AUSTRALIAN PRODUCT INFORMATION – GLUCOSE 5% & 10% FREEFLEX (SOLUTION FOR INJECTION)

1 NAME OF THE MEDICINE

Glucose

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose 10% is a sterile hypertonic solution of glucose 10% w/v in Water for Injections, containing no preservatives. pH 3.5 to 6.5.

Glucose 5% Freeflex is a sterile isotonic solution of glucose 5% w/v in Water for Injections, containing no preservatives. pH 3.5 to 6.5.

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

3 PHARMACEUTICAL FORM

Solution for Injection

Clear colourless to slightly yellow solution

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

The solutions are indicated for intravenous fluid therapy designed to correct deficiencies in energy levels. Glucose 5% is also used to correct hydration levels. The solutions may also be used as solvents for intravenously administered drugs where compatibility has been established.

4.2 DOSE AND METHOD OF ADMINISTRATION

Glucose 5% Injection may be administered intravenously via a peripheral vein. The maximum rate at which glucose can be administered without producing glycosuria is 0.5 g/kg/h.

Glucose 10% Injection is hypertonic and should preferably be administered via an IV catheter in a large central vein. If a peripheral vein is used a large arm vein should be selected and the infusion site changed daily. The rate of infusion should not exceed 0.5 g/kg/h to avoid glycosuria.

The dose of glucose is dependent on the age, weight and fluid, electrolyte, glucose and acid-base balance of the patient.

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

Glucose is contraindicated in the following:

- diabetic coma where blood sugar levels are excessively high
- glucose-galactose malabsorption syndrome
- anuria
- intraspinal or intracranial haemorrhage
- in dehydrated delirium tremens patients
- known allergy to corn (maize) and corn products
- patients at risk for ischaemic stroke
- use after an ischaemic stroke episode

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Glucose solutions should be used with caution in patients with overt or known subclinical diabetes mellitus, or with carbohydrate intolerance.

Intravenous administration of glucose solutions, especially as infusions, may cause fluid overload and a resultant dilution of serum electrolytes and possible peripheral and pulmonary oedema. Prolonged therapy should be monitored for changes in fluid balance, electrolyte concentration and acid/base balance.

Hyperglycaemia and glucosuria may occur as a result of an over rapid rate of infusion or metabolic insufficiency. Blood and urine glucose should be monitored regularly.

Glucose solutions should not be infused concomitantly through the same intravenous set as blood as agglomeration or haemolysis may occur.

Prolonged parenteral administration of glucose may affect insulin production. To avoid this it may be necessary to add insulin to the infusion. A review of the patient's oral hypoglycaemic agent or insulin requirements may be necessary.

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

Thiamine diphosphate cocarboxylase is an essential coenzyme in carbohydrate metabolism, therefore patients having thiamine deficiency should be treated cautiously with glucose injection. This is particularly important in patients who chronically abuse alcohol as this may precipitate an overt deficiency syndrome, e.g. Wernicke's encephalopathy.

Use in the elderly

No data available.

Paediatric use

Glucose solutions, particularly hypertonic ones, should be used with care and under expert supervision in paediatric patients. Dosage should be adjusted accordingly. Use with caution in infants of diabetic mothers.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Glucose intravenous infusion preparations (an aqueous, ie 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.

Caution is advised when administering glucose intravenous Infusion to patients treated with drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatraemia following treatment with IV fluids.

- Drugs 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 antiinflammatories (NSAIDS), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Parenteral fluids, especially those containing sodium ions, should be administered with caution to patients receiving corticosteroids or corticotrophin.

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

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

Pregnancy Category B3

Safety in pregnancy has not been established. Use only when clearly needed and potential benefits outweigh risk to the foetus.

Use in lactation.

No data available

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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 glycosuria may occur if glucose is administered at a rate greater than 0.5 g/kg/h. Disruption of the fluid and acid-base balance and dilution of electrolyte concentrations may occur during prolonged usage, resulting in oedema, hypokalaemia, hypomagnesaemia and hypophosphataemia (see Section **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**).

Vitamin B complex deficiency may occur with glucose administration.

Post-marketing adverse reactions

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

- IMMUNE SYSTEM DISORDERS: hypersensitivity/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 reactions reported with other similar products include:

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

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 Overdose

Hyperglycaemia and glycosuria, if undetected, can lead to mental confusion, dehydration, hyperosmolar coma and death.

Treatment

Appropriate treatment may include decreasing the infusion rate of glucose and administration of insulin.

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

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Glucose is a monosaccharide that provides the principal source of energy for the body. It is also involved in many additional areas of protein and fat metabolism.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

Absorption

Glucose is stored in the body as fat and in the muscles and liver as glycogen. When a rapid rise in blood sugar is required, glycogen quickly liberates glucose. However, when this supply is insufficient the body mobilises its fat stores to release energy.

Distribution

Glucose also has a protein sparing function in the body. In the absence of glucose, energy can be produced from oxidation of deaminated amino acid fractions.

Metabolism

Glucose is the probable source of glucuronic acid, hyaluronates and chondroitin sulphates and can be converted to a pentose used for nucleic acid formation.

Glucose is metabolised to carbon dioxide and water thus providing water for body hydration as well as calories.

Excretion

No data available

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for Injection.

Hydrochloric acid and sodium hydrochloride 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

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

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C

6.5 NATURE AND CONTENTS OF CONTAINER

Glucose 5 % injection in polyolefin **free***flex*® bags:

50 mL AUST R 144669 - 40, 60, 65 and 70 bags/carton.

100 mL AUST R 144671-40, 50, 55 and 60 bags/carton

250 mL AUST R 144672- 20, 30, 35 and 40 bags/carton

500 mL AUST R 29599- 1 bag/carton.

1000 mL AUST R 47389- 1 bag/carton.

Glucose 10 % injection in **free***flex*® bags:

500 mL AUST R 29790 - 1 bag/carton.

Not all pack sizes are available

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 Physicochemical properties

Chemical structure

Chemical name alpha-D-(+)-glucopyranose.

$C_6H_{12}O_6$

CAS number

14431-43-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Australia: Unscheduled

8 SPONSOR

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9 DATE OF FIRST APPROVAL

9 May 2006

10 DATE OF REVISION

13 October 2023

Summary table of changes

Section Changed	Summary of new information
4.5	Addition of potential interactions
4.8	Addition of post-marketing information
7 & 8	Removal of NZ details