

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Half Strength Compound Sodium Lactate Intravenous Infusion BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | | |
|----------------------------|------|------|
| Sodium Lactate | 1.61 | g/l |
| Potassium Chloride | 200 | mg/l |
| Sodium Chloride | 3.0 | g/l |
| Calcium Chloride Dihydrate | 135 | mg/l |

This provides 66mmol/l Na⁺, 2.7mmol/l K⁺, 1mmol/l Ca²⁺, 56mmol/l Cl⁻ and 14mmol/l Lactate.

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion

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

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Half Strength Compound Sodium Lactate Intravenous Infusion is indicated 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

The solution is for administration by intravenous infusion.

4.3 Contraindications

Half Strength Compound Sodium Lactate Intravenous Infusion is contraindicated in patients with congestive heart failure, severe impairment of renal function or oedema with Sodium retention. It is also 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.

4.4.3 Do not administer unless solution is clear and container undamaged.

4.4.4 Discontinue infusion if adverse reaction occurs.

4.5 Interaction with other medicinal products and other forms of interaction

Check additive compatibility before use.

4.6 Pregnancy and lactation

Not stated.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

As with any prolonged intravenous infusion, venous irritation and thrombophlebitis may occur at the injections site.

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 infusion 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
Lactic acid
Water for Injection

6.2 Incompatibilities

Check additive compatibilities before use.

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) infusion bag, overwrapped with high-density polyethylene or polypropylene and containing 500ml or 1000ml of solution.

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

For single use only. Discard any unused portion.

Use only if the solution is clear, without visible particles and if the container is undamaged. Solutions containing visible solid particles must not be used. Do not reconnect partially used bags.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 167/55/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2003

10 DATE OF REVISION OF THE TEXT

December 2005