1. NAME OF THE MEDICINAL PRODUCT

Glucose Injection BP Minijet 50% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose anhydrous 500 mg in 1 ml.

For excipients see 6.1

3. PHARMACEUTICAL FORM

Sterile aqueous solution for intravenous injection.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

a) As a source of energy in parenteral nutrition.

b) In severe hypoglycaemia due to insulin excess or other causes.

c) For reduction of cerebrospinal pressure and/or cerebral oedema due to delirium tremens or acute alcohol intoxication.

Glucose injection 50% w/v is strongly hypertonic and is used partly because of its dehydrating effects.

4.2. Posology and Method of Administration

Hypertonic solutions of glucose should be administered via a central vein. The dose is variable and depends upon the indication, clinical condition and size of the individual.

The rate of utilisation of glucose varies considerably from patient to patient. In general, the maximal rate has been estimated at 500-800 mg/kg body
weight/hour. If the patient's capacity to utilise glucose is exceeded, glycosuria and diuresis will occur.

**Adults, elderly, children over 6 years:**

*Hypoglycaemia:* 20-50ml of a 50% w/v solution, repeated as necessary according to the patient's response, by slow intravenous injection, e.g. 3ml/minute. After 25g of glucose has been given, it is advisable to interrupt the injection and evaluate the effect. The exact dose required to relieve hypoglycaemia will vary. After the patient responds, supplemental oral feeding is indicated to avoid relapse, especially after insulin shock therapy.

*Acute alcoholism:* 50ml of glucose 50% w/v solution should be administered intravenously. Unmodified insulin (20 units) and thiamine hydrochloride (100mg) should be added to the infusion.

### 4.3 Contra-Indications

The intravenous use of strongly hypertonic solutions of glucose is contraindicated in patients with anuria, intracranial or intraspinal haemorrhage, or delirium tremens if the patient is already dehydrated.

Known sensitivity to corn or corn products, hyperglycaemic coma, or ischaemic stroke.

### 4.4 Special warnings and precautions for use

Hypertonic solutions of glucose should be administered via a large central vein to minimise the damage at the site of injection.

Use with caution in patients with diabetes mellitus, severe undernutrition, carbohydrate intolerance, thiamine deficiency, hypophosphataemia, haemodilution, sepsis and trauma. Rapid infusion of hypertonic glucose solution may lead to hyperglycaemia. Patients should be observed for signs of mental confusion or loss of consciousness.

Prolonged use in parenteral nutrition may affect insulin production; blood and urine glucose should be monitored. Fluid and acid-base balance and electrolyte status should also be determined during therapy with dextrose.

Hyperglycaemia may be caused by physiological stress during ischaemic stroke, and this worsens cerebral ischaemic damage and impairs recovery. During cerebral ischaemia, cellular hypoxia causes a shift from aerobic to anaerobic metabolism of glucose leading to intracellular lactic acidosis, which is toxic to the cell. Hyperglycaemia provides more glucose for anaerobic metabolism, further worsening intracellular acidosis. Blood-glucose concentrations should therefore be monitored...
and hyperglycaemia avoided or treated. Hypoglycaemia must also be avoided and for patients who do require glucose, it should be given by continuous infusion, avoiding large infusions or boluses that can cause hyperglycaemia.

Glucose solutions should not be given through the same infusion equipment as whole blood as haemolysis and clumping can occur.

4.5. Interaction with other Medicinal Products and other Forms of Interaction

None known.

4.6 Fertility, pregnancy and lactation

Intravenous glucose may result in considerable foetal insulin production, with an associated risk of rebound hypoglycaemia in the new-born. Infusion should not exceed 5-10g/hour during labour or Caesarean section.

4.7 Effects on ability to drive and use machines

This preparation is intended for use only in emergencies.

4.8 Undesirable effects

Anaphylactoid reactions have been reported in patients with asthma and diabetes mellitus.

Local pain, inflammation, irritation, thrombophlebitis and fever may occur.

Hypokalaemia, hypomagnesaemia or hypophosphataemia may result from the use of hypertonic solutions via the intravenous route.

Prolonged or rapid administration of hyperosmotic (>5%) solutions may lead to dehydration.

The administration of glucose without adequate levels of thiamine (which form the coenzyme systems in its metabolism), may precipitate overt deficiency states, e.g. Wernicke’s encephalopathy.

Excess glucose infusion produces increased CO2, which may be important in respiratory failure, and stimulates catecholamine secretion.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

The patient becomes hyperglycaemic and glycosuria may occur. This can lead to dehydration, hyperosmolar coma and death.
Treatment: The infusion should be discontinued and the patient evaluated. Insulin may be administered and appropriate supportive measures taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Glucose, the natural sugar occurring in the blood, is the principle source of energy for the body. It is readily converted to fat and is also stored in the liver and muscles as glycogen. When a rapid rise in blood sugar is demanded by the body, glycogen is quickly liberated as d-glucose. When the supply of glucose is insufficient, the body mobilises fat stores which are converted to acetate with production of energy by the same oxidative pathways employed in the combustion of glucose.

It may decrease body protein and nitrogen losses. Glucose is also the probable source of glucuronic acid with which many foreign substances and their metabolites combine to form excretion products. It probably provides the basic substances required for the formation of hyaluronates and chondroitin sulfates, the supporting structures of the organism. It can be converted to a pentose essential for the formation of nucleic acids by the cells.

5.2 Pharmacokinetic Properties

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

5.3 Pre-clinical Safety Data

Not applicable since glucose has been used in clinical practice for many years and its effects in man are well known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Water for Injection

6.2 Incompatibilities

Glucose solutions which do not contain electrolytes should not be administered concomitantly with blood through the same infusion set as haemolysis and clumping may occur.
6.3. Shelf-Life

3 years.

6.4. Special Precautions for Storage

Store below 25°C.

6.5. Nature and Content of Container

The solution is contained in a USP type I glass vial with an elastomeric closure which meets all the relevant USP specifications. The product is available as 10ml and 50ml.

6.6. Instructions for Use, Handling and Disposal

The container is specially designed for use with the IMS Minijet injector. Do not use the injection if crystals have separated.

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 03265/0008R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORIZATION
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