SCHEDULING STATUS:

S3

1. NAME OF THE MEDICINE

GLUCOSE 5 % INFUSION B.BRAUN, infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL contains 50 mg glucose as glucose monohydrate.

1000 mL contain 50,0 g glucose (as glucose monohydrate, 55,0 g).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intravenous Infusion

A clear to slightly straw-coloured fluid.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

It is used to treat dehydration and mild energy deficits. Each 1000 mL of **GLUCOSE 5 % INFUSION B.BRAUN** provides approximately 200 kcal.

4.2 Posology and method of administration

As directed by a physician. The rate of administration and the total volume infused are determined by the individual needs and requirements of the patient.

4.3 Contraindications

GLUCOSE 5 % INFUSION B.BRAUN is contraindicated in patients with glucose-galactose malabsorption syndrome.

Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour; Lactic Acidosis.

If it should be necessary to administer large volumes further contra-indications can arise on account of the glucose and/or fluid load:

- Hypotonic hyperhydration
- Isotonic hyperhydration
- Acute congestive heart failure
- Pulmonary oedema

This solution must not be used alone for fluid supply/rehydration because it does not contain electrolytes. See section 4.4.

4.4 Special warnings and precautions for use

Use only if solution is clear and free form visible particles.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Electrolyte free carbohydrate solutions must not be used for fluid substitution, especially rehydration therapy, without adequate electrolyte administration, because this could lead to markedly decreased serum electrolyte values, notably severe hyponatraemia and hypokalaemia, with potentially detrimental effects on the patient, e.g., brain damage or heart affections. Especially children, elderly patients and patients in poor general conditions are at risk.

Additionally, serum electrolytes, fluid and acid-base balance should be monitored. Especially, adequate sodium and – in relation to glucose metabolism – potassium supply should be ensured.

In states of electrolyte deficiencies like hyponatraemia or hypokalaemia the solution must not be used without adequate electrolyte substitution. In patients with disturbed glucose metabolism, as present e.g. in postoperative or posttraumatic conditions, or in patients with diabetes mellitus, **GLUCOSE 5 % INFUSION B.BRAUN** must be administered with caution, i.e. with frequent monitoring (see below), and dosage must be adapted as required. States of hyperglycaemia should be adequately monitored and treated with insulin. The application of insulin causes additional shifts of potassium into the cells and may therefore cause or increase hypokalaemia.

Patient monitoring should include regular checks of the blood glucose level. This fluid should also be administered with great caution to patients with renal insufficiency.

Administration of glucose solutions is not recommended after acute ischaemic strokes as hyperglycaemia has been reported to worsen ischaemic brain damage and impair recovery. In prehospital management of acute ischemic stroke, glucose-containing solutions should be avoided unless hypoglycaemia is present or strongly suspected.

GLUCOSE 5 % INFUSION B.BRAUN must not be administered in the same infusion equipment, simultaneously, before, or after administration of blood products of the possibility of pseudo-agglutination.

Paediatric population

Intravenous fluid therapy should be closely monitored in the paediatric population as they may have impaired ability to regulate fluids and electrolytes. Adequate hydration and urine flow must be ensured, and careful monitoring of fluid balance, plasma and urinary electrolyte concentrations are mandatory.

The infusion of hypotonic fluids such as **GLUCOSE 5 % INFUSION B.BRAUN** together with the non-osmotic secretion of ADH (in pain, anxiety, the post-operative state, nausea, vomiting, pyrexia, sepsis, reduced circulating volume, respiratory disorders, CNS infections, and metabolic and endocrine disorders) may result in hyponatraemia. Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death, therefore acute symptomatic hyponatraemia (e.g., hyponatraemic encephalopathy) is considered a medical emergency.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with medicinal products with an influence on glucose metabolism should be considered. Prescribers should refer to the information provided with the product concerned.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data (less than 200 pregnancy outcomes) from the use of glucose monohydrate in pregnant women.

Animal studies do not indicate direct or indirect harmful effects at the therapeutic dose with respect to reproductive toxicity (see section 5.3).

GLUCOSE 5 % INFUSION B.BRAUN can be used during pregnancy, if indicated as vehicle solution.

Breastfeeding

Glucose/metabolites are excreted in human milk, but at therapeutic doses of **GLUCOSE 5 % INFUSION B.BRAUN** no effects on the breastfed new born/infants are anticipated.

GLUCOSE 5 % INFUSION B.BRAUN can be used during breastfeeding as indicated.

4.7 Effects on ability to drive and use machines

GLUCOSE 5 % INFUSION B.BRAUN has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Metabolism and nutrition disorders:

Frequency unknown: Continuous infusion may lead to intracellular overhydration with dilutional effects on intra- and extracellular electrolytes. Electrolyte imbalance, e.g., hyponatraemia and hypokalaemia.

Vascular disorders:

Frequency unknown: The infusion of glucose solution may cause vein irritation and thrombophlebitis, but these effects tend to be more common with more concentrated glucose solutions.

General disorders and administration site conditions:

Other reactions may occur because of the injection or the technique of administration include febrile response, infection at the site of infusion, venous thrombosis or phlebitis extending from the site of infusion, extravasation and hypervolaemia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continues monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

At a fluid infusion rate of between 30 – 40 mL/kg/day, there is little or no risk of exceeding the body's metabolic rate for glucose with a 5 % glucose concentration.

Symptoms

Symptoms of glucose overdose

Excessive glucose infusions can cause hyperglycaemia, glucosuria, hyperosmolar dehydration and in extreme case overdose can lead to hyperglycaemic-hyperosmolar coma.

Symptoms of fluid overdose

Fluid overdose may result in hyperhydration with increase skin tension, venous congestion, oedema increased skin tension, voedema-, dilution of serum electrolytes, electrolyte imbalances, notably hyponatraemia and hypokalaemia (see section 4.4), and acid-base imbalances.

Clinical symptoms of water intoxication may occur like nausea, vomiting, spasm.

Further symptoms of overdose may arise depending on the nature of the additive.

Emergency treatment, antidotes

The disturbances can – depending on the type and the degree of severity – be treated by stopping the infusion, by administration of electrolytes, diuretics, or insulin.

For correction of hyponatraemia the following formula(1) can be used:

mmol of Na^+ required = (target Na^+ level(2) – actual Na^+) x TBW(3)

(1) modified with [2]

(2) should not be lower than 130 mmol/L

(3) TBW: Total body water, calculated as a fraction of body weight: 0,6 in children, 0,6 and 0,5 in nonelderly men and women respectively, and 0,5 and 0,45 in elderly men and woman, respectively.

During treatment, serum electrolytes should be monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group:

ATC code: V07AB

A.24 Mineral substitutes, electrolytes

Pharmacodynamic effects

Low concentration glucose solutions are suitable diluents for medicines because glucose, as a natural substrate of the cells in the organism, is ubiquitously metabolised. Under physiological conditions glucose is the most important energy supplying carbohydrate with a caloric value of approximately 17 kJ/g or 4 kcal/g.

In adults, the normal concentration of glucose in blood is reported to be 70 – 100 mg/100 mL, or 3,9 – 5,6 mmol/L (fasting).

5.2 Pharmacokinetic properties

Absorption

Since the solution is administered intravenously, its bioavailability is 100 %.

Distribution

On infusion glucose initially distributes in the intravascular space and is then take up in the intracellular space.

Biotransformation

In glycolysis, glucose is metabolized to pyruvate. Under aerobic conditions pyruvate is completely oxidised to carbon dioxide and water. In case of hypoxia, pyruvate is converted to lactate. Lactate can be partially reintroduced into the glucose metabolism (CORI cycle).

Glucose utilisation disturbances (glucose intolerance) can occur under pathological metabolic conditions. These are primarily diabetes mellitus, states of metabolic stress (e.g., intra-, and postoperatively, severe disease, injury), and hormonally induced reduction of glucose tolerance, which can lead to hyperglycaemia even without exogenous glucose

intake. Hyperglycaemia can – depending on its degree – lead to osmotically mediated renal fluid losses with consequent hypertonic dehydration, to hyperosmotic disorders up to and including hyperosmotic coma.

Metabolism of glucose and electrolytes are closely related to each other. Insulin facilitates potassium influx into cells. Phosphate and magnesium are involved in the enzymatic reactions associated with glucose utilization. Potassium, phosphate, and magnesium requirements may therefore increase following glucose administration and may therefore have to be monitored and supplemented according to individual needs. Especially cardiac and neurological functions may be impaired without supplementation.

Elimination

The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water).

Practically no glucose is excreted renally by healthy persons. In pathological metabolic conditions associated with hyperglycaemia (e.g., diabetes mellitus, postaggression metabolism), glucose is also excreted via the kidneys (glucosuria) when (at blood glucose levels higher than 160 – 180 mg/dL or 8,8 her thmmol/L) the maximum tubular resorption capacity is exceeded.

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 and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injection

6.2 Incompatibilities

Because **GLUCOSE 5 % INFUSION B.BRAUN** has an acid pH incompatibilities can occur on mixing other medicinal products.

Erythrocyte concentrates must not be suspended in **GLUCOSE 5 % INFUSION B.BRAUN** because of the risk of pseudo agglutination.

Also see section 4.4.

6.3 Shelf life

Unopened

2 Years (24 Months)

After first opening the container

Containers once opened must be used immediately. See section 6.6.

After admixture of additives

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

6.4 Special precautions for storage.

Store at or below 25 °C.

For storage conditions after admixture of additives see section 6.3.

Keep out of reach of children.

6.5 Nature and contents of container

A primary plastic vacuum-packed polyvinylchloride bag within a high density slightly opaque polyethylene overwrap.

Contents available in 200 mL and 1000 mL.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

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