IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0167/096/003
Case No: 2067495

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Baxter Healthcare Limited

Caxton Way, **Thetford**, **Norfolk IP24 3SE**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Glucose Intravenous Infusion BP 20% w/v Solution for Infusion

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **08/01/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion BP 20% w/v Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Anhydrous Glucose 20.0% w/v which may be present as Glucose Monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion
Sterile, pyrogen-free, clear aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Hypertonic Glucose Intravenous Infusion BP 20% w/v indicated for the supplementation of energy and fluid in parenteral nutrition.

4.2 Posology and method of administration

The quantity and rate of administration is dependent upon the age, weight, clinical state and degree of deficiency of the patient and must be determined on an individual basis.

4.3 Contraindications

There are no known contraindications to this solution.

4.4 Special warnings and precautions for use

The product should not be infused into peripheral veins. Administration should be carried out only under specialist surveillance. This fluid should only be administered with great care to patients with diabetes mellitus or renal insufficiency. The need for electrolyte control should be kept in mind. Insulin may have to be administered simultaneously.

4.5 Interaction with other medicinal products and other forms of interaction

Glucose Intravenous Infusion 20% w/v should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because of the possibility of pseudo-agglutination.

The solution should not be used in conjunction with additives known to be incompatible with glucose.

4.6 Pregnancy and lactation

The safety of the use of Glucose Intravenous BP 20% w/v during pregnancy or lactation has not been established.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Glucose Intravenous Infusion BP 20% w/v is hypertonic and liable to cause venous thrombosis at the site of injection.

4.9 Overdose

The method of administration of this product makes the possibility of overdose very unlikely. However in the event of an overdose, it is recommended that the infusion is discontinued.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Glucose Intravenous Infusion BP 20% w/v provides an alternative or additional source of energy or fluid for patients who are unable to ingest sufficient glucose for their metabolic needs.

5.2 Pharmacokinetic properties

After infusion into the blood stream, Glucose Intravenous Infusion BP 20% w/v is metabolised, distributed and excreted in the same manner as glucose taken orally.

5.3 Preclinical safety data

No data is presented as glucose is a basic and widespread element in mammalian metabolism and therefore conventional animal safety testing is not appropriate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections
Concentrated Hydrochloric Acid (for pH adjustment)

6.2 Incompatibilities

Glucose Intravenous Infusion 20% should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because of the possibility of pseudo-agglutination.

The solution should not be used in conjunction with additives known to be incompatible with glucose.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Clear, collapsible poly (vinylchloride) (Viaflex) infusion bag overwrapped with High Density Polyethylene or Polypropylene, containing 500 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

Discard any unused portion.
Do not reconnect partially used bags.
Observe strict aseptic technique when infusing through a central vein.
Avoid air embolus.
If additions are necessary, check incompatibilities and mix thoroughly.
For single use only.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 167/96/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 January 1980

Date of last renewal: 08 January 2010

10 DATE OF REVISION OF THE TEXT

July 2010