Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride Solution for Infusion 0.9% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000ml of solution contains:

Sodium Chloride	9.00g

Equivalent to:

Sodium	approximately	150mmol/l
Chloride	approximately	150mmol/l

For full list of excipients, see section 6.1.

Osmolarity: 308 mOsm/L Isotonic

3 PHARMACEUTICAL FORM

Solution for Infusion.

Clear, colourless, sterile, non-pyrogenic solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Electrolyte replacement

- Maintenance or replacement of deficits of extracellular fluid(Osmolarity – 308 mOsm/L)
- Vehicle for drug admixtures
- Hypovolemia

4.2 Posology and method of administration

Adult: intravenous infusion, according to the clinical situation and intake-output balance (500 to 3000 ml/24h).

4.3 Contraindications

- Hypervolemia and hypernatremia
- Cardiac insufficiency
- Oedema and cirrhotic ascitis

4.4 Special warnings and precautions for use

Sodium Chloride must be used cautiously in patients with renal impairment or insufficiency.
Use an aseptic method to set up infusion (disinfection of stopper and injection site, use a new sterile infusion set).
Check flow regulation.
Use only if solution is clear and free from particles.

4.5 Interaction with other medicinal products and other forms of interaction

Preparing drug admixture, take care of pH value (acid) and of sodium and chloride ions.
Classical examples of chemical incompatibilities: hydrocortisone, tetracyclines, cephalothin, and amphotericin.
Before mixing, check compatibility.
Before administration, check limpidity and colour of solutions.
Solutions containing additives should be used immediately.

4.6 Pregnancy and lactation

No specific warning.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Not relevant.

4.9 Overdose

Hypervolemia is treated by diuretics.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Infusions solutions of Sodium Chloride 0.9% w/v in Water for Injections are sterile and non pyrogenic. Also, they are isotonic with the blood (physiological solution). They belong to the therapeutic category: Electrolytical, re-hydrates. They are transparent and colourless.

5.2 Pharmacokinetic properties

Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections.

6.2 Incompatibilities

- Silver and lead salts.
- Hydrocortisone hemisuccinate, tetracyclines, cefalotin and amphotericin.

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

6.3 Shelf Life

Unopened: Three years.
For single use only. Discard any unused contents.

6.4 Special precautions for storage

Do not store above 25ºC.
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 longer than 24 hours at 2 to 8ºC, unless the additives were introduced in controlled and validated aseptic conditions.

6.5 Nature and contents of container

Collapsible bag made of polyethylene, nylon, polypropylene (inner layer in polyethylene) of 50ml, 100ml, 250ml, 500ml or 1000ml.

Not all pack sizes may be marketed.

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

- Before use, check the integrity of the container.
- Use only if the solution is clear, without visible particles and administer immediately following the insertion of the infusion set. An aseptic technique is to be used. Additives may be introduced before infusion through the main outlet port or during infusion through the injection site using an aseptic technique.
- Mix thoroughly after introduction of an additive.
- Solutions containing additives should not be stored,
- Single use product. Do not reconnect partially used bags.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0751/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 June 1996
Date of last renewal: 10 June 2006

10 DATE OF REVISION OF THE TEXT

May 2007