

NEW ZEALAND DATA SHEET

1 5% Glucose (infusion, solution)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient

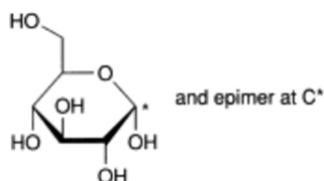
50g/L (5%) glucose monohydrate, in water for injection.

The chemical name is D-(+) glucopyranose.

Molecular formula is $C_6H_{12}O_6 \cdot C_6H_{12}O_6$.

Molecular Weight is 180.2.

CAS is 50-99-7.



For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Infusion, solution, in AVIVA bag.

Glucose is a monosaccharide, having physical characteristics as a white or almost white, crystalline powder, freely soluble in water, sparingly soluble in ethanol (96 per cent). The **5% Glucose** infusions are clear, colourless solutions, practically free from visible particles and are sterile, non-pyrogenic parenteral solutions. The concentrations of glucose dissolved in a litre of Water for Injections are shown in the table in section 6.5. They do not contain an antimicrobial agent or added buffer and have a pH of 3.2 - 6.5 for 5% glucose concentrations.

The isotonicity of these preparations is shown in the table in section 6.5. The **5% Glucose** infusion is an isotonic solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

5% Glucose infusions are mainly indicated:

- Whenever non-electrolyte fluid replacement is required
- As a vehicle for drug delivery, provided that the added components are compatible with glucose.

4.2 Dose and method of administration

Posology

To be used for intravenous administration as directed by the physician. The dosage of the **5% Glucose** infusion solution is dependent upon the age, weight, concomitant therapy, clinical and metabolic conditions of the patient as well as laboratory determinations. Electrolyte supplementation may be indicated according to the clinical needs of the patient.

When glucose is used as a diluent, the dosage administered will be principally dictated by the nature of the additive and the infusion rate will depend upon the dose regimen of the prescribed medicine. The **5% Glucose** infusion may be administered intravenously to healthy individuals at a rate of 0.5g/kg

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per hour without producing glycosuria; the maximum infusion rate should not exceed 0.8g/kg per hour.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to the administration (see section 4.4); only sterile and nonpyrogenic equipment must be used for intravenous administration. Do not administer unless the solution is clear and the seal is intact. Use of an in-line filter is recommended during administration of all parenteral solutions where possible.

Additives may be introduced before infusion or during infusion through the injection site. Additives may be incompatible, see section 4.4 and section 6.2.

Directions for use of AVIVA plastic container

Do not remove unit from over-wrap until ready for use. The inner bag maintains the sterility of the product. Do not use plastic containers in series connections. Such use could result in air 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 rate can also 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 also 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 plastic 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

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

Additives may be incompatible. Check the prescribing information of the medication(s) and other relevant literature prior to their addition to **5% Glucose** infusion solution.

To add medication before solution administration

Prepare medication site. Using syringe with 19 to 22-gauge needle, puncture re-sealable 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. Close clamp on the set. Prepare medication site. Using syringe with 19 to 22-gauge needle, puncture re-sealable medication port and inject. Remove container from IV pole and/or turn to upright position. Evaluate 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.

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To add medication during solution administration

Close clamp on the set. Prepare medication site. Using syringe with 19 to 22-gauge needle, puncture re-sealable medication port and inject. Remove container from IV pole and/or turn to upright position. Evaluate 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.

This product is for single use in one patient only. Unused portions must be discarded. Do not reconnect partially used bags.

4.3 Contraindications

5% Glucose infusion is contraindicated in patients with:

- Known hypersensitivity to the product
- Known allergy to corn or corn products, because cornstarch is used as raw material for glucose productions
- Clinically significant hyperglycaemia.

Avoid use after an ischaemic stroke episode or head trauma within 24h, as the induced lactic acidosis aggravates the recovery of the damaged brain tissue, with blood glucose concentrations also being closely monitored during intracranial hypertension.

4.4 Special warnings and precautions for use

General

The safety of the AVIVA plastic container used in the glucose infusion preparations has been confirmed in tests with animals according to the USP biological tests for plastic containers, as well as by tissue culture toxicity studies. Nevertheless, care should be exercised regarding a possible incompatibility outcome resulting either from the interaction between the plastic container or active ingredients and the added therapeutic substances, see section 4.2 and section 6.2.

Do not administer glucose intravenous infusions unless clear and the seals intact.

In a dilute condition, osmolarity/L is approximately the same as osmolality/kg.

Hypersensitivity reactions

Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported with glucose infusions. The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Dilution and other effects on serum electrolytes

The administration of glucose infusions 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.

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 can cause:

- hyperosmolality, osmotic diuresis and dehydration
- hypoosmolality

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- electrolyte disturbances such as
 - hyponatraemia (see below)
 - hypokalaemia
 - hypophosphataemia
 - hypomagnesaemia
 - overhydration/hypervolaemia and, for example, congested states, including pulmonary congestion and oedema.

The above effects do not only result from the administration of electrolyte-free fluid but also from glucose administration. In addition:

- 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 in electrolyte losses
- hyperglycaemia also causes a transcellular shift of water, leading to a decrease in extracellular sodium concentrations and hyponatraemia
- since glucose is metabolised, infusion of the glucose solution corresponds to increasing the body's load of free water, possibly leading to hypoosmotic hyponatraemia.

Hypoosmotic hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema, and death. Acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

The risk for developing hypoosmotic hyponatraemia is increased, for example:

- in children
- in elderly patients
- in women
- postoperatively
- in persons with psychogenic polydipsia.

The risk for developing encephalopathy as a complication of hypo-osmotic hyponatraemia is increased, for example:

- in paediatric patients (≤ 16 years of age)
- in women (in particular, premenopausal women)
- in patients with hypoxemia
- in patients with underlying central nervous system disease.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in 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.

Particular caution is advised in patients at increased risk of and from water and electrolyte disturbances that could be aggravated by increased free water load. Hyperglycaemia or possibly required insulin administration (see Hyperglycaemia).

Preventive and corrective measures must be instituted as clinically indicated.

Hyperglycaemia

Rapid administration of glucose solutions may produce substantial hyperglycaemia and a 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.

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Intravenous glucose solution should be administered with caution in patients with, for example:

- 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)
- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load.

Thiamine diphosphate, cocarboxylase, is an essential co-enzyme in the carbohydrate metabolism; therefore, patients having thiamine deficiency (e.g. in patients with chronic alcoholism [risk of severe lactic acidosis due to impaired oxidative metabolism of pyruvate]) should be treated cautiously with glucose infusions. The glucose intravenous infusions should be used with caution in patients with overt or subclinical diabetes mellitus, see section 4.5.

Other groups of patients in whom high concentration glucose infusions should be used with caution include:

- patients with severe traumatic brain injury. Early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury, (see also section 4.3.
- 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 intakes while avoiding overfeeding can prevent these complications.

Paediatric use

5% Glucose infusion solution is safe and effective for the stated indications in paediatric patients, see section 4.2. The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the child and concomitant therapy. Only Consulting Physicians experienced in paediatric intravenous fluid therapy should determine glucose infusion rates and volumes.

Hypo-/hyperglycaemia

As reported in the literature, the dosage selection and constant infusion rate of intravenous glucose must be selected with caution in paediatric patients. Frequent monitoring of serum glucose concentrations is required when glucose is prescribed to paediatric patients.

Newborns, especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycaemia. 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 can cause prolonged seizures, coma and cerebral injury.

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.

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Hyponatraemia

Children (including neonates and older children) are at increased risk of developing hypoosmotic hyponatraemia as well as for developing hyponatraemic encephalopathy. Hypoosmotic hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death; therefore, acute symptomatic hyponatraemic encephalopathy is considered a medical emergency. Plasma electrolyte concentrations should be closely monitored in the paediatric population. Rapid correction of hypoosmotic 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

Use in the elderly

Clinical studies of Glucose injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not been identified in responses between the elderly and younger patients. In general, dose selection for the elderly should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or drug therapy.

This medicine is known to be substantially excreted by the kidney, and the risk of toxic reactions to glucose may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and thus renal function may be monitored.

4.5 Interaction with other medicines and other forms of interaction

5% Glucose infusion solution preparations (an aqueous, i.e. electrolyte-free glucose solution) should not be administered simultaneously with blood preparations through the same administration set, because of the possibility of pseudo-agglutination or haemolysis.

Use of these glucose infusions may necessitate review of a patient's oral hypoglycaemic or insulin requirements, so close monitoring of serum glucose levels is required.

Both the glycaemic effects of **5% Glucose** infusion and its effects on water and electrolyte balance should also be taken into account when using glucose infusions in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.

4.6 Fertility, pregnancy and lactation

Use in pregnancy (Category C)

Animal reproduction studies have not been conducted with the glucose infusion solutions. It is also not known whether glucose infusions cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Intrapartum maternal intravenous glucose infusion may result in foetal insulin production, with an associated risk of foetal hyperglycaemia and metabolic acidosis as well as rebound hypoglycaemia in the neonate. Physicians should carefully consider the potential risks and benefits for each specific patient before administering glucose infusion preparations.

Use in lactation

Safety in lactation has not been established. Use glucose infusion solutions in nursing women 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

Not relevant.

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4.8 Undesirable effects

Intravenous infusion of glucose can lead to the development of fluid and electrolytes disturbances including hypokalemia, hypomagnesaemia, and hypophosphatemia.

Hyperglycaemia and dehydration have resulted from inappropriate parenteral use. If administered to diabetic patients, insulin requirements may be modified, see section 4.5.

Reactions that may occur because of the solution (e.g. from contamination), additive drugs or techniques of administration include fever response (due to possible introduction of pyrogens), infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia. In case of such adverse reactions, the infusion should be stopped. If hypertonic glucose solutions are infused too rapidly, local pain and rarely, vein irritation may occur.

Hyperglycaemia and glucosuria may occur if the rate of infusion is greater than 0.5g/kg/h; if undetected and untreated, this can lead to dehydration, hyperosmolar coma, and death. Continual clinical monitoring is recommended (see Precautions). Vitamin B-complex deficiency, thiamine and pantothenic acid in particular may occur in patients under prolonged parenteral nutrition.

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 additives 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:

IMMUNE SYSTEM DISORDERS: Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, including reactions with mild manifestations, e.g., pruritus, and reactions with severe manifestations, e.g., bronchospasm, cyanosis, angioedema and hypotension; pyrexia, chills

METABOLISM AND NUTRITION DISORDERS: Hyperglycaemia

SKIN AND SUBCUTANEOUS TISSUE DISORDERS: Rash

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Infusion site reactions including, infusion site phlebitis, infusion site erythema

Other adverse reactions reported with **5% Glucose** injection/infusions include: hyponatraemia (which may be symptomatic).

Reporting of suspected adverse reactions

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

4.9 Overdose

Excessive administration of **5% Glucose** infusion solution may result in significant hypokalaemia. It can also cause hyperglycaemia, adverse effects on water and electrolyte balance, and corresponding complications, see section 4.4. For example, severe hyperglycaemia and severe dilutional hyponatraemia, and their complications, can be fatal. Clinically significant overdose of **5% Glucose** infusion solution may, therefore, constitute a medical emergency.

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Symptoms

Prolonged administration or rapid infusion of large volumes of isotonic solutions may cause oedema or water intoxication. Typical overdose is manifested by symptoms of hyperglycaemia and glycosuria. If these symptoms are not detected and treated, they can lead to dehydration, mental confusion, hyperosmolar coma and death.

The signs and symptoms of over infusion will also be related to the nature of any additive medicines.

Treatment

The infusion should be discontinued and the patient observed for appropriate signs and symptoms related to glucose and/or additive medicines administered, and appropriate symptomatic and supportive measures instituted as required, such as administration of insulin.

Fluid overload and biochemical imbalance resulting from overdose with glucose should be treated with appropriate corrective therapy.

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:

GENERAL NUTRIENTS, OTHER NUTRIENTS, CARBOHYDRATES

ATC Code:

V06DC01

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 calories. In addition, it may reduce catabolic loss of nitrogen from the body and aids in prevention of depletion of liver glycogen. That is, in the absence of glucose, amino acids undergo deamination. It is followed by oxidation, with a release of energy. Thus, **5% Glucose** infusion has value as a source of water and energy.

Glucose is readily converted into fat in the body which can be used as a source of energy as required. Under a similar conversion into storage of energy, glucose is stored in the liver and muscles as glycogen. For a quick rise in plasma glucose, glycogen is readily converted into glucose.

5.2 Pharmacokinetic properties

A glucose preparation administered by the oral route is rapidly absorbed from the gastro-intestinal tract by an active mechanism. Following oral administration a hypoglycaemic individual's plasma glucose is built up within 10 – 20 minutes and peaks at about 40 minutes.

As the glucose intravenous infusion preparations are directly administered to the systemic circulation by infusion, the bioavailability of the active components is complete (100%).

5.3 Preclinical safety data

Genotoxicity/Carcinogenicity

The active ingredient, glucose, in **5% Glucose** infusion solution is not a carcinogen or mutagen. It is a basic nutrient in all living cells.

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water of injection, q.s.

6.2 Incompatibilities

Additives

Additives may be introduced before infusion or during infusion through the injection site. Additives may be incompatible, see section 4.2 and section 4.4. Consult with a pharmacist, if available. Check additive compatibility with both the solution and container prior to use. Complete information is not available. Those additives known to be incompatible should not be used. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of the **5% Glucose** infusion solution is appropriate. The instructions for use of the medication to be added and other relevant literature must be consulted. When introducing additives to the **5% Glucose** infusion solution, aseptic technique must be used. After addition, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored. Administration of hyperosmolar solutions may cause venous irritation and phlebitis.

Container

The introduction of additives to any solution, regardless of type of container, requires special attention to assure that no incompatibilities result. While some incompatibilities are readily observed, one must be aware that subtle physical, chemical and pharmacological incompatibilities can occur. The medical literature and other available sources of information should be reviewed for a thorough understanding of possible incompatibility problems. In particular, the prescribing information document of any added medication should be checked for any incompatibility with the glucose infusion.

6.3 Shelf life

Bag, plastic AVIVA 250mL 15 months from date of manufacture.
Bag, plastic AVIVA 500mL 22 months from date of manufacture.
Bag, plastic AVIVA 1,000mL 24 months from date of manufacture.

6.4 Special precautions for storage

Store at or below 25°C.

6.5 Nature and contents of container

5% Glucose infusion solutions are sterile, non-pyrogenic solutions supplied in AVIVA plastic bags, either as a single unit or multiple units in a box. They are available in several strengths as shown in the following table.

Not all pack sizes may be marketed.

5% Glucose infusion solution preparations (isotonic)			
Item Code	Active components [Conc. (% , mmol/1000mL)] Energy (kJ/L)	Osmolarity ^α (mOsmol/L)	Pack size (mL)
AH6E0062	Glucose (5%, 278); 835kJ/L	252 (252)	250
AH6E0063	Glucose (5%, 278); 835kJ/L	252 (252)	500
AH6E0064	Glucose (5%, 278); 835kJ/L	252 (252)	1000

Note: Osmolarity^α is calculated as anhydrous glucose.
The figures in the bracket are mOsmol/kg printed on the AVIVA bags.
1 gram of glucose provides 16.7 kilojoules (kJ) of energy.

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6.6 Special precautions for disposal

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

7 MEDICINE SCHEDULE

General Sale Medicine.

8 SPONSOR

5% Glucose is distributed in New Zealand by:

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060.

Baxter Healthcare Ltd
PO Box 14 062
Panmure
Auckland 1741

Phone (09) 574 2400.

5% Glucose is 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:
15 May 2014.

10 DATE OF REVISION OF THE TEXT

6 April 2017.

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Entire document reformatted to new standard format based on the European Summary of Product Characteristics (SPC).
10	Date of Revision of Text updated.

Based on Australian PI most recent amendment 27 May 2014, and (2.5% - 10%) ccsi430 2013 1101.

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

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