# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Glucose 4.3% w/v and Sodium Chloride 0.18% w/v Solution for Intravenous Infusion

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml of solution contains:

| | | |
|---|---|---|
| Sodium Chloride | 1.80 | g |
| Glucose (as monohydrate) | 43.0 | g |
| Equivalent to | | |
| Sodium | 30 | mmol/1 |
| Chloride | 30 | mmol/1 |
| Glucose | 237 | mmol/1 |
| For excipients, see 6.1 | | |
| Total Osmolarity | 300 | mOsm/1 |

## 3 PHARMACEUTICAL FORM

Solution for infusion.

Clear colourless, sterile, non-pyrogenic solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

- Electrolyte balancement.
- Energetic re-hydration (100g of Glucose are equivalent to 400kcals).
- Saving of protein reserves in case of fasting and treatment of ketosis due to malnutrition.
- To vehicle another medicinal product for slow intravenous infusions.

### 4.2 Posology and method of adminstration

Intravenous infusion according to the clinical situation and the intake output balance. 500 ml to 3000 ml per 24 hours.

### 4.3 Contraindications

- Cardiac failure.
- Hypovolaemia, hypernatraemia, hyperkalaemia.
- Bloating-ascitis syndrome in cirrhosis.
- Uncontrolled diabetes, Hyperglycaemia.
- Hyperosmotic coma.
- Lactacidosis.
- Intracranial and intraspinal bleeding.

## 4.4 Special warnings and special precautions for use

- This solution must be administered with caution to diabetic subjects, or subjects suffering from cardiac problems, hypertension and kidney failure.
- Caution must be taken where clinical situations of peripheric and lung bloating and in toxanaemia cases linked to pregnancy.
- In regimens poor in Sodium, the composition of this solution must be considered.
- Prior to use, check the condition of the bag. Do not use damaged bags.
- Verify that the solution is clear and free of visible particles.
- Use an aseptic technique when spiking or making an addition to the bag.
- Check the blood level of Sodium.
- Verify the state of the vein prior to infusion (check for any inflammatory phenomena) and control glycaemia, glycosuria and kalaemia.
- In some situations use a supplementary parenteral infusion of insulin or potassium.
- Check flow regulation.

## 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. Classic examples of interactions are described under ‘Incompatibility’.

## 4.6 Pregnancy and lactation

Pregnancy and lactation do not represent a contraindication for the use of Glucose 4.3% in Sodium Chloride 0.18%.

## 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 may occur after overdosage.
Symptoms:
- Hypervolaemia, dilution of electrolytes in the blood.
- Hyperhydrosis, bloat formation.
- Hyponatraemia, decrease in osmotic pressure.
- Extreme clinical situations: allophasis, coma, consumption of cells and tissue of the brain.

Treatment:
Stop the perfusion and eliminate the excess of water with administration of diuretics; such treatment is dependant on the age of the patient. In order to balance the osmotic pressure, a strong hypertonic solution can be administered (e.g. mannitol 20% solution in water). Control the cardiac parameters of the subject (Central Venous Pressure, ECG, Pulse). A hyperglycaemia may occur, suitable treatment will depend on the individual clinical situation.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Glucose 4.3% in Sodium Chloride 0.18% is a sterile nonpyrogenic for intravenous infusion. This solution is isotonic with the blood.

Glucose is a physiological sugar the most simple and assimilating energetic source for organism.
Glucose in parenteral nutrition is used to supply calories, save proteins, contribute to the maximum use of acidic amines in synthesis of proteins, equilibrate lipidic metabolism, and store energy as reserve fats.
The presence of Sodium Chloride ensures a supply of electrolytes. As matter of fact Sodium and Chloride are the most important ions of the extracellular fluid. These ions contribute to the repartition mechanism of liquids, to electrolytic balance and to acid-basic balance.

## 5.2 Pharmacokinetic properties

After administration, **Glucose** is carried from the blood to the tissues or is immediately used. The glycaemic metabolism maintains the blood concentration of glucose at about 0.8 g/l. Glucose can be metabolised through different ways: glycolysis to pyruvic acid, formation of carbon dioxide and water through the pentose phosphates cycle, or storage in liver and muscle tissues.
In the kidney, glucose is normally filtered by glomerulus; at glycaemic levels less than 1.8 g/l, total reabsorption occurs at the proximal tubule.
**Sodium** is principally distributed into the extracellular liquid (44%), skeleton (47%), and intracellular liquid (8%). Its half-life period is about 11-13 days. The excretion of sodium occurs essentially at kidney level, where it is filtered by glomerulus and afterwards reabsorbed by the proximal tubule. A small quantity of Sodium is excreted through spittle, perspiration and faeces. The pharmacokinetics of chloride ion is linked to that of sodium.

## 5.3 Preclinical safety data

Not relevant.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Water for injections

## 6.2 Incompatibilities

Glucose 4.3% in Sodium Chloride 0.18 % intravenous infusion solution is incompatible with the following preparations:

- Silver and lead salts
- Hydrocortisone hemisuccinate, tetracyclines, cephalothin, amphotericin, benzylpenicillin and chlortetracycline
- Cyanocobalamin, sodium calcium edetate
- Histamine, kanamycin, novamycin and warfarin.

No other 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 1000 ml Clear-Flex bags.

## 6.6 Instructions for use and handling

- 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 751/2/2

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th February 1997
Date of last renewal: 7th February 2002

## 10 DATE OF REVISION OF THE TEXT

May 2004