Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Compound Sodium Lactate (Hartmann's Solution) Solution for Intravenous Infusion (1000 ml)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of solution contains:

Active Ingredients:				mmol
Sodium Chloride Ph. Eur.	6.00	g	Sodium	131
Potassium Chloride Ph. Eur.	0.40	g	Potassium	5
Calcium Chloride Ph. Eur.	0.27	g	Calcium	2
Lactic Acid Ph. Eur.	2.60	g*	Chloride	111
Sodium Hydroxide Dihydrate Ph. Eur.	1.17	g*	Lactate	29

*Such quantities correspond to Anhydrous Sodium Lactate 3.25 g derived from Sodium Lactate 60%

Total osmolarity	279.56	mOsm/1

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Solution for infusion.

Colourless, clear solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- Electrolyte replenisher.
- Maintenance or replacement of deficits in extracellular fluid.
- Hypervolaemia.
- Acid-base balance regulation.

4.2 Posology and method of adminstration

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

4.3 Contraindications

- Cardiac insufficiency.
- Hypovolaemia, hypernatraemia, hyperkalaemia and hypercalcemia.
- Oedema and cirrhotic ascites.
- Lactic acidosis, alkalosis.

4.4 Special warnings and special precautions for use

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.
- Check flow regulation.

Prior to administration the solution should be warmed to approximately body temperature and after removal of the overwrap the bag should be squeezed to check for leaks.

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 Hartmann’s Solution.

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 which may be treated with diuretics.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Infusion solutions of Ringer's Lactate in water for injeciton are sterile and non pyrogenic.
They are isotonic wih the blood (phsioological solution).
They belong to the therapeutic category: fluid and electrolyte replenisher, supplying the three important cations of the extracellular fluid.

5.2 Pharmacokinetic properties

Na^{+}, K^{+}, Ca^{2+} and CO^{-} ions follow the normal metabolism of these ions. The lactate is ultimately metabolised to bicarbonate and thus has an alkalinisating effect on the body fluids.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

6.2 Incompatibilities

Classic examples of incompatibles are:

Hydrocortisone, hemisuccinate, tetracyclines, cefalotin and amphotericin.

6.3 Shelf Life

3 years

The product should be used immediately after opening.

6.4 Special precautions for storage

Do not store above 25°C.
Keep in the outer carton.

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 chlorbutyl 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 and available in 500 ml or 1000 ml.

6.6 Instructions for use and handling

- Single use product.
- 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.
- Solution containing additives should not be stored.

7 MARKETING AUTHORISATION HOLDER

Bieffe Medital S.p.A.
Via Nuovo Provinciale
23034 Grosotto (SO)
Italy.

8 MARKETING AUTHORISATION NUMBER

PA751/4/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 7th February 2002

10 DATE OF REVISION OF THE TEXT

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