2.1 Name of the Medicinal Product

Glucose Intravenous Infusion B.P (D50)

2.2 Qualitative and Quantitative Composition

Each 1ml of solution contains 500mg glucose B.P.

2.3 Pharmaceutical Form

Intravenous solution

2.4 Clinical Particulars

2.4.1 Therapeutic Indications

- Glucose 50% w/v Solution for Infusion BP is indicated:
- As a source of energy in parenteral nutrition.
- In severe hypoglycemia due to insulin excess or other cause.
- 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.

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

Adults and 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.

Administration:
Administration is usually via a central vein.

Monitoring:
Treatment should be carried out under regular and careful surveillance. Clinical and biological parameters, in particular plasma-glucose concentration, fluid balance and electrolyte balance should be monitored on regular basis and during treatment.

2.4.2 Contraindications

- 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*.
- Hyperglycaemic coma,
- Ischaemic stroke
- Known sensitivity to corn or corn products

2.4.3 Special Warnings And Precautions For Use

- Hypertonic solutions of glucose should be administered via a large central vein to minimize 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.

2.4.4 Interaction with Other Medicinal Products And Other Forms Of Interaction

None known

2.4.5 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.

2.4.6 Effects On Ability To Drive And Use Machines

Not Applicable. This preparation is intended for use only in emergencies.

2.4.7 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.

2.4.8 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.

2.5 Pharmacological Properties

2.5.1 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 mobilizes 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 hyalluronates and chondroitin sulphates, the supporting structures of the organism. It can be converted to a pentose essential for the formation of nucleic acids by the cells.

2.5.2 Pharmacokinetic Properties

Glucose is metabolized via pyruvic or lactic acid to carbon dioxide and water with the release of energy.

2.6 Pharmaceutical Particulars

2.6.1 List Of Excipients

Water for Injections B.P.

2.6.2 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.

2.6.3 Shelf Life

24 months when unopened

2.6.4 Special Precautions For Storage

Store below 30°C, but do not freeze.

2.6.5 Nature And Contents Of Container

Bottle sizes: 100 mL

The bottles are made from Low Density Polyethylene plastic; the bottles are then overwrapped with a protective plastic pouch composed of polyamide/polypropylene which are ultimately packed in individual baby cartons.

Corrugated box contents: 100 bottles of 100 ml

2.6.6 Special Precautions For Disposal And Other Handling

Use as directed by the physician.

Keep out of reach of children.

2.7 Marketing Authorisation Holder

Abacus Parenteral Drugs Ltd. Uganda

2.8 Marketing Authorisation Number(s)

To be inserted after approval.

2.9 Date Of First Authorisation/Renewal Of The Authorisation

2.10 Date Of Revision Of The Text