Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glucose 5% w/v Solution for Intravenous Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml contains:

Glucose (as Monohydrate) 50.0 g

For excipients, see 6.1.

Total Osmolarity 277.49 mOsm/1.

3 PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless, sterile and non-pyrogenic solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Readily metabolised nutrient (100g Glucose = 400 calories).
- Provides both fluid and Carbohydrates.
- Prevents dehydration: (provides water without electrolytes) Used when water losses are greater than electrolyte losses.
- Allows protein sparing during starvation.
- Vehicle for drug administration (slow intravenous infusion).

4.2 Posology and method of administration

Intravenous infusion according to the clinical situation and the intake output balance. 500ml to 1000 ml per 24 hours.

4.3 Contraindications

Hypervolaemia.

4.4 Special warnings and precautions for use

- Use aseptic method to set up the infusion (disinfect both the infusion and injection ports and use a new sterile infusion set).
- Check limpidity and visible particles before use.
- Check flow regulation (low and constant) thus avoiding osmotic diuresis.

4.5 Interaction with other medicinal products and other forms of interaction

- In preparation of mixtures with other drugs, it is advisable to consider the pH (slightly acidic) of the solution.
- Before mixing check compatibility.

4.6 Pregnancy and lactation

Pregnancy and lactation do not represent a contraindication for the use of Glucose 5%.

4.7 Effects on ability to drive and use machines

Not relevant. No specific warning.

4.8 Undesirable effects

Not relevant.

4.9 Overdose

Hypervolaemia and hyperglycaemia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Infusion solutions of Glucose 5% w/v in water for injection are sterile and non pyrogenic. They are isotonic with blood, belong to the category Energetic re-hydrate and transparent and colourless.

5.2 Pharmacokinetic properties

After administration, **Glucose** is carried from the blood tissues or is immediately used. The glycemic metabolism maintains the blood concentration of glucose at about 0.80 g/L. Glucose can be metabolised through different ways; glycolysis to pyruvic acid, formation of carbon dioxide and water through the pentoses cycle or storage in liver and muscle tissue.
In the kidney, glucose is normally filtered by glomerules at glycemic level less than 1.8 g/L. Total reabsorption occurs at the proximal tubule.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Glucose 5% intravenous infusion solution is incompatible with the following products:

- Benzylpenicillin, Cefalotin, Chlortetracycin.
- Cyanocobalamin, Sodium Calcium Edetate.
- Histamine, Hydrocortisone.
- Kanamicin, Novomicin, Warfarin.

No substance should be added to the solution for infusion unless its compatibility is known.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
From a microbiological point of view, solutions containing additives 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 2-8° C, unless the additives were introduced in controlled and validated aseptic conditions.

6.5 Nature and contents of container

Collapsible bag made of polyethylene, nylon and polypropylene. The inner layer consisting of polyethylene. The bag is automatically sealed in the filling process. A chlorobutyl rubber disk is welded into the access port which is made from the same material as the outer layer of the bag (i.e. polypropylene). There is no contact between the solution and the elastomeric access port. The bag is overwrapped with a polypropylene/polyamide film. The product is presented in 500 ml bags.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

- Single use only.

- Before use, check the integrity of the container.

- Use only if the solution is clear, without visible particles.

- Administer immediately following the insertion of the administration set.

- An aseptic technique is to be used.

- Additives may be introduced before infusion through the main outlet port during the infusion through the injection site using an aseptic technique.

- Mix thoroughly after introduction of an additive.

7 MARKETING AUTHORISATION HOLDER

Bieffe Medital SpA.
Via Nuova Provinciale
23034 Grosotto (SO)
Italy

8 MARKETING AUTHORISATION NUMBER

PA 751/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 February 1997

Date of last renewal: 02 February 2002

10 DATE OF REVISION OF THE TEXT

December 2005