEET

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Glucose and Sodium Chloride infusion solution is indicated for replenishing fluid losses, as an energy source and for restoration or maintenance of sodium and chloride ion concentrations. It may be used as a vehicle of medication delivery where intravenous delivery is appropriate and the medicine is compatible with this solution.

4.2 Dose and method of administration

General Directive

To be used only as directed by the physician. The dosage, volume, rate and duration of administration of **Glucose and Sodium Chloride** infusion solution are dependent upon the age, weight, clinical condition of the patient, laboratory determinations and concomitant therapy. For patients with electrolyte and glucose abnormalities and for paediatric patients, consult a physician experienced in intravenous fluid therapy. Electrolyte supplementation may be indicated according to the clinical needs of the patient.

A gradual increase of flow rate should be considered when starting administration of glucose containing products.

Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit (see section 4.4). Do not administer **Glucose and Sodium Chloride** infusion solution unless the solution is clear, colourless and free of particles, and the seals are intact.

Sterile and nonpyrogenic equipment must be used for intravenous administration. The equipment should be primed with the solution in order to prevent air embolism due to the residual air in the system. Use of an in-line filter is recommended during administration of all parenteral solutions.

Additives may be introduced before infusion or during infusion through the injection site. Additives may be incompatible. Check relevant literature for additive, solution and container compatibility prior to use. Complete information is not available. Those additives known to be incompatible should not be used. Consult with a pharmacist, if available.

Before adding a substance or medication, verify that it is soluble and/or stable in **Glucose and Sodium Chloride** infusion solution and the pH range of **Glucose and Sodium Chloride** infusion solution is appropriate.

If in the informed judgment of the physician, it is deemed advisable to introduce additives, aseptic technique must be used. Mix thoroughly and carefully when additives have been introduced. After addition, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals. Do not store solutions containing additives.

The product should be used once only. Any unused portion should be discarded. Do not reconnect partially used bags.

The osmolarity of a final admixed solution must be taken into account when peripheral administration is considered (see Section 3 for osmolarity). Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, any hyperosmolar solutions are recommended to be administered through a large central vein, for rapid dilution of the hypertonic solution. If hypertonic solutions are administered peripherally, a large arm vein should be used and, if possible, the injection site should be altered daily. Rapid infusion in peripheral arm veins may be harmful.

NEW ZEALAND DATA SHEET

Directions for use of Viaflex plastic container

Do not remove unit from over-wrap until ready for use. The inner bag maintains the sterility of the product.

WARNING: Do not use plastic containers in series connections. Such use could result in embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Pressurising intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

To open

Tear over-wrap down side at slit and remove solution container.

Check solution for limpidity and absence of foreign matter. If solution is not clear or contains foreign matter, discard the solution. Some opacity of the Viaflex plastic container due to moisture absorption during the sterilisation process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

If supplemental medication is desired, follow directions below.

Preparation for administration

Glucose and Sodium Chloride infusion solution is a sterile preparation. Thus, aseptic technique must be applied throughout the administration.

- (1) Suspend container from eyelet support.
- (2) Remove plastic protector from outlet port at the bottom of container.
- (3) Attach administration set, use an aseptic method to set up the infusion.

To add medication

WARNING: Additives may be incompatible. Check the Product Information Document(s) of the medication(s) prior to their addition to **Glucose and Sodium Chloride** infusion solution.

To add medication before solution administration

Prepare medication site. Using syringe with 19 to 22-gauge needle, puncture resealable medication port and inject. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

Close clamp on the set. Prepare medication site. Using syringe with 19 to 22-gauge needle, puncture resealable medication port and inject. Remove container from IV pole and/or turn to upright position. Evacuate both ports by squeezing them while container is in the upright position. Mix solution and medication thoroughly. Return container to in use position, re-open the clamp and continue administration.

NEW ZEALAND DATA SHEET

4.3 Contraindications

Glucose and Sodium Chloride infusion solutions are contraindicated in patients with the following medical conditions:

- know hypersensitivity to the product or active substances
- known allergy to corn or corn products, because cornstarch is used as raw material for glucose production
- cardiac failure including congestive heart failure
- lactacidosis
- uncontrolled diabetes
- clinically significant hyperglycaemia
- hyperkalaemia
- severe impairment of renal function
- bloating-ascitic syndrome in cirrhosis
- acute ischaemic stroke
- patients who have had a head trauma within 24 hours
- patients presenting with a clinical state in which there exists oedema with sodium retention, or with renal, hepatic or cardiac impairment with oedema, hypervolaemia, hypernatraemia.

Glucose and Sodium Chloride infusion solutions containing $\leq 0.225\%$ sodium chloride are contraindicated in patients presenting with severe hyponatraemia.

4.4 Special warnings and precautions for use

General

The safety of the Viaflex plastic container used to contain **Glucose and Sodium Chloride** infusion solution preparations has been confirmed in tests with animals according to the USP biological tests for plastic container, as well as by tissue culture toxicity studies. Nevertheless, care should be exercised regarding possible incompatibility outcomes resulting either from the interaction between the plastic container or active ingredients and the added therapeutic substances (see also Section 4.2).

When used as a vehicle of intravenous medication delivery, the product information document of these medicines must be examined to ensure compatibility with **Glucose and Sodium Chloride** infusion solution.

In a dilute condition, osmolarity/L is approximately the same with osmolality/kg. As shown in Section 3, **Glucose 5% Sodium Chloride 0.9%** and **Glucose 5% Sodium 0.45%** are hypertonic solutions (with osmolarity of 586mOsmol/L and 432mOsmol/L, respectively), whilst the other strengths are isotonic.

The administration of a substantially hypertonic solution may lead to a wide variety of complications. These include crenation (shrinkage) of red blood cells and general cellular dehydration.

The administration of **Glucose and Sodium Chloride** infusion solution can cause fluid and/or solute overloading resulting in dilution of the serum electrolyte concentrations, over-hydration, congested states, or pulmonary oedema. The risk of dilution states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary oedema is directly proportional to the electrolyte concentrations of the injections. Thus, caution must be exercised when administering **Glucose and Sodium Chloride** infusion solution to patients with or at risk of:

NEW ZEALAND DATA SHEET

- hypernatraemia
- hyperchloraemia
- metabolic acidosis
- hypervolaemia
- conditions that may cause sodium retention, fluid overload and oedema (central and peripheral), for example: hypertension, heart failure including congestive heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia or other conditions associated with sodium retention.

Similarly, care should be exercised with the administration of these products to patients receiving corticosteroids or corticotropin, because of a potential sodium and water retention.

Patients receiving fluid replacement therapy should be monitored as fluid and electrolyte disturbances such as hyponatraemia and hypokalaemia may occur. Excessive administration of **Glucose and Sodium Chloride** infusion solution without addition of potassium, may result in significant hypokalaemia. Prolonged therapy should be monitored for changes in fluid balance, electrolyte concentration and acid-base balance.

Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurologic complications). Dosage, rate and duration of administration should be determined by a physician experienced in intravenous fluid therapy.

Glucose and Sodium Chloride infusion solution should be used with caution in patients with thiamine deficiency, hypophosphataemia and diabetes mellitus (see Section 4.5).

Hypersensitivity reactions

Hypersensitivity/infusion reactions, including anaphylaxis, have been reported with **Glucose and Sodium Chloride** infusion solution (see Section 4.8). If signs or symptoms of hypersensitivity/infusion reactions develop, stop the infusion immediately. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Hyponatraemia

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism. Monitoring of serum sodium is particularly important for hypotonic fluids. 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 metabolise glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic hyponatraemia.

The infusion of solutions with sodium concentrations < 0.9% may result in hyponatraemia, which may warrant close clinical monitoring. Hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterised by headache, nausea, seizures, lethargy and vomiting which can lead to coma and death. Patients with brain oedema are at particular risk of severe, irreversible and life threatening brain injury. Acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia.

NEW ZEALAND DATA SHEET

The risk of hyponatraemia is increased in children, elderly patients, women, postoperatively, in patients with psychogenic polydipsia and in patients treated with medications that increase the risk of hyponatraemia (such as certain antiepileptic and psychotropic medications) see section 4.5.

The risk of developing hyponatraemic encephalopathy is increased, for example, in paediatric patients, women (in particular, premenopausal women), in patients with hypoxemia and in patients with underlying central nervous system disease.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may also result in hyponatraemia.

Hypokalemia

The infusion of **Glucose and Sodium Chloride** infusion solution may result in hypokalaemia. **Glucose and Sodium Chloride** infusion solution should be used with particular caution in patients with or at risk of hypokalaemia, close clinical monitoring may be warranted in patients with, but not limited to:

- metabolic alkalosis
- thyrotoxic periodic paralysis, administration of intravenous glucose has been associated in aggravating hypokalaemia
- increased gastrointestinal losses (e.g. diarrhoea, vomiting)
- prolonged low potassium diet
- primary hyperaldosteronism
- medication and treatments that increase the risk of hypokalaemia (e.g. diuretics, beta-2 agonist, or insulin).

Risk of hypo-/hyper-osmolality, serum electrolytes & water imbalance

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolise glucose, intravenous administration of **Glucose and Sodium Chloride** infusion solution can cause:

- hypoosmolality
- hyperosmolality, osmotic diuresis and dehydration
- electrolyte disturbances such as hyponatraemia, hypokalaemia, hypophosphataemia and hypomagnesaemia
- acid-base imbalance
- overhydration/hypervolaemia and congested states, including central (e.g. pulmonary congestion) and peripheral oedema
- an increase in serum glucose concentration is associated with an increase in serum osmolality. Osmotic diuresis associated with hyperglycaemia can result in or contribute to the development of dehydration and electrolyte losses.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes to fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Hyperglycaemia

Rapid administration of glucose solutions may produce substantial hyperglycaemia and hyperosmolar syndrome. In order to avoid hyperglycaemia, the infusion rate should not exceed the patient's ability to utilise glucose. To reduce the risk of hyperglycaemia-associated complications, the infusion rate must be adjusted and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

NEW ZEALAND DATA SHEET

Intravenous glucose should be administered with caution in patients with, but not limited to:

- impaired glucose tolerance (such as in diabetes mellitus, renal impairment, or in the presence of sepsis, trauma, or shock)
- severe malnutrition (risk of precipitating a refeeding syndrome)
- thiamine deficiency (risk of severe lactic acidosis due to impaired oxidative metabolism of pyruvate)
- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load.

Other groups of patients in whom Glucose and Sodium Chloride infusion solution should be used with caution include:

- patients with ischaemic stroke. Hyperglycaemia has been implicated in increasing cerebral ischaemic brain damage and impairing recovery after acute ischaemic strokes
- patients with severe traumatic brain injury. Early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury
- Newborns (See Paediatric use).

Prolonged intravenous administration of glucose and associated hyperglycaemia may result in decreased rates of glucose-stimulated insulin secretion.

Refeeding syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterised by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intake while avoiding overfeeding can prevent these complications.

Use in patients with or at risk of severe renal impairment

Glucose and Sodium Chloride infusion solution should be administered with particular caution, to patients with or at risk of (severe) renal impairment. In such patients, administration of **Glucose and Sodium Chloride** infusion solution may result in sodium retention and/or fluid overload.

Blood

Glucose and Sodium Chloride infusion solution should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or haemolysis.

Risk of air embolism

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

Pressurising intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers (see Section 4.2).

Use in the elderly

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant medicines therapy.

NEW ZEALAND DATA SHEET

Paediatric use

Neonates, 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 neonate can cause prolonged seizures, coma and brain damage. Hyperglycaemia has been associated with cerebral injury, including intraventricular haemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotising enterocolitis, increased oxygen requirements, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Infants and children may have an impaired ability to regulate fluid and electrolytes. Fluid replacement therapy (including plasma electrolyte concentrations) should be closely monitored in these populations as fluid and electrolyte disturbances (such as hyponatraemia and hypokalaemia) may occur.

Children (including neonates and older children) are at increased risk of developing hyponatraemia as well as developing hyponatraemic encephalopathy. For this reason, intravenous infusions containing $\leq 0.225\%$ sodium chloride are generally not recommended for use in children. The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may also result in hyponatraemia. Hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterised by headache, nausea, seizures, lethargy and vomiting which can lead to coma and death. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury. Acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

Rapid correction of hyponatraemia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in paediatric intravenous fluid therapy.

Effects on laboratory tests

The effect of this medicine on laboratory tests has not been established.

4.5 Interaction with other medicines and other forms of interaction

Glucose and Sodium Chloride infusion solution should not be administered simultaneously with blood preparation through the same administration set, because of the possibility of pseudo-agglutination or haemolysis.

If using this solution to administer medicines, the Product Information document(s) of such medicine(s) must be reviewed to ensure compatibility, including pH and ion concentrations, with the solution.

Both the glycaemic effects of **Glucose and Sodium Chloride** infusion solution and its effects on water and electrolyte balance should be taken into account when using these products in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be decreased during administration of **Glucose and Sodium Chloride** infusion solution and can result in increased lithium levels.

Caution is advised when administering **Glucose and Sodium Chloride** infusion solution to patients treated with medication leading to an increased vasopressin effect. The below listed drugs increase

NEW ZEALAND DATA SHEET

the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatraemia following treatment with IV fluids. (see sections 4.4 and 4.8):

- Drugs stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3,4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, opioids.
- Drugs potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDs), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Caution is advised when administering **Glucose and Sodium Chloride** infusion solution to patients treated with drugs that may increase the risk of hyponatraemia, such as diuretics and antiepileptics (e.g. oxcarbazepine).

Caution should also be exercised with the administration of **Glucose and Sodium Chloride** infusion solution to patients receiving corticosteroids or corticotropin, because of a potential sodium and water retention.

4.6 Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy (Category C)

Animal reproduction studies have not been conducted with **Glucose and Sodium Chloride** infusion solution. It is also not known whether these dosage forms can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity.

Intrapartum maternal intravenous glucose infusion may result in foetal hyperglycaemia and metabolic acidosis as well as rebound neonatal hypoglycaemia due to foetal insulin production.

Physicians should carefully consider the potential risks and benefits for each specific patient before administering **Glucose and Sodium Chloride** infusion solution.

Breast-feeding

Safety in lactation has not been established. Use this product in a nursing woman only when it is clearly needed and the potential benefits outweigh the potential risks to the baby.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Undesirable effects

Adverse effects of sodium salts are attributable to electrolyte imbalances from excess sodium. Retention of excess sodium in the body can lead to accumulation of extracellular fluid to maintain normal plasma osmolality, which may result in pulmonary and peripheral oedema with their consequent effects.

Hypernatraemia rarely occurs with therapeutic doses of sodium chloride but may occur after inappropriate intravenous administration of hypertonic saline. The most serious consequence of this is dehydration of the brain causing somnolence and confusion, progressing to convulsion, coma and ultimately respiratory failure and death. Other symptoms include thirst, reduced salivation and lachrymation, fever, tachycardia, hypertension, headache, dizziness, restlessness, weakness and irritability.

NEW ZEALAND DATA SHEET

Metabolism and nutrition disorders: hyponatraemia, which could lead to death, have been reported.

Adverse reactions which may occur because of the solution (e.g. contamination), additive medicines or the technique of administration include fever response (due to possible introduction of pyrogens), infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolaemia.

Anaphylactic reactions, hypersensitivity and chills have also been reported.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary. The nature of any additive should be considered in the event of other undesirable effects.

Post-marketing adverse reactions

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC), then where feasible, by Preferred Term in order of severity.

IMMUNE SYSTEM DISORDERS: Hypersensitivity, Anaphylactic reaction

METABOLISM AND NUTRITION DISORDERS: Hyponatraemia, Hypernatraemia, Hyperglycaemia

VASCULAR DISORDERS: Phlebitis

SKIN AND SUBCUTANEOUS TISSUE DISORDERS: Rash, Pruritus

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Injection site reactions such as Infusion site pain, Injection site vesicles, Chills, Pyrexia.

Other adverse reactions (Class reactions)

Other adverse reactions reported with similar products include:

- hyponatraemia, which may be symptomatic
- hyponatraemic encephalopathy
- acidosis hyperchloraemic.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

4.9 Overdose

Overdosage with **Glucose and Sodium Chloride** infusion solution can cause:

- hyperglycaemia, adverse effects on water and electrolyte balance, and corresponding complications. For example, severe hyperglycaemia and severe dilutional hyponatraemia, and their complications can be fatal
- hyponatraemia, which can lead to CNS manifestations (including seizures, coma, cerebral oedema and death)
- hypernatraemia especially in patients with severe renal impairment. Retention of excess sodium when there is defective renal sodium excretion may result in pulmonary and peripheral oedema. The most serious effect of hypernatraemia is dehydration of the brain which causes somnolence and confusion progressing to convulsions, coma, respiratory failure and death. Other symptoms

NEW ZEALAND DATA SHEET

include thirst, reduced salivation and lacrimation, fever, tachycardia, headache, dizziness, restlessness, irritability and weakness

- fluid overload, which can lead to central and/or peripheral oedema.

Excessive administration of chloride salts may cause a loss of bicarbonate with an acidifying effect.

Prolonged or rapid administration of large volumes of isotonic solutions may cause oedema or water intoxication. Prolonged or rapid administration of hypertonic solutions containing glucose may result in dehydration as a consequence of the induced hyperglycaemia.

When assessing an overdose, any additives in the solution must also be considered. Clinically significant overdose of **Glucose and Sodium Chloride** infusion solution may therefore constitute a medical emergency. Interventions include discontinuation of **Glucose and Sodium Chloride** infusion solution administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical group.

For advice on the management of overdose please contact the National Poisons Centre on phone number: 0800 764 766 [0800 POISON] in New Zealand (or 131126 in Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Electrolytes with Carbohydrates.

ATC code

B05BB02.

Mechanism of action

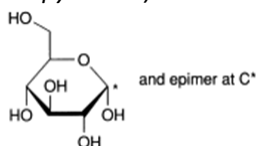
Glucose is readily metabolised into carbon dioxide and water, with a release of energy. As such, an administration of a glucose solution either by oral or parenteral route provides water for body hydration as well as energy (for conversion to kJ units, see table in Section 6.5). In addition, it may reduce catabolic loss of nitrogen from the body and aid in prevention of depletion of liver glycogen. That is, in the absence of glucose, amino acids undergo deamination followed by oxidation in order to release energy.

Sodium is the major cation of extracellular fluid and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids. Chloride, the major extracellular anion, closely follows the physiological disposition of the sodium cation in maintenance of acid-base balance, isotonicity and electrodynamic characteristic of the cells.

Thus, **Glucose and Sodium Chloride** infusion solutions have value as a source of water, electrolytes and energy.

Chemical structure and CAS number

Glucose (D-(+))glucopyranose



Molecular formula: C₆H₁₂O₆

Molecular Weight: 180.2

CAS No.: 50-99-7

Appearance: a white or almost white, crystalline powder

Solubility: freely soluble in water, sparingly soluble in ethanol (96%).

NEW ZEALAND DATA SHEET

Sodium chloride

Molecular formula: NaCl

Molecular Weight: 58.44

CAS No.: 7647-14-5

Appearance: colourless or white crystal

Solubility: freely soluble in water and practically insoluble in anhydrous ethanol.

5.2 Pharmacokinetic properties

As **Glucose and Sodium Chloride** infusion solution is directly administered to the systemic circulation by infusion, the bioavailability (absorption) of the active components is complete (100%). Excess sodium is predominantly excreted by the kidney, with small amounts lost in faeces and sweat.

5.3 Preclinical safety data

Genotoxicity/Carcinogenicity

The active ingredients glucose and sodium chloride are not carcinogenic or mutagenic. They are basic constituents in all living cells.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections.

6.2 Incompatibilities

Check relevant literature for additive, solution and container compatibility prior to use. Those additives known to be incompatible should not be used. See sections 4.2 and 4.5.

6.3 Shelf life

24 months from date of manufacture.

The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store at or below 30°C. do not freeze.

6.5 Nature and contents of container

Glucose and Sodium Chloride infusion solutions are supplied in Viaflex plastic bags as shown in the following table:

| Glucose and Sodium Chloride infusion solution preparations | | | |
|--|---|--------|-----------------|
| Code No. | Product | TT50- | Pack Size* (mL) |
| AHB1023 | Glucose 2.5% Sodium Chloride 0.45% Infusion solution, [209kJ/500mL] | 5535 | 500 |
| AHB1253 | Glucose 4% Sodium Chloride 0.18% Infusion solution, [334kJ/500mL] | 5535/1 | 500 |
| AHB1254 | Glucose 4% Sodium Chloride 0.18% Infusion solution, [668kJ/L] | 5535/1 | 1000 |
| AHB6028 | Glucose 5% Sodium Chloride 0.45% Infusion solution, [835kJ/L] | 1433/2 | 1000 |
| AHB1064 | Glucose 5% Sodium Chloride 0.9% Infusion solution, [835kJ/L] | 5535/2 | 1000 |

1 gram of glucose provides 16.7 kilojoules (kJ) of energy.
* Not all packs may be marketed.

NEW ZEALAND DATA SHEET

6.6 Special precautions for disposal and other handling

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

7 MEDICINE SCHEDULE

General Sale Medicine.

8 SPONSOR

Glucose and Sodium Chloride infusion solutions are distributed in New Zealand by:

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060
Phone (09) 574 2400.

Baxter Healthcare Ltd
PO Box 14 062
Panmure
Auckland 1741

Glucose and Sodium Chloride infusion solutions are distributed in Australia by:

Baxter Healthcare Pty Ltd
1 Baxter Drive
Old Toongabbie, NSW 2146.

9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:

Glucose 2.5% Sodium Chloride 0.45% Infusion solution: 29 September 1980.

Glucose 4% Sodium Chloride 0.18% Infusion solution: 29 September 1980.

Glucose 5% Sodium Chloride 0.45% Infusion solution: 17 May 1991.

Glucose 5% Sodium Chloride 0.9% Infusion solution: 22 August 1974.

10 DATE OF REVISION OF THE TEXT

8 August 2019.

SUMMARY TABLE OF CHANGES

| Section changed | Summary of new information |
|-----------------|---|
| 3 | Appearance of Glucose and appearance of Sodium Chloride moved to section 5.1. Appearance of Glucose and Sodium Chloride included. Intravenous administration and single use statements included. Osmolarity table updated. |
| 4.2 | General directive clarified. Additional warning relating air embolism. |
| 4.4 | Additional warnings relating to hyponatraemia and in paediatric use. |
| 4.5 | Caution relating to use with medication leading to increased vasopressin effect. |
| 4.6 | Fertility statement simplified. |
| 4.8 | Hyponatraemic encephalopathy listed as a class reaction. |
| 5.1 | Chemical structure and CAS number included. |

Based on Australian PI most recent amendment 29 July 2019; and CCSI438 2018 Jul 17.

Please refer to the Medsafe website (www.medsafe.govt.nz) for most recent data sheet.

Baxter and Viaflex are trademarks of Baxter International Inc.