1 PRODUCT NAME

Glucose 5%
Glucose 10% w/v

Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient is Glucose (as monohydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion

Glucose 5% is a sterile isotonic solution of glucose 5% w/v in Water for Injections, containing no preservatives. Glucose 5% is an isotonic Solution.

Glucose 10% is a sterile hypertonic solution of glucose 10% w/v in water for injections, containing no preservatives.

pH ranges from 3.5-6.5.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Isotonic (Glucose 5%) infusion solutions 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.

Hypertonic (Glucose > 10%) infusion solutions are indicated:

- As a source of energy incorporated with parenteral nutrition with minimal dilution effect
- For use with an appropriate protein (nitrogen) source in the prevention of nitrogen loss or in the treatment of negative nitrogen balance in patients where:

  a) the alimentary tract cannot or should not be used
  b) gastrointestinal absorption of protein is impaired
  c) metabolic requirements for protein are substantially increased, as with extensive burns.

4.2 Dose and method of administration

To be used for intravenous administration as directed by the physician.

The dosage of the glucose infusion solutions 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 Glucose 5% infusion solution may be administered intravenously to healthy individuals at a rate of 0.5 g/kg per hour without producing glycosuria; the maximum infusion rate should not exceed 0.8g/kg per hour

A hypertonic glucose infusion solution, such as the Glucose 10% (556 mOsmol/L), should preferably be administered via intravenous catheter in a large central vein. A gradual increase of flow rate should be considered when starting administration of hypertonic glucose infusions. To reduce the risk of hypoglycaemia after discontinuation, a gradual decrease in flow rate before stopping the infusion should be considered. The usual dose is 20-50mL of 50% glucose injection administered slowly, at a rate of 3mL/minute. If a peripheral vein is used, a large arm vein should be selected and the infusion site should be changed daily.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to their administration (see Section 4.4 **Precautions**); 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 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 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 glucose infusion solution, aseptic technique must be used. After addition, check for a possible color 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. 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.

Solutions containing glucose should not be administered through the same lines as those containing whole blood due to the risk of haemolysis and clumping. It does not contain antimicrobials. For use in one patient on one occasion only. Residue should be discarded. Care should be taken with intravenous administration and injection technique to avoid injection site reactions and infections.

4.3 Contraindications

The infusion of hypertonic glucose preparations are contraindicated in patients:
• having intracranial or intraspinal haemorrhage
• with delirium tremens or those who are severely dehydrated
• who are anuric and
• with diabetic coma
•with hypersensitivity to the active substance or to any of the excipients listed in section 6.1

Infusion of both isotonic and hypertonic glucose preparations 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 corn starch is used as raw material for glucose production
- with clinically significant hyperglycaemia.
- with hypersensitivity to the active substance or to any of the excipients listed in section 6.1

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 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.

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

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. Excessive administration of high concentration glucose infusions may result in significant hypokalaemia, requiring possible administration of concomitant potassium.

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

-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. 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 life-threatening 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 infusions. The glucose infusion solutions should be used with caution in patients with overt or subclinical diabetes mellitus **(See Section 4.5 Interactions with Other Medicines).**

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

•patients with ischemic stroke. Hyperglycaemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic 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 **Contraindications**).
• 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.

Liver disorders

Hepatobiliary disorders including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis are known to develop in some patients on parenteral nutrition. The etiology of these disorders is thought to be multifactorial and may differ between patients. Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

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.

Precipitates

Pulmonary vascular precipitates have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred. Excessive addition of calcium and phosphate increases

the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Precipitation distal to the in-line filter and suspected precipitate formation in the blood stream has also been reported.

In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates.

If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated.

Others
In a dilute condition, osmolarity/L is approximately the same as osmolality/kg. As shown in Table 2 of **Section 6.5 Presentation and Storage Conditions**, high concentration Glucose (≥10%) infusions are hypertonic, whereas the 5% preparations are isotonic (278mOsmol/L, Table 1, **Presentation and Storage Conditions)**.

Glucose tolerance may be impaired in patients with renal failure. In patients with deficiency of sodium, administration of hypertonic glucose intravenous infusions without sodium may lead to peripheral collapse and oligouria.

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.

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 infusion rates and volumes.

Hypo-/hyperglycaemia
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 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 enterocolitits, 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, naus ea, 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. 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). Dos age, rate, and duration of administration should be determined by a physician experienced in paediatric intravenous fluid therapy.

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.

4.5 Interaction with other medicines and other forms of interaction

Caution is advised when administering glucose intravenous infusion solutions to patients treated with drugs 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 sections 4.4 and 4.8).

• Medicines stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsycotics, opioids.

• Drugs potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDS), cyclophosphamide.

• Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin. Caution is advised when administering glucose intravenous infusions to patients treated with medicines that may increase the risk of hyponatraemia, such as diuretics and antiepileptics (e.g., oxcarbazepine).

The glucose infusion 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 glucose infusion solution 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.

Caution must be taken with hypertonic glucose infusions in patients receiving corticosteroids or corticotropin.

4.6 Fertility, pregnancy and lactation

Fertility
There are no fertility data presented

Use in pregnancy (Category C)

Animal reproduction studies have not been conducted with glucose infusions. It is also not known whether the 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

There is no information on the effects of glucose intravenous infusion solutions 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 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** Interactions with Other Medicines).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. If hypertonic glucose solutions are infused too rapidly, local pain and rarely, vein irritation may occur.

Glucose 5% Injection is iso-osmotic with blood and may be administered intravenously via a peripheral vein. Local reactions such as phlebitis or venous thrombosis and extravasation may occur. A fever response and infection at the site of injection may also occur due to contamination of the solution or poor techniques of administration.

Hyperglycaemia and glucosuria may occur if the rate of infusion is greater than 0.5g/kg/h, particularly with hypertonic glucose intravenous infusions; if undetected and untreated, this can lead to diuresis, dehydration, hyperosmolar coma, and death. Continual clinical monitoring is recommended (**see Section 4.4 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

VASCULAR DISORDERS: Phlebitis

Other adverse reactions reported with other similar products include:

- hyponatraemia (which may be symptomatic)
- infusion site thrombophlebitis (associated with hyperosmolar solutions)
- adverse reactions reported with parenteral nutrition to which the glucose component may play a causal or contributory role include:

- hepatic failure, hepatic cirrhosis, hepatic fibrosis, cholestasis, hepatic steatosis, blood bilirubin increased, hepatic enzyme increased, cholecystitis, cholelithiasis

- pulmonary vascular precipitates.

- hyponatraemic encephalopathy

Reporting of suspected adverse reactions

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

4.9 Overdose

Excessive administration of glucose infusion solutions can cause hyperglycaemia, adverse effects on water and electrolyte balance, and corresponding complications (**see Sections 4.4 and 4.8 Precautions**). For example, severe hyperglycaemia and severe dilutional hyponatraemia, and their complications, can be fatal. Clinically significant overdose of glucose infusion solutions 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 overdosage 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.

Typical initial signs of hypertonic solution overdose are extracellular fluid excess, hyperglycaemia, lowering of haemoglobin and haematocrit, lowering of serum electrolyte concentrations, potassium transfer from the cell to the extracellular space and increased plasma osmolarity. In patients with intact renal function, overdosage causes osmotic diuresis to a greater or lesser extent-commensurate with the hyperosmolarity of the infused solution-accompanied by a concomitant loss of electrolytes, especially potassium. Through increased water binding of the infused hypertonic carbohydrate solution, overdosage may lead to dehydration to a greater or lesser extent during the course of osmotic diuresis. Dehydration is characterised by lowering of initially raised plasma osmolarity. Haemoglobin and haematocrit, which are lowered immediately after overdosage, may thus return more or less to normal during the course of diuresis.

If diuresis is slow to develop, metabolic disturbances associated with glucose overdose may occur, characterised in particular by increased lactic acid build-up and lowering of pH. If diuresis does not occur, this may result in symptoms of circulatory overload-in particular oedema (including pulmonary oedema) and heavy intracellular potassium loss.

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 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).

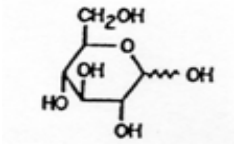
5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: General Nutrients, Other Nutrients, Carbohydrates
ATC Code: V06DC01

Chemical Name D-(+) glucopyranose
Molecular formula $C_6H_{12}O^6$

Structural formula



Molecular Weight	180.2
CAS	50-99-7

Mechanism of Action

Glucose is metabolised to carbon dioxide and water thus providing water for body hydration as well as calories. 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, the Glucose 5% infusion solutions and the Glucose $\geq$10% infusion solutions 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.

5.2 Pharmacokinetic properties

A glucose preparation administered by the oral route is rapidly absorbed from the gastrointestinal 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

Carcinogenicity/mutagenicity
The active ingredient, glucose, in the glucose infusion solutions is not a carcinogen or mutagen. It is a basic nutrient in all living cells.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections
Sodium hydroxide & Hydrochloric acid used for pH adjustment

6.2 Incompatibilities

Additives may be incompatible with glucose. Do not administer such preparations unless the solution is clear. Do not store solutions containing additives unless compatibility has been proven. 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 a thorough understanding of possible incompatibility problems. In particular, the product information document of any added medication should be checked for any incompatibility with the glucose injection

6.3 Shelf life

Glucose 5% Infusion

Strength & Pack Size	**Shelf Life**
Glucose 5% 50mL	18 months
Glucose 5% 100mL	24 months
Glucose 5% 250mL	24 or 36 months
Glucose 5% 500mL, 1000mL	36 months

Glucose 10% Infusion

Strength & Pack Size	Shelf Life
Glucose 10%, 500mL	3 years

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Freeflex bag

6.6 Special precautions for disposal <and other handling

No special requirements for disposal

7 MEDICINE SCHEDULE

General Sales Medicine

8 SPONSOR

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Tel: (61-2) 9391 5555

Fresenius Kabi New Zealand Limited
c/o GNZCC
HSBC Tower, Level 14
188 Quay Street, Auckland 1010, New Zealand
Freecall: 0800 144 892

9 DATE OF FIRST APPROVAL

5th May 2022

10 DATE OF REVISION OF THE TEXT

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
Na	New data sheet format
	Addition of Glucose 10% Freeflex Infusion, Solution