Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride Intravenous Infusion BP 0.9%w/v (Viaflex container).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each litre contains 9.0g (0.9% w/v) sodium chloride. This provides 150 mmol/l sodium and 150 mmol/l chloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion.

A clear, colourless, sterile, non-pyrogenic solution free from visible particles.

pH: 4.0-7.0.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use in prophylactic and replacement therapy requiring the use of sodium chloride or as a vehicle for the reconstitution and administration of intravenous medications.

4.2 Posology and method of administration

Dosage

The dosage is dependant upon the age, weight and clinical condition of the patient, and must be determined on an individual basis.

Administration

The solution is for intravenous infusion.

4.3 Contraindications

Administration is contraindicated in congestive heart failure, in conditions of severe impairment of renal function or in oedema with sodium retention.

4.4 Special warnings and precautions for use

Administration should be carried out under regular and careful surveillance. Serum electrolytes should be monitored. Discontinue use should adverse reaction occur.

4.5 Interaction with other medicinal products and other forms of interaction

No other medication or substance should be added to this fluid unless compatibility is known.

4.6 Pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None stated.

4.9 Overdose

If adverse reaction occurs, discontinue use.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not stated.

5.2 Pharmacokinetic properties

Not stated.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injection
Sodium Hydroxide (for pH adjustment)
Hydrochloric Acid (For pH adjustment)

6.2 Incompatibilities

In the absence of stability studies, this medicinal product must not be mixed with other medicinal products. Only medications stable in solution at the pH range of this solution (4.0-7.0) should be added.

6.3 Shelf Life

250, 150, 100ml – the shelf life is 24 months providing the unit has not been opened.

50 ml – the shelf life is 18 months providing the unit has not been opened.

50 ml with Reconstitution Device – the shelf life is 12 months providing the unit has not been opened.

Once opened, use immediately. Discard any unused portion. Do not reconnect partially used bags.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Clear, collapsible poly (vinyl chloride) (Viaflex) infusion bags overwrapped with high density polyethylene or polypropylene, containing 50, 100, 150 or 250 ml 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

Do not use unless solution is clear and the container is undamaged. Further information is given in the user information leaflet.

For single use only. Discard any remaining contents after use and do not reconnect partially used bags.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd
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Thetford
Norfolk
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8 MARKETING AUTHORISATION NUMBER

PA 0167/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

May 2007