NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Glucose 5% Freeflex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient is Glucose 50g/L (as Glucose monohydrate)

3 PHARMACEUTICAL FORM

Infusion, solution

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

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.

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 or insulin requirements may be necessary.

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

Use in children

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.

4.5 Interaction with other medicines and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

Use in pregnancy

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

4.7 Effects on ability to drive and use machines

Not applicable

4.8 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 glucosuria 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 (refer section 4.4 **Special Warnings and Precautions for use**).

Vitamin B complex deficiency may occur with glucose administration.

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

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

In case of overdose please contact the Poisons Information Centre on 131126 (Australia) or 0800 764 766 (New Zealand) for advice on management.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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.

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.

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.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

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

50mL bag- 18 months
100mL bag – 24 months
250mL bag – 24 months or 36 months
500mL, 1000mL bag – 36 months

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
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine 21 August 2009.

10 DATE OF REVISION OF THE TEXT

27 May 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
Na	New data sheet format
6.3 Shelf life	Shelf life change for 50mL bag
2	Change to active ingredient expression