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Glucose 5% Intravenous Infusion BP
(Viaflo® Container)

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Glucose 5% Intravenous Infusion BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose (as monohydrate) : 50.0 g/l

Each ml contains 50 mg glucose (as monohydrate)

Approximately 840 kJ/l (or 200 kcal/l)

For excipients : see 6.1

3. PHARMACEUTICAL FORM

Solution for infusion.

Clear solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS

Glucose 5% Intravenous Infusion is indicated for the treatment of carbohydrate and fluid depletion.

Glucose 5% is also used as a vehicle and diluent for compatible medicinal products for parenteral administration.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

Adults, the Elderly and Children :

The concentration and dosage of glucose solution for intravenous use is determined by several factors including the age, weight, and clinical condition of the patient. Serum-glucose concentrations may need to be carefully monitored.

The recommended dosage for treatment of carbohydrate and fluid depletion is:
- for adults : 500 ml to 3 Liters / 24h
- for babies and children :
  - 0-10 kg body weight: 100 ml/kg/24 h.
  - 10-20 kg body weight: 1000 ml + 50 ml /kg over 10 kg / 24 h.
  - > 20 kg body weight : 1500 ml + 20 ml / kg over 20 kg / 24 h.

The infusion rate depends on the patient's clinical condition.

Infusion rate should not exceed the patient’s glucose oxidation capacities in order to avoid hyperglycaemia. Therefore, the maximum dose ranges from 5mg/kg/min for adults to 10-18 mg/kg/min for babies and children depending on the age and the total body mass.

The recommended dosage when used as a vehicle or diluent ranges from 50 to 250 ml per dose of medicinal product to be administered.

When glucose 5% is used as a diluent for injectable preparations of other drugs, the dosage and the infusion rate will be principally dictated by the nature and the dose regimen of the prescribed drug.

Administration:

The solution is for administration by intravenous infusion (peripheral or central vein).

When the solution is used for dilution and delivery of therapeutic additives for administration by intravenous infusion, the direction for use with additive therapeutic substances will dictate the appropriate volumes for each therapy.

4.3. CONTRA-INDICATIONS

The solution is contraindicated in case of uncompensated diabetes, other known glucose intolerances (such as metabolic stress situations), hyperosmolar coma, hyperglycaemia, hyperlactatemia.

Glucose solution should not be used after acute ischemic strokes as hyperglycemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery.

Infusion of glucose solution is contraindicated in the first 24 hours following head trauma, and blood glucose concentration should be closely monitored during intracranial hypertension episodes.

4.4. SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

Glucose 5% intravenous infusion is an isotonic solution.

High volume infusion must be used under specific monitoring in patients with water intoxication, cardiac, pulmonary or severe renal failure and/or with oliguria/anuria.

Administration of Glucose 5% solution may lead to hyperglycaemia.

Special clinical monitoring is required at the beginning of any intravenous infusion.
Administration should be carried out under regular and careful surveillance. Clinical and biological parameters, in particular blood-glucose, should be monitored.

If hyperglycaemia occurs, rate of infusion should be adjusted or insulin administered.

If necessary, provide parenteral supplements in potassium.

Glucose tolerance may be impaired in patients with renal failure or diabetes mellitus.
If administered to diabetic or patients with renal insufficiency, close monitoring of glucose levels is required, and insulin and/or potassium requirements may be modified.

Use a slow flow rate because of the risk of undesirable osmotic diuresis.

Glucose solution should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because hemolysis and clumping can occur.

4.5. INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

None known.

4.6. PREGNANCY AND LACTATION

Glucose solutions are commonly employed during pregnancy as hydrating fluids and as vehicles for the administration of other drugs (particularly for oxytocin).

There are no indications for adverse effects on progeny by use of Glucose 5% Intravenous Infusion during pregnancy, labour and lactation.

4.7. EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES

None known.

4.8. UNDESIRABLE EFFECTS

Intravenous infusion of glucose 5% can lead to the development of fluid and electrolyte disturbances including hypokalemia, hypomagnesemia, and hypophosphatemia.

Hyperglycemia and dehydration have resulted from inappropriate parenteral use.

Polyuria may also occur.

Adverse reactions may be associated to the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

The nature of the additive will determine the likelihood of any other undesirable effects.

Discontinue use should adverse drug reaction occur.

4.9. OVERDOSE

Prolonged administration or rapid infusion of large volumes of glucose 5% solution may cause hyperosmolarity, dehydration, hyperglycaemia, hyperglycosuria, osmotic diuresis (due to the hyperglycaemia). Prolonged administration or rapid infusion may create a fluid inflation with oedema or water intoxication (with hyponatremia).

The signs and symptoms of over infusion will be related to the nature of the additive being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant symptomatic and supportive measures should be provided as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: “Other IV Solution Additives”
ATC code: B05XX

The pharmacodynamic properties of this solution are those of glucose, which forms the principal source of energy in cellular metabolism. Glucose is given as a source of carbohydrate in parenteral nutrition. The Glucose 5% solution provides a caloric intake of 200 kcal/l. Furthermore, this glucose solution for infusion allows hydric supplementation without ionic supplementation.

Glucose 5% intravenous infusion is an isotonic solution, with an approximate osmolarity of 278 mOsm/l.

The pharmacodynamics of the additive will depend on the nature of the drug used.

5.2. PHARMACOKINETIC PROPERTIES

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

The pharmacokinetics of the additive will depend on the nature of the drug used.

5.3. PRECLINICAL SAFETY DATA

The safety of glucose in animals is not relevant in view of its presence as a normal component in animal and human plasma.

The safety of the additive should be considered separately.

6. PHARMACEUTICALS PARTICULARS

6.1. LIST OF EXCIPIENTS

Water for Injections.

6.2. INCOMPATIBILITIES

As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Glucose 5% Intravenous Infusion solution by checking for eventual color change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify if it is soluble and stable in water at the pH of Glucose 5% Intravenous Infusion.

When a compatible medication is added to the Glucose Intravenous Infusion, the solution must be administered immediately.

Those additives known to be incompatible should not be used.

6.3 SHELF LIFE

Shelf life as packaged:
50 ml bag: 18 months.
100 ml bag: 24 months
150 ml bag: 30 months.
250, 500 and 1000 ml bags: 3 years

In-use shelf life: Additives.

Chemical and physical stability of any additive at the pH of Glucose 5% Intravenous Infusion in the Viaflo container should be established prior to use.

From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

No special precautions for storage.

6.5 NATURE AND CONTENTS OF CONTAINERS

Bag sizes: 50, 100, 150, 250, 500 or 1000mL .

The bags known as Viaflo are composed of polyolefin/polyamide co-extruded plastic (PL-2442).

The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene.

Outer carton contents: 50 bags of 50 ml
50 bags of 100 ml
35 bags of 150 ml
30 bags of 250 ml
20 bags of 500 ml
10 bags of 1000 ml

6.6 INSTRUCTIONS FOR USE/HANDLING

Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Additives may be introduced before infusion or during infusion through the injection site

When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Adding other medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

1. Opening
   a. Remove the Viaflo container from the overpouch just before use.
   b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.
   c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.
2. Preparation for administration

   Use sterile material for preparation and administration.
   a. Suspend container from eyelet support.
   b. Remove plastic protector from outlet port at bottom of container:
      - grip the small wing on the neck of the port with one hand,
      - grip the large wing on the cap with the other hand and twist,
      - the cap will pop off.
   c. Use an aseptic method to set up the infusion

d. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible.

To add medication before administration

a. Disinfect medication site.
b. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medication during administration

a. Close clamp on the set.
b. Disinfect medication site.
c. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
d. Remove container from IV pole and/or turn to an upright position.
e. Evacuate both ports by tapping gently while the container is in an upright position.
f. Mix solution and medication thoroughly.
g. Return container to in use position, re-open the clamp and continue administration.

7. REGISTRATION NUMBERS

129 03 30797 00

134 06 31397 00

8. MANUFACTURER

Baxter Healthcare Ltd.
Thetford, United Kingdom.

and

Bieffe Medital S.A.,
Sabinanigo (Huesca), Spain.

9. IMPORTER

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