GLUCOSE 50%

(GLUCOSE MONOHYDRATE) INTRAVENOUS INFUSION

1 NAME OF THE MEDICINE

Glucose monohydrate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose 50% contains glucose monohydrate 27.5 g in 50 mL equivalent to glucose anhydrous 25 g per 50 mL (500 mg/mL or 50%) in water for injections.

Glucose 50% is strongly hypertonic. The solution has a pH range of 3.5 to 6.5.

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

3 PHARMACEUTICAL FORM

Glucose 50% is a clear, colourless to faintly straw coloured, particle-free solution for intravenous infusion.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Glucose 50% intravenous infusion is strongly hypertonic and may be used to reduce increased cerebrospinal pressure and/or oedema due to delirium tremens or acute alcoholic intoxication. It may also be used to treat severe hypoglycaemia due to an excess of insulin and to provide concentrated calories in total parenteral nutrition regimes.

4.2 DOSE AND METHOD OF ADMINISTRATION

Glucose 50% intravenous infusion is strongly hypertonic and must be administered via the intravenous (IV) route only. Except in the emergency treatment of severe hypoglycaemia, Glucose 50% intravenous infusion should be appropriately diluted and administered via an IV catheter carefully placed in a large central vein.

For emergency treatment of hypoglycaemia, Glucose 50% intravenous infusion may be administered slowly (e.g. 3 mL/minute) via a small bore needle carefully placed in a large peripheral vein.

The dose of glucose is dependent on the age, weight and fluid, electrolyte, glucose and acid-base balance of the patient. The rate of infusion should not exceed 0.5 g/kg/hr to avoid glycosuria.

Acute hypoglycaemia

Adults and children: 20-50 mL of Glucose 50% intravenous infusion administered by slow IV injection as an initial dose. The total dose will vary depending on the patient's response and blood glucose levels. Provision must be made to maintain the patient's blood glucose level after the initial response.

Neonates and infants: 1 mL/kg of Glucose 50% then adjust as required. Due to the increased risk of phlebitis with glucose solutions over 10% a central line should be considered.

4.3 CONTRAINDICATIONS

Glucose 50% intravenous infusion is contraindicated in:

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

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The use of hypertonic glucose solutions may result in dehydration, therefore, regular monitoring of the hydration status of the patient is recommended. It is important that hypertonic glucose solutions are administered slowly, because rapid administration may produce a local rise in the osmotic tension of the blood at the point of injection.

Intravenous administration of hypertonic glucose solutions may cause venous thrombosis, so it is important to employ proper techniques to avoid vein damage. It is recommended that the intravenous injection be given slowly, using a small bore needle and avoiding the walls of the vein if possible. The tourniquet should be removed as soon as venipuncture has occurred. Warming the arm and the solution to room temperature will help to avoid adverse sequelae.

Intravenous administration of glucose solutions, especially as infusions, may cause fluid overload with 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.

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

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

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

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

Cautious use of glucose solutions is required in patients with thiamine deficiency, hypokalaemia, hypophosphataemia, hypomagnesaemia, haemodilution, sepsis and trauma.

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 a patient's oral hypoglycaemic or insulin requirements may be necessary. 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 Glucose 50%.

Use in the elderly

No data available.

Paediatric use

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

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

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

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

Use in lactation

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

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)

Intravenous administration of hypertonic glucose solutions may cause local phlebitis or venous thrombosis and extravasation. If the solution is infused too rapidly, local pain and vein irritation 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/hr. 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.

High concentrations of glucose administered intravenously may induce an increased histamine release from blood cells resulting in anaphylactoid reactions. Anaphylactoid effects have been reported in two patients with both asthma and diabetes mellitus.

Rapid infusion of glucose 25-30 g over 3 minutes may occasionally cause a generalised flush. This subsides within 10 minutes.

Reporting suspected adverse reactions

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

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

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Glucose is a monosaccharide which provides the principal source of energy for the body. It is also involved in many additional areas of protein and fat metabolism. Glucose is stored in the body as fat and in the muscles and liver as glycogen. Glucose is rapidly metabolised from glycogen; it increases blood glucose concentrations and provides energy. However, when this supply is insufficient the body mobilises its fat stores to release energy. Glucose may also decrease body protein and nitrogen losses, promote glycogen deposition. Glucose is metabolised to carbon dioxide and water thus providing water for body hydration as well as calories.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Distribution

Glucose is stored in the body as fat and in the muscles and liver as glycogen.

Metabolism

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

Glucose 50% is a sterile solution of anhydrous glucose in water for injections, adjusted to pH 3.5-6.5 with sodium bicarbonate or hydrochloric acid.

6.2 INCOMPATIBILITIES

See Section 4.4 Special Warnings and Precautions for Use and 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 ARTG[1]. 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

It is presented in a 50 mL glass vial as a pack of 10.

Phebra product code - INJ128.

[1] AUST R 12420

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

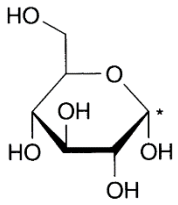
In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical name: monohydrate of (+)-D-glucopyranose.

The molecular weight of the compound is 198.2. The molecular formula is $C_6H_{12}O_6,H_2O$.

Chemical structure



and epimer at C* , H_2O

CAS number

5996-10-01

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled.

8 SPONSOR

Phebra[2] Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.
Ph: 1800 720 020

9 DATE OF FIRST APPROVAL

13 Aug 1991

10 DATE OF REVISION

5 Feb 2021

11 REFERENCES

Section Changed	Summary of new information
All	PI reformat
2	Revise the AAN and the quantity of the active ingredient

[2] Phebra and the Phi symbol are trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.

3	Revise the name of dosage form per TGO91
4.3	Minor editorial change
8	Update of Sponsor contact number