

**AUSTRALIAN PRODUCT INFORMATION –
BAXTER SODIUM CHLORIDE AND GLUCOSE
INTRAVENOUS INFUSION
(SODIUM CHLORIDE, GLUCOSE)**

1 NAME OF THE MEDICINE

Sodium chloride and glucose.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Baxter Sodium Chloride and Glucose Intravenous (IV) Infusions are sterile, nonpyrogenic solutions, and are for single use in one patient on one occasion only. The solution is clear, colourless to faintly straw-coloured solution, practically free from visible particles. Baxter Sodium Chloride and Glucose IV Infusions contain glucose and sodium chloride in Water for Injections. The concentrations of the active ingredients dissolved in Water for Injections are shown in Table 1 (see Section 6.5 Nature and Contents of Container). They are iso-osmotic as indicated by their osmolarity shown in Table 1, except AHB6028, AHB1064 and AHB2026 are hypertonic solutions as indicated by the osmolarities: Sodium Chloride 0.45% and Glucose 5% with osmolarity of 432 mOsmol /L, Sodium Chloride 0.9% and Glucose 5% IV Infusion with osmolarity of 586 mOsmol/L, and Sodium Chloride 0.22% and Glucose 10% IV Infusion with osmolarity of 630 mOsmol/L.

They do not contain an antimicrobial agent or added buffer, and have a pH of 3.5 - 6.5.

For the full list of excipients, see Section 6.1 List of Excipients.

3 PHARMACEUTICAL FORM

Solution for intravenous infusion

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Baxter Sodium Chloride and Glucose IV Infusion 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 drug delivery where intravenous delivery is appropriate and the drug 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 Baxter Sodium Chloride and Glucose IV Infusion are dependent on 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 drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit (see Section 4.4 Special Warnings and Precautions for Use). Do not administer Baxter Sodium Chloride and Glucose IV Infusion 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 Baxter Sodium Chloride and Glucose IV Infusion and the pH range of Baxter Sodium Chloride and Glucose IV Infusion 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 Table 1 in Section 6.5 Nature and Contents of Container for the products' 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.

Direction 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 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

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: Baxter Sodium Chloride and Glucose IV Infusion 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 Medications:

Warning: Additives may be incompatible. Check the Product Information Document(s) of the medication(s) prior to their addition to Baxter Sodium Chloride and Glucose IV Infusion.

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.

4.3 CONTRAINDICATIONS

Baxter Sodium Chloride and Glucose IV Infusion is contraindicated in patients with the following medical conditions:

- known hypersensitivity to the product
- known allergy to corn or corn products, because cornstarch is used as raw material for glucose production
- cardiac failure including congestive heart failure
- lactic acidosis
- 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.

Baxter Sodium Chloride and Glucose IV 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 the Baxter Sodium Chloride and Glucose IV Infusion 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 a possible incompatibility outcomes resulted either from the interaction between the plastic container or active ingredients and the added therapeutic substances (see also Section 4.2. Dose and Method of Administration).

When used as a vehicle of intravenous drug delivery, the product information document of these drugs must be examined to ensure compatibility with Baxter Sodium Chloride and Glucose IV Infusion.

In a dilute condition, osmolarity/L is approximately the same as osmolality/kg. As shown in Table 1 (see Section 6.5 Nature and Contents of Container), Sodium Chloride 0.9% and Glucose 5.0%, Sodium Chloride 0.45% and Glucose 5%, and Sodium Chloride 0.22% and Glucose 10% intravenous infusion solution are hypertonic as indicated by the osmolarities of

586 mOsmol/L, 432 mOsmol/L and 630 mOsmol/L respectively, whilst the other strengths are isotonic.

The administration of 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 Baxter Sodium Chloride and Glucose IV Infusion 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 Baxter Sodium Chloride and Glucose IV Infusion to patients with or at risk of:

- 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 Baxter Sodium Chloride and Glucose IV Infusion 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.

Baxter Sodium Chloride and Glucose IV Infusion should be used with caution in patients with thiamine deficiency, hypophosphataemia and diabetes mellitus (see Section 5.4 Interactions with Other Medicines and Other Forms of Interactions).

Hypersensitivity reactions

Hypersensitivity/infusion reactions, including anaphylaxis, have been reported with Baxter Sodium Chloride and Glucose IV Infusion (see Section 4.8 Adverse Effects). 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 hyptonic 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.

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 Interactions with Other Medicines and Other Forms of Interactions.

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.

Hypokalaemia

The infusion of Baxter Sodium Chloride and Glucose IV Infusion may result in hypokalaemia. Baxter Sodium Chloride and Glucose IV Infusion 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 and 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 Baxter Sodium Chloride and Glucose IV Infusion 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.

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 Baxter Sodium Chloride and Glucose IV Infusion 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

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

Blood

Baxter Sodium Chloride and Glucose IV Infusion 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.

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 drug therapy.

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 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Baxter Sodium Chloride and Glucose IV Infusion 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 drugs, the Product Information document(s) of such drug(s) must be reviewed to ensure compatibility, including pH and ion concentrations, with the solution.

Both the glycaemic effects of Baxter Sodium Chloride and Glucose IV Infusion 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 Baxter Sodium Chloride and Glucose IV Infusion and can result in increased lithium levels.

Caution is advised when administering Baxter Sodium Chloride and Glucose IV Infusion to patients treated with drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatraemia following treatment with IV fluids. (see section 4.4 Special Warnings and Precautions for Use and section 4.8 Adverse Reactions (Undesirable Effects)):

- 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 Baxter Sodium Chloride and Glucose IV Infusion 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 Baxter Sodium Chloride and Glucose IV Infusion to patients receiving corticosteroids or corticotropin, because of a potential sodium and water retention.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy (Category C)

Animal reproduction studies have not been conducted with Baxter Sodium Chloride and Glucose IV Infusion. 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 Baxter Sodium Chloride and Glucose IV Infusion.

Use in lactation

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 Adverse effects (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.

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 drugs 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 other similar products include:

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

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Overdosage with Baxter Sodium Chloride and Glucose IV Infusion 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 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 Baxter Sodium Chloride and Glucose IV Infusion may therefore constitute a medical emergency. Interventions include discontinuation of Baxter Sodium Chloride and Glucose IV Infusion administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical group.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

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 1 in Section 6.5 Nature and Contents of Container). 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, Baxter Sodium Chloride and Glucose IV Infusion has a value as a source of water, electrolytes and energy.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

As Baxter Sodium Chloride and Glucose IV Infusion 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

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

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

Hydrochloric acid may be used for pH adjustment.

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 Section 4.2 Dose and Method of Administration and Section 4.5 Interactions with Other Medicines and Other Forms of Interactions).

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C. Do not freeze.

6.5 NATURE AND CONTENTS OF CONTAINER

Baxter Sodium Chloride and Glucose IV Infusion solution are supplied in VIAFLEX plastic bags.

Table 1: Baxter Sodium Chloride and Glucose IV Infusion preparations

Code No.	Product	Osmolarity ^a (mOsmol/L)	ARTG	Pack Size* (mL)
AHB1023	Sodium Chloride 0.45% and Glucose 2.5% IV Infusion, 500 mL [209 kJ / 500 mL]	294	19495	500
AHB1033**	Sodium Chloride 0.3% and Glucose 3.3% IV Infusion, 500 mL [276 kJ / 500 mL]	288	19498	500

Baxter Sodium Chloride and Glucose IV Infusion

AHB1034	Sodium Chloride 0.3% and Glucose 3.3% IV Infusion, 1000 mL [551 kJ / L]	285	48522	1000
AHB1243	Sodium Chloride 0.225% and Glucose 3.75% IV Infusion, 500 mL [313 kJ / 500 mL]	284	19499	500
AHB1253	Sodium Chloride 0.18% and Glucose 4% IV Infusion, 500 mL [334 kJ / 500 mL]	282	19501	500
AHB1254	Sodium Chloride 0.18% and Glucose 4% IV Infusion, 1000 mL [668 kJ / L]	284	48523	1000
AHB1064	Sodium Chloride 0.9% and Glucose 5% IV Infusion, 1000 mL [835 kJ / L]	586	19502	1000
AHB6028	Sodium Chloride 0.45% and Glucose 5% IV Infusion, 1000 mL [835 kJ / L]	432	228198	1000
AHB2026	Sodium Chloride 0.22% and Glucose 10% IV Infusion, 500 mL [835 kJ / 500 mL]	630	82805	500

^aOsmolarities (mOsmol/L) are calculated figures which equate to the approximate Osmolalities (mOsmol/kg); AHB6028, AHB1064 and AHB2026 are hypertonic solutions as indicated by the osmolarities of 432 mOsmol/L, 586mOsmol/L and 630 mOsmol/L respectively.

1 gram of glucose provides 16.7 kiloJoules (kJ) of energy

*Not all packs are marketed

**Product discontinued

Package size: 500 mL, 1000 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

6.7 Physicochemical properties

Chemical structure and CAS number

Sodium chloride

Molecular formula: NaCl

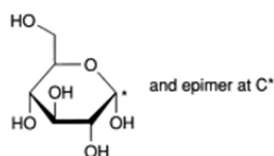
Molecular Weight: 58.44

CAS No.: 7647-14-5

Appearance: colourless or white crystal

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

Glucose (*D*-(+)*gluco*pyranose)



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%)

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled

8 SPONSOR

Baxter Healthcare Pty Ltd
1 Baxter Drive
OLD TOONGABBIE NSW 2146
AUSTRALIA

9 DATE OF FIRST APPROVAL

30 September 1991
AUST R 19495, 19498, 19499, 19501 and 19502

21 April 1994
AUST R 48522 and 48523

18 July 2002
AUST R 82805

20 April 2016
AUST R 228198

10 DATE OF REVISION

29 July 2019

Summary table of changes

Section Changed	Summary of new information
2, 4.2, 4.4	Minor editorial changes
4.2, 4.4, 4.5, 4.8	Safety related changes

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