AUSTRALIAN PRODUCT INFORMATION – GLUCOSE INTRAVENOUS INFUSION BP 5% (GLUCOSE MONOHYDRATE)

1. NAME OF THE MEDICINE

Glucose monohydrate

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of solution contains 54.99 mg glucose monohydrate (equivalent to 50 mg glucose). When necessary, pH is adjusted with sodium hydroxide and/or hydrochloric acid. pH is 3.5 to 6.5 and osmolality 250 to 350 mOsm/kg.

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

3. PHARMACEUTICAL FORM

Injection, intravenous infusion

Sterile isotonic preservative-free solutions containing glucose monohydrate.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- for fluid and carbohydrate depletion wherever a non-electrolyte fluid is required
- in the treatment of hypoglycaemia
- in the treatment of acute diarrhoeal disease
- as a vehicle for the administration of other medications

4.2 Dose and method of administration

Dosage

Dosage will be dependent upon individual patient circumstances, such as age, weight and clinical condition and is determined by the attending physician.

Method of administration

The infusion rate should not exceed 0.5 g/kg/hour to avoid potential glycosuria.

Glucose Intravenous Infusion BP 5% may be administered via a peripheral vein, preferable large arm vein and the site of infusion should be changed daily if more than one infusion is required.

Do not use if any visible particles are observed.

4.3 Contraindications

- Glucose-Galactose Malabsorption Syndrome
- Diabetic coma where blood sugar levels are excessively high;
- Avoid use in ischaemic stroke, as under this condition, the induced lactic acidosis aggravates the recovery of the damaged brain tissue.
- intracranial or intraspinal haemorrhage
- patients with delirium tremens who are severely dehydrated
- patients who are anuric
- patients who are known to have an allergy reaction to corn (maize) or corn products.

4.4 Special warnings and precautions for use

- Glucose injections, even if iso-osmotic, should not be mixed with whole blood as haemolysis and agglomeration may occur.
- 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 thorough understanding of possible of incompatibility problems. In particular, the product information document of any added medication should be checked for any incompatibility with the glucose infusion.
- Peripheral and pulmonary oedema may occur from intravenous administration of glucose solution, especially by over dilution of body serum electrolyte, overhydration, congested states from infusions. 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.
- Hyperglycaemia and glycosuria may occur in patients with metabolic insufficiency or as a result of an over rapid rate infusion.
- Glucose solution should be used with caution in patients with suspected or diagnosed diabetes mellitus or with carbohydrate intolerance.
- Prolonged parenteral administration of glucose may affect insulin production. To avoid this it may be necessary to add insulin to the infusion.

- Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in blood, urinary glucose, fluid balance, electrolyte concentrations and acid-base balance should be monitored during administration especially during prolonged parenteral therapy.

- When used as a vehicle of drug delivery, the product information document of the drug(s) for infusion should be examined to ensure compatibility with the solution.

- Administration of a substantially hypertonic solution may lead to a wide variety of complications. These include crenation (shrinkage) of red blood cells and general cellular dehydration. Thus, unless appropriately diluted, the infusion of hypertonic glucose injection solution into a peripheral vein may result in vein irritation, vein damage, and thrombosis. Strongly hypertonic nutrient solutions should only be administered through an indwelling intravenous catheter with the tip located in a large central vein such as the superior vena cava.

- Similarly, administration of hypertonic glucose injection and amino acid solutions via central venous catheter may be associated with complications that can be prevented or minimised by careful attention to all aspects of the procedure.

- Caution should be exercised in the administration of the glucose intravenous injection containing sodium ions to patients receiving corticosteroids or corticotropin as it may lead to hypernatraemia. Thiamine diphosphate, cocarboxylase, is an essential co-enzyme in the carbohydrate metabolism; therefore, patients having thiamine deficiency should be treated cautiously with glucose intravenous infusion. The glucose injections should be used with caution in patients with overt or subclinical diabetes mellitus.

Use in the elderly

No data available.

Paediatric use

Caution should be taken when used in infants with diabetic mothers.

Effects on laboratory tests

No data available.

4.5 Interactions with other medicines and other forms of interactions

Glucose solutions should not be administered concomitantly with blood through the same infusion set, as haemolysis and clumping may occur.

Use of these glucose infusions may necessitate review of a patient’s oral hypoglycaemic or insulin requirements.

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. Glucose Intravenous Infusion should be used during pregnancy only when clearly needed and the benefits of therapy outweigh the potential risks.

Use in lactation

No information 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)

- infusion of glucose at a rate greater than 0.5 g/kg/hr may cause hyperglycaemia and glycosuria. Rapid infusion of 25 - 50 g over 3 minutes may occasionally cause a generalised flush which usually subsides within 10 minutes.

- oedema, hypokalaemia, hypophosphataemia and hypomagnesaemia. The utilisation of glucose will cause the intracellular movement of phosphate and potassium; in certain conditions provision must be made for replacing these products.

- dilute electrolyte concentrations and disrupted fluid and acid-base balance with prolonged use

- Vitamin B complex deficiency. The administration of glucose without adequate provision of certain B vitamins, which form the coenzyme systems in its metabolism, will exhaust tissue stores of these factors, leading to deficiency states. This is particularly important in alcoholics when subclinical thiamine deficiency may precipitate an overt deficiency syndrome such as Wernicke's encephalopathy.

- local reactions at site of infusion, such as fever, infection at the site of injection, phlebitis or venous thrombosis and extravasation. Thrombophlebitis may result from the use of hypertonic solutions via the intravenous route.

- Anaphylactoid effects have been reported in two patients with both asthma and diabetes mellitus.

- Glucose administration can exacerbate diabetes mellitus.

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

Symptoms

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

Treatment

Decrease the glucose infusion rate and administer insulin if appropriate.

Fluid overload and biochemical imbalance should be treated with 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 naturally occurring monosaccharide found in the blood and is the principle source of energy for the body.

Glucose is metabolised in the body to carbon dioxide and water with the release of energy and calories.

It is stored in the body as fat and in the liver and muscles as glycogen. Glycogen is broken down and converted to glucose when body glucose level is depleted. As well as providing a source of energy, glucose infusions may reduce catabolic loss of nitrogen from the body and help prevent depletion of liver glycogen. It is also a source to be converted for nucleic acid formation.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

Data regarding mutagenic potential during pregnancy is not available.

Carcinogenicity

Glucose is not carcinogenic.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium hydroxide (when necessary, for pH adjustment)
- Hydrochloric acid (when necessary, for pH adjustment)
- Water for injections

6.2 Incompatibilities

See section 4.4 – Special warnings and precautions for use and section 4.5 - Interactions with other medicines and other forms of interactions

6.3 Shelf life

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

6.4 Special precautions for storage

Store below 25 °C

Single use only. Discard unused portion.

6.5 Nature and contents of container

Glucose Intravenous Infusion BP 5% 100 mL Glass Vial, Aust R 11371

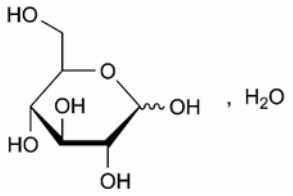
6.6 Special precautions for disposal

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

6.7 Physicochemical properties

Chemical structure

The molecular formula is $C_6H_{12}O_6.H_2O$ and the chemical structure is



CAS number

77938-63-7, 14431-43-7

7. MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8. SPONSOR

Pfizer Australia Pty Ltd
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9. DATE OF FIRST APPROVAL

31 July 2000.

10. DATE OF REVISION

26 February 2020

Summary Table of Changes

Section changed	Summary of new information
All	Reformatted Product Information
8	Update to sponsor details.