4/12606529/0911

SUMMARY OF PRODUCT CHARACTERISTICS

B. Braun Melsungen AG · 34209 Melsungen · Germany

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in september 2008

Dextrose 5%

1 NAME OF THE MEDICINAL PRODUCT

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 50 mg glucose as glucose monohydrate
1000 ml contain 50000 mg (= 50 g) glucose as 55000 mg (= 55 g) glucose monohydrate.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless aqueous solution

Osmolarity:	278 mOsm/l
pH:	3.5 – 5.5

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Energy supply, Hypertonic dehydration,Vehicle solution for supplementary medication.

4.2 Posology and method of administration

A volume that yields the desired concentration of the medicinal product for which Dextrose 5%
is to be used as vehicle solution should be chosen, having regard to the maximum dose stated below.

Maximum daily dose

Up to 40 ml per kg body weight per day, corresponding to 2 g of glucose per kg body weight per day. For a 70 kg person this corresponds to a maximum infusion of 140.0 g/d of glucose, respectively 560 kcal. The maximum daily dose is in accordance with usual limitations of the daily fluid intake.

Maximum infusion and drip rate

The maximum infusion rate is 5 ml per kg body weight per hour, corresponding to 0.25 g (250 mg) of glucose per kg body weight per hour.
The maximum drip rate is 1.7 drops per kg body weight per minute.

Method of administration

Intravenous use. The solution must not be used if container or closure are damaged. Solutions containing visible solid particles musts not be administered.
For single use only.
Partially used containers must not be reconnected.
After first use, the container and any unused contents should be discarded.

4.3 Contraindications

- Hyperglycaemia,
- Hypokalaemia,
- Acidosis.

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

- Hyperhydration,
- Diabetic coma while blood sugar is excessively high,

4.4 Special warnings and precautions for use

Monitoring of blood glucose, fluid balance serum electrolytes, acid-base balance and serum potassium is necessary during administration of Glucose B. Braun 50 mg/ml Solution for Infusion.
In patients with disturbed glucose metabolism, as present e.g. in postoperative or posttraumatic conditions, Dextrose 5% must be administered with care, i.e. under blood glucose monitoring, and dosage must be adapted in order to prevent physiological stress. Dextrose 5% should only be administered with caution in patients with diabetes mellitus.
Glucose infusions should not be administered through the same infusion equipment, simultaneously with, before, or after administration of blood, because of the possibility of pseudo-agglutination.
Hyperglycemia and glycosuria may be functions of rate of administration or metabolic insufficiency. To minimize these conditions, slow the infusion rate, monitor blood and urine glucose; if necessary, administer insulin. When concentrated dextrose infusion is abruptly withdrawn, administer 5% dextrose to avoid hypoglycemic reactions. Administer so that extravasation does not occur. If thrombosis occurs during administration, stop infusion and correct.
Clinical supervision should include regular checks of blood glucose level, serum electrolytes and water balance. Electrolytes are to be supplemented as required.
Hypokalemia: Excessive administration of potassium free solutions may result in significant hypokalemia. Add potassium to dextrose solutions and administer to fasting patients with good renal function, especially those on digitalis therapy.
Vitamin B complex deficiency may occur with dextrose administration.
Caution is to be exercised in patients with hyponatremia.
No other medication or substance should be added to this fluid, unless it is known to be compatible.

Warnings
This fluid should only be administered with great care to patients with renal insufficiency.

Fluid/solute overload
Dextrose solutions I.V. can cause fluid or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states of pulmonary edema.
Hypertonic dextrose solutions may cause thrombosis if infused via peripheral veins, therefore, administer via a central venous catheter.
Diabetes mellitus: Use dextrose-containing solutions with caution in patients with sub-clinical or overt diabetes mellitus or carbohydrate intolerance.
Rapid administration of hypertonic solutions may produce significant hyperglycemia or hyperosmolar syndrome, especially in patients with chronic uremia or carbohydrate.

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Standort MEG

Lätus 5837

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4.5 Interactions with other medicinal products and other forms of interaction
None known

4.6 Pregnancy and lactation
For this medicinal product no restrictions of use during pregnancy and lactation are known.
Safety for use during pregnancy has not been established. Use only when clearly needed and when the potential benefits outweigh the potential hazards to the fetus.
Lactation: Exercise caution when administrating dextrose to a nursing woman.

Children
Use with caution in infants of diabetic mothers, except as may be indicated in hypoglycemic neonates.

4.7 Effects on ability to drive and use machines
This medicinal product has no effect on ability to drive and use machines.

4.8 Undesirable effects
Febrile response; infection at the injection site; tissue necrosis; venous thrombosis or phlebitis extending from the site of the injection; extravasation; hypovolemia, hypervolemia; dehydration; mental confusion or unconsciousness. These may occur because of the solution of administration technique. Use the largest available peripheral vein and a well placed small bore needle.
Hypertonic solution are more likely to cause irritation; administer into larger central veins. Significant hyperglycemia, hyperosmolar syndrome and glycosuria may occur with too rapid administration of hypertonic solutions.

4.9 Overdose
Symptoms
Overdose may result in hyperhydration, electrolyte and acid-base imbalances, hyperglycaemia, glucosuria and serum hyperosmolarity, up to hyperglycaemic hyperosmotic coma.
Emergency treatment, antidotes.
In case of overdose, the infusion should be discontinued, and electrolytes, diuretics, or insulin should be administered depending on type and severity of the symptoms.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmaco-therapeutic group: Solvents and diluting agents incl. irrigating solutions
ATC code: V07AB
Low concentration glucose solutions are suitable diluents for active substances because glucose, as a natural substrate of the cells in the organism, is ubiquitously metabolized. Under physiological conditions glucose is the most important energy-supplying carbohydrate with a caloric value of 17 kJ/g or 4 kcal/g. In adults, the normal concentration of glucose in blood is reported to be 60 – 100 mg/100 ml, or 3.3 – 5.6 mmol/l (fasting).

5.2 Pharmacokinetic Properties
On infusion glucose is first distributed in the intravascular space and then is taken up into the intracellular space.
In glycolysis glucose is metabolized to pyruvate or to lactate. Lactate can be partially re-introduced into the glucose metabolism (CORI cycle). Under aerobic conditions pyruvate is completely oxidized to carbon dioxide and water. The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water).

5.3 Preclinical Safety Data
No preclinical studies on toxicity and safety pharmacology have been conducted with Dextrose 5%.
Since glucose is a natural substrate of human metabolism, Dextrose 5% is not expected to have toxic effects when used as directed.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Water for injections

6.2 Incompatibilities
Because Dextrose 5% has an acid pH, incompatibilities can occur on mixing with other medicinal products.
Erythrocyte concentrates must not be suspended in Dextrose 5% because this can lead to pseudo-agglutination.
Glucose solutions should not be infused through the same equipment as blood, see section 4.4.

6.3 Shelf life
Shelf life of the medicinal product as packaged for sale
bottles: 3 years
Shelf life after first opening the container
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 and would normally not be longer than 24 hours at 2 to 8 °C.

6.4 Special precautions for storage
Store below 25 °C.

6.5 Nature and contents of container
50ml, 100 ml glass bottles and 500 ml and 1000 ml plastic containers.

6.6 Special precautions for disposal and other handling
Containers are for single use only. After use, the container and any residual content should be discarded (see also section 4.2).

7 MANUFACTURER
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8 LICENSE HOLDER
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9. License Number
35-64-25554

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