Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Compound Sodium Lactate Intravenous Infusion BP, (Hartmann's Solution) Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride	6.0	g/l
Sodium Lactate	3.22	g/l
Potassium Chloride	400	mg/l
Calcium Chloride Dihydrate	270	mg/l

Each litre provides the following concentration of electrolytes:

Na^+	131	mmol/l
K^+	5	mmol/l
Cl^-	111	mmol/l
Lactate	29	mmol/l
Ca^+	2	mmol/l

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Sterile, non-pyrogenic, clear, colourless, aqueous solution for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For prophylactic and replacement therapy requiring the use of Sodium Chloride and lactate, with minimal amounts of calcium and potassium.

4.2 Posology and method of administration

4.2.1 Dosage
The dosage is dependant upon the age, weight and clinical condition of the patient.

4.2.2 Administration
Intravenous.

4.3 Contraindications

4.3.1 Administration in congestive heart failure, or in conditions of severe impairment of renal function, or in oedema with sodium retention.
4.3.2 Lactate containing solutions are contraindicated in patients with liver disease.

4.4 Special warnings and precautions for use

4.4.1 Administration should be carried out under regular and careful surveillance; plasma electrolyte levels should be monitored during use.
4.4.2 This fluid should be administered with great care to patients with renal insufficiency.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

The safety of this medicinal product for use in human pregnancy has not been established.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Patients with doubtful renal function may result in excessive sodium chloride retention. Prolonged infusion may cause thrombophlebitis extending from the site of infusion.

Allergic reactions or anaphylactic /anaphylactoid symptoms such as localised or generalised urticaria, skin rash and erythema and itching/ pruritis, skin swelling, periorbital facial and or laryngeal oedema (Quincke's oedema); chest tightness, chest pain with tachycardia or bradycardia; nasal congestion, coughing, sneezing, bronchospasm and/or difficulty breathing have been reported during administration of Lactated Ringer's Injection, USP.

4.9 Overdose

Discontinue if adverse reaction occurs.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Hydroxide (for pH adjustment)
Lactic Acid (for pH adjustment)
Water for Injections

6.2 Incompatibilities

Ceftriaxone must not be mixed with calcium-containing solutions including Compound Sodium Lactate (Ringer Lactate) solution . See also section 4.3.

As with all parenteral solutions additives may be incompatible. Compatibility of the additives with the Compound Sodium Lactate (Ringer Lactate) solution must be assessed before addition. After addition of the additive, incompatibility may become visible by a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

The Instructions for Use of the medication to be added and other relevant literature must be consulted.
Before adding a substance or medication, verify it is soluble and/or stable in water and that the pH range of Compound Sodium Lactate (Ringer Lactate) solution is appropriate (pH 5.0 to 7.0).

When making additions to the Compound Sodium Lactate (Ringer Lactate) solution , aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

As a guidance the following medications are incompatible with the Compound Sodium Lactate (Ringer Lactate) solution (***non-exhaustive listing***):
Medications incompatible with Compound Sodium Lactate (Ringer Lactate):

- Aminocaproic acid
- Amphotericin B
- Metaraminol tartrate
- Cefamandole
- Cortisone acetate
- Diethylstilbestrol
- Etamivan
- Ethyl alcohol
- Phosphate and carbonate solutions
- Oxytetracycline
- Thiopental sodium
- Versenate disodium

Medications with partial incompatibility with Compound Sodium Lactate (Ringer Lactate):

- Tetracycline stable for 12 hours
- Ampicillin sodium
  concentration of 2%-3% stable for 4 hours
  concentration >3% must be given within 1 hour
- Minocycline stable for 12 hours
- Doxycycline stable for 6 hours

Additives known or determined to be incompatible should not be used.

6.3 Shelf life

Unopened: 2 years.

The product should be used immediately after opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The solution is supplied in a clear, collapsible, polyvinyl chloride (Viaflex®) container, overwrapped with high density polyethylene and polypropylene and containing 500ml or 1000ml of solution.
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

After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion.

Discard after single use.
Discard any unused portion.
Do not reconnect partially used bags.

Opening

- Remove the Viaflex container from the overpouch just before use.
- Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.
- Check the solution for clarity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

Preparation for administration
Use sterile material for preparation and administration.

- Suspend container from eyelet support.
- Remove blue protector from outlet port
- Use an aseptic method to set up the infusion.
- Attach administration set. Refer to directions accompanying set for connection, priming of the set and administration of the solution.

Techniques for injection of additive medications
Warning: Some additives may be incompatible. Check additive compatibility with both the solution and container prior to use. 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.

To add medication before administration

- Disinfect medication site.
- Using syringe with 20 gauge (0.90 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
- 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

- Close clamp on the set.
- Disinfect medication site.
- Using syringe with 20 gauge (0.90 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
- Remove container from IV pole and/or turn to an upright position.
- Evacuate both ports by tapping gently while the container is in an upright position.
- Mix solution and medication thoroughly.
- Return container to in use position, re-open the clamp and continue administration.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.
Caxton Way
Thetford
Norfolk
IP24 3SE
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 167/55/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

May 2013