Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion BP 0.3% w/v.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Anhydrous Glucose 3 g/l
or
Glucose Monohydrate 3.3 g/l

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Solution for Infusion.
Clear, colourless or straw coloured, sterile non-pyrogenic.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Glucose Intravenous Infusion BP 0.3% w/v is used to be a diluent for Intravenous drug administration.

4.2 Posology and method of adminstration

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 special precautions for use

Glucose tolerance may be impaired in patients with renal failure.
If administered to diabetics for appropriate clinical reasons, they should be monitored very closely.

As with all parenterals, compatibilities should be checked when additives are used. Thorough and careful aseptic mixing of any additive is mandatory.
Do not use unless solution is clear and the container undamaged.
The product should be rendered isotonic prior to intravenous administration.
Discontinue if adverse reaction occurs.

4.5 Interaction with other medicinal products and other forms of interaction

Check additive compatibility before use.
This solution should not be administered simultaneously with, before or after an administration of blood through the

same infusion equipment because of possibility of pseudoagglutination.

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

Check additives compatibilities before use.

6.3 Shelf Life

The shelf life is 30 months providing the unit has not been opened.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer that 24 hours at 2 to 8°C, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The product will be presented in 100ml or 150ml Viaflex plastic containers.
The plastic used to manufacture the containers is a PVC plastic designated PL-146.

The containers will be sealed in a plastic overpouch.

6.6 Instructions for use and handling

Do not use unless solution is clear and the container is undamaged.
Discard any unused portion.
Do not reconnect partially used bags.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd
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Thetford
Norfolk
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IP24 3SE

8 MARKETING AUTHORISATION NUMBER

PA 167/9/26

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th January 1987

Date of last renewal: 26th January 2002

10 DATE OF REVISION OF THE TEXT

March 2003