1 5% GLUCOSE (5%, infusion solution)

5% Glucose, 5% infusion solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient

50g/L (5%) glucose in Water for Injections.

For the full list of excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Infusion solution, in VIAFLO bag.

5% Glucose intravenous infusion solutions are sterile, non-pyrogenic parenteral solutions containing glucose (5%) in Water for Injections. They do not contain an antimicrobial agent or added buffer, and have a pH of 3.5 - 6.5. The isotonicity of this preparation is shown in Table 1 (see Section 6.5). *VIAFLO* **5% Glucose** infusions are isotonic solutions.

Appearance

Clear colourless solution for intravenous (IV) infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

5% Glucose infusions are 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

To be used for intravenous administration as directed by the physician. The infusion rate and volume of the **5% Glucose** IV infusions are 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 medication. **5% Glucose** IV infusions may be administered intravenously to healthy individuals at a rate of 0.5g/kg 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 their 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. Consult with 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 **5% Glucose** IV infusion is appropriate. The instructions for use of the medication to be added and other relevant literature must be

consulted. When introducing additives to **5% Glucose** IV infusion, 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.

5% Glucose IV Infusion is single use only. Discard any unused portion. Do not reconnect partially used bags.

The osmolarity of a final admixed infusion solution must be taken into account when peripheral administration is considered. Administration of hyperosmolar solutions may cause venous irritation and phlebitis.

Direction for use of VIAFLO plastic container

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

Do not connect 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

5% Glucose 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 medications

Warning: Additives may be incompatible. Check the Product Information Document(s) of the medication(s) and other relevant literature prior to their addition to the **5% 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. Evaluate both ports by squeezing them while container is in the upright position. Mix solution and medication thoroughly. Return container to in-use position, reopen the clamp and continue administration.

4.3 Contraindications

5% Glucose IV Infusions are contraindicated in patients:

- who have had head trauma within 24 hours, with blood glucose concentrations being closely monitored during intracranial hypertension
- with known hypersensitivity to the product
- with known allergy to corn or corn products, because cornstarch is used as raw material for glucose production
- with clinically significant hyperglycaemia.

Avoid use after an ischaemic stroke episode as under this condition, the induced lactic acidosis aggravates the recovery of the brain damage tissue.

4.4 Special warnings and precautions for use

General

The safety of the *VIAFLO* plastic container used in **5% Glucose** IV infusion 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 outcome resulting either from the interaction between the plastic container or active ingredients and the added therapeutic substances (see also section 4.2).

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

Do not administer 5% Glucose IV infusion unless the solution is clear and the seals intact.

Hypersensitivity reactions

Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported with glucose intravenous 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 **5% Glucose** IV 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
- electrolyte disturbances such as:
 - hypo- or hyperosmotic hyponatraemia (see below)
 - hvpokalaemia
 - 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.

Monitoring of serum sodium is particularly important. 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.

Acute 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 cerebral oedema are at particular risk of severe, irreversible and lifethreatening brain injury. 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 hypoosmotic 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

As with the intravenous administration of nutrients (e.g., glucose, amino acids and lipids) in general, metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.

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.

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 metabolisation of pyruvate) should be treated cautiously with glucose intravenous infusion.

5% Glucose infusion solution should be used with caution in patients with overt or subclinical diabetes mellitus (see section 4.5).

Other groups of patients in whom glucose intravenous infusions 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 (see section 4.3)
- patients with severe traumatic brain injury. Early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury (see section 4.3).
- Newborns (see Paediatric use below).

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.

Catheter infection and sepsis

Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters or contaminated solutions.

Immunosuppression and other factors such as hyperglycaemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications.

Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycaemia can help recognise early infections. The occurrence of septic complications can be decreased with heightened emphasis on aseptic technique in catheter placement, maintenance, as well as aseptic technique in nutritional formula preparation.

Others

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patients warrants such evaluation.

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

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 intravenous infusion rate and volume.

Hypo-/hyperglycaemia

Neonates, 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 is needed to ensure adequate glycaemic control in order to avoid potential long-term adverse effects. Hypoglycaemia in the neonate 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, necrotizing enterocolitis, increased oxygen requirements, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Hyponatraemia

Children (including neonates and older children) are at increased risk of developing hypo-osmotic hyponatraemia as well as for developing hyponatraemic encephalopathy. Acute 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 cerebral oedema are at particular risk of severe, irreversible and life-threatening brain injury. Acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

Plasma electrolyte concentrations should be closely monitored in the paediatric population. Rapid correction of hypo-osmotic 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

5% Glucose IV infusion (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.

Both the glycaemic effects of **5% Glucose** IV infusion and its effects on water and electrolyte balance should also be taken into account when using **5% Glucose** IV infusion in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance. Use of **5% Glucose** IV infusion may necessitate review of a patient's oral hypoglycaemic or insulin requirements, so close monitoring of serum glucose levels is required.

Caution is advised with administering **5% Glucose** IV infusion to patients treated with medicines leading to an increased vasopressin effect. The below listed medicines 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 and 4.8):

- Medicines stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4-methylenedioxy-Nmethamphetamine, ifosfamide, antipsychotics, opioids.
- Medicines potentiating vasopressin action such as chlorpropamide, non-steroidal antiinflammatories (NSAIDS), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Caution is advised when administering **5% Glucose** IV infusion to patients treated with medicines that may increase the risk of hyponatraemia, such as diuretics and antiepileptics (e.g. oxycarbazepine) (see section 6.2).

4.6 Fertility, pregnancy and lactation

Effects on fertility

No data available.

Pregnancy (Category C)

Animal reproduction studies have not been conducted with **5% Glucose** IV infusions. It is also not known whether **5% Glucose** IV 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 **5% Glucose** IV infusion preparations.

Breast-feeding

Safety in lactation has not been established. Use **5% Glucose** IV infusions in nursing woman only when clearly needed and the potential benefits outweigh the potential risks to the baby.

4.7 Effects on ability to drive and use machines

There is no information on the effects of **5% Glucose** IV infusion on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

Intravenous infusion of glucose can lead to the development of fluid and electrolytes disturbances including hypokalaemia, 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 medicines 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.

Hyperglycaemia and glycosuria may occur if the rate of infusion is greater than 0.5g/kg/h, if undetected and untreated, this can lead to diuresis, dehydration, hyperosmolar coma, and death. Continual clinical monitoring is recommended (see section 4.4).

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-marketina 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/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

VASCULAR DISORDERS: Phlebitis

SKIN AND SUBCUTANEOUS TISSUE DISORDERS: Rash

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

Other adverse reactions (Class reactions)

Other adverse reaction reported with similar products include:

- hyponatraemia (which may be symptomatic).
- Hyponatraemic encephalopathy.

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** IV infusion can 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 glucose intravenous infusion may, therefore, constitute a medical emergency.

Symptoms

Prolonged administration or rapid infusion of large volumes of isotonic solutions may cause oedema or water intoxication. Typical over dosage 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 drugs administered, and appropriate symptomatic and supportive measures instituted as required, such as administration of insulin.

Fluid overload and biochemical imbalance resulting from overdosage with glucose should be treated with appropriate corrective therapy. If diuresis is adequate, administration of a slightly hypotonic electrolyte solution in a quantity calculated to replace the net quantity of fluid and specific electrolytes (particularly potassium) lost to osmodiuresis, whilst continuously monitoring serum electrolytes, fluid balance and acid-base status is recommended.

A suitable basic solution for replacing fluids and major electrolytes could be made up according to the following formulation per 1000mL: Na+: approx. 120mmol, K+: approx. 30mmol, Cl-: approx. 150mmol. Other electrolytes should also be replaced to make up for losses incurred.

In addition to replacement of net losses of fluids and electrolytes to diuresis, any acid-base imbalance should be corrected whilst continuing to monitor laboratory values.

In patients with oliguria or those with anuria, peritoneal dialysis or extracorporeal haemodialysis using carbohydrate-free solutions can be considered as a last resort.

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** IV infusions have 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.

Clinical trials

No data available.

Chemical name D-(+)glucopyranose.

Molecular formula C₆H₁₂O₆

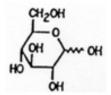
Molecular weight 180.2

Appearance A white crystal or granular powder

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

CAS Number 50-99-7

Chemical structure



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 an oral administration in hypoglycaemic individual's plasma glucose is built up within 10-20 minutes and peaks at about 40 minutes.

As **5% Glucose** IV infusions are directly administered to the systemic circulation by infusion, the bioavailability of the active components is complete (100%).

5.3 Preclinical safety data

Genotoxicity

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

Carcinogenicity

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections, q.s.

6.2 Incompatibilities

Additives may be incompatible. Consult with pharmacist, if available. Check the Product Information Document(s) of the medication(s) and other relevant literature prior to their addition **5% Glucose** IV infusion. Complete information is not available. Those additives known to be incompatible should not be used (see section 4.2).

5% Glucose IV infusion (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.

6.3 Shelf life

50mL: 17 months from date of manufacture. 100mL: 24 months from date of manufacture. 250mL: 18 months from date of manufacture. 500mL: 24 months from date of manufacture. 1000mL: 18 months from date of manufacture.

The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store at or below 25°C.

Exposure to the heat should be minimised. Avoid excessive heat.

6.5 Nature and contents of container

5% Glucose IV Infusions are sterile, non-pyrogenic solutions supplied in *VIAFLO* plastic bags. They are available in several pack sizes as shown in Table 1.

Table 1: Glucose 5 % Intravenous Infusion preparations (isotonic)				
Code No.	Active components & Conc. % (mmol/1000mL); Energy (kJ/L)	Osmolarity ^a (mOsmol/L)	NZ TT50-	Pack size* (mL)
BSE0086G	Glucose 5% (278); 835kJ/L	278 (278)	10414	50
BSE0087	Glucose 5% (278); 835kJ/L	278 (278)	10414	100
BSE0062	Glucose 5% (278); 835kJ/L	278 (278)	10414	250
BSE0063	Glucose 5% (278); 835kJ/L	278 (278)	10414	500
BSE0064	Glucose 5% (278); 835kJ/L	278 (278)	10414	1000

^{*} Not all packs are marketed.

VIAFLO 5% Glucose infusions are isotonic solutions.

6.6 Special precautions for disposal

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

7 MEDICINE SCHEDULE

General Sale Medicine.

 $^{^{\}alpha}$ Osmolarity is calculated as glucose. The figures in the bracket are Osmolality in mOsmol/kg printed on the *VIAFLO* bags. 1 gram of glucose provides 16.7 kiloJoules (kJ) of energy.

8 SPONSOR

5% Glucose is distributed in New Zealand by:

Baxter Healthcare Ltd Baxter Healthcare Ltd

33 Vestey Drive PO Box 14 062
Mt Wellington Panmure
Auckland 1060. Auckland 1741

Phone (09) 574 2400.

5% Glucose is distributed in Australia by:

Baxter Healthcare Pty Ltd
ABN: 43 000 392 781
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: 20 December 2018.

10 DATE OF REVISION OF THE TEXT

14 April 2020.

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information	
All	Consistent formatting, use of headings, spacing, grammar,	
3	Appearance included.	
6.3	Shelf life updated.	
6.4	Storage conditions updated.	
6.5	Concentration and energy per 1000mL rather than per container.	

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

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