Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion BP 5% w/v (Viaflex container).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each litre contains:

Glusose monohydrate	55	g/l	
equivalent to Anhydrous Glucose	50	g/1	(5% w/v)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion.

Clear, colourless solution, free from visible particles.

pH: 3.5-6.5 and Osmolarity (approx): 278 mOsm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use in prophylactic and replacement therapy requiring the use of Glucose. Glucose Intravenous Infusion BP 5.0% w/v can be used to increase the volume of circulating blood in shock and haemorrhage and counteracts dehydration. It may also be used as a vehicle for the reconstitution and administration of intravenous medications known to be compatible with 5% glucose.

4.2 Posology and method of administration

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

Administration
The solution is for administration by intravenous infusion.

4.3 Contraindications

Administration in congestive heart failure or in conditions of severe impairment of renal function.

4.4 Special warnings and precautions for use

i. Glucose tolerance may be impaired in patients with renal failure or diabetes mellitus. If administered to diabetics or patients with renal insufficiency for appropriate clinical reasons, they should be monitored very closely. The need for electrolyte control should be kept in mind.

ii. The solution should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment because of the possibility of pseudoagglutination.

iii. Administration should be carried out under regular and careful surveillance.

iv. Discontinue should adverse reaction occur.

4.5 Interaction with other medicinal products and other forms of interaction

Check additive compatibility before use.

4.6 Pregnancy and lactation

Not contraindication.

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 injection site.

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

Water for Injections

6.2 Incompatibilities

As with all parenterals, compatibilities should be checked when additives are used. Thorough and careful aseptic mixing of any additive is mandatory.

Only medications stable in solution at the pH range of this solution (3.5 – 6.5) should be added.

Do not administer this solution through the same giving set as blood.

6.3 Shelf Life

1000, 500, 250, 150, 100ml – the shelf life is 24 months providing the unit has not been opened.

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The solution is contained in plastic PVC Viaflex containers and is available in volumes of 50ml, 100ml, 150ml, 250ml, 500ml and 1000ml. In addition, the 50ml, 100ml and 250ml volumes may be available in a plastic viaflex container incorporating a polycarbonate reconstitution device (Minibag plus).

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 if solution is cloudy, contains sediment or appears in any way unusual.

For single use only.

Discard any remaining contents after use

Do not reconnect partially used bags

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd
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8 MARKETING AUTHORISATION NUMBER

PA 0167/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th August 1979

Date of last renewal: 9th August 2004

10 DATE OF REVISION OF THE TEXT

May 2007