National Agency for Food & Drug Administration & Control
(NAFDAC)

Registration & Regulatory Affairs

(R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
5% DEXTROSE INFUSION
(GLUCOSE 5%)

1. Name of the medicinal product

5% Dextrose Infusion

2. Qualitative and quantitative composition

Dextrose (glucose) monohydrate equivalent to 50.00g anhydrous dextrose per litre.

3. Pharmaceutical form

Solution for infusion.

Colourless to faintly straw-coloured solution without visible particles in bags, individually overwrapped.

4. Clinical particulars

4.1 Therapeutic indications

5% Dextrose Infusion Solution is indicated for:

- Fluid replacement administered alone or in regimens with electrolytes or additives known to be compatible with 5% Dextrose.
- Medium for intravenous administration of medicinal products known to be compatible with 5% Dextrose.

4.2 Posology and method of administration

Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients comedicated with vasopressin agonist drugs due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. 5% Dextrose Infusion Solution may become extremely hypotonic after administration due to glucose metabolization in the body.

To avoid dehydration in a healthy adult or in patients with no complicating factors such as fever or excessive fluid losses, daily fluid requirements are 1.5 to 2.5 litres. The volume of glucose solution needed to replenish deficits will vary with body weight, complementary treatment, severity of the clinical condition and hydration status of the patient, but in adults will usually lie between 2 and 10 litres. The pathophysiological response to dehydration, to electrolyte loss and to glucose infusion will vary with the age of the patient being treated and this should be considered during rehydration therapy. There is no recommended dose as this is a matter for clinical judgment and laboratory assessment in each case. The dose range is typically 500 – 3000ml in a 24-hour period and typical maximum rates are 800mg/kg/hr or 600ml/hr.

For intravenous infusion under medical supervision. Single use only.

4.3 Contraindications

Hyperglycaemia. Conditions of water excess

4.4 Special warnings and precautions for use

The rate of infusion should be sufficiently slow to allow detection of osmotic diuresis

- Prior to and during infusion, serum and/or urinary electrolytes and glucose should be monitored to assess the nature and severity of fluid depletion and electrolyte imbalance. Close monitoring of

patients with diabetes mellitus, and in patients with renal failure, is necessary during glucose infusion.

- Glucose infusions are incompatible with blood for transfusion as haemolysis or clumping can occur; do not administer through the same infusion equipment as blood or blood components for transfusion (either before, during or after their administration)
- Use with care in patients who have suffered an acute ischaemic stroke.
- Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization.

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia:

Patients with non-osmotic vasopressin release (e.g., in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain oedema are at particular risk of severe, irreversible, and life-threatening brain injury. Children, women in the fertile age and patients with reduced cerebral compliance (e.g., meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs leading to an increased vasopressin effect

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids.

- Drugs stimulating vasopressin release, e.g.:
- Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.:
- Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues, e.g.:

Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

Check compatibility of medicinal products with 5% Dextrose before administration with the solution.

4.6 Fertility, Pregnancy and Lactation
It is particularly important to avoid maternal hyperglycaemia during intravenous glucose infusion in the perinatal period in view of the possibility of inducing neonatal hypoglycaemia.

5% Dextrose Infusion Solution should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia.

4.7 Effects on ability to drive and use machines.
Not relevant

4.8 Undesirable effects
The frequency of adverse events listed below is defined using the following convention: very common (≥1/10); common (≥1/100 to < 1/10); uncommon (≥1/1,000 to < 1/100); rare (≥1/10,000 to < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).

Metabolism and nutrition disorders

Not known fluid and electrolyte disturbances including hypokalaemia, hypomagnesaemia and hypophosphatasemia, hyperglycaemia, glycosuria. Hypokalaemia may complicate glucose infusions, especially when combined with insulin in the treatment of diabetic ketoacidosis. Not known: Hospital Acquired Hyponatraemia*

General and administration site disorders

Not known: Irritation and discomfort at the site of infusion

Nervous system disorders

Not known: Hyponatraemic encephalopathy*

* Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy.

In the event of adverse reaction stop infusion immediately

4.9 Overdose
Administration of excessive amounts of 5% Dextrose may result in fluid overload and water intoxication. Severe over-infusion is usually limited to infusion with higher concentrations of glucose solutions, which may cause plasma hyperosmolality and osmotic diuresis. Treatment is symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: electrolyte with carbohydrate. ATC code: B05BB02

Glucose is rapidly absorbed into cells and metabolized into carbon dioxide and water with the release of energy. 5% Dextrose infusion solution allows intracellular rehydration and glucose also serves as a carbohydrate source for cellular nutrition.

5.2 Pharmacokinetic properties

The maximum rate of glucose utilization has been estimated to be about 500-800 mg/ kg body weight /hour.

5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. Pharmaceutical particulars

6.1 List of excipients
Water for Injections.

6.2 Incompatibilities
No studies for compatibility have been conducted with this product. Confirm additive compatibility before use.

Glucose infusions are incompatible with blood for transfusion as haemolysis or clumping can occur; do not administer through the same infusion equipment as blood or blood components for transfusion (either before, during or after their administration).

6.3 Shelf life
3 years

Use immediately on removal from overwrap.

6.4 Special precautions for storage
- Store in the original pack.
- Store below 30°C.
- Keep medicine away from direct sunlight.
- Keep all medicine out of the reach of children.

6.5 Nature and contents of container
Transparent liquid placed in a 250ml, 500ml and 1000ml LDPE Bottle

6.6 Special precautions for disposal and other handling

7. SUPPLIER AND MANUFACTURER
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