

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0167/009/018

Case No: 2053013

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 10% w/v

The particulars of which are set out in Part I and Part II of 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 **20/05/2009**.

Signed on behalf of the Irish Medicines Board this

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 10% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Anhydrous Glucose 100 g/l
or
Glucose Monohydrate 110 g/l

For a full list of excipients, see section 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 10% w/v is a carbohydrate energy source for intravenous administration and is indicated for use in prophylactic and replacement therapy requiring the use of glucose.

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

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

4.4 Special warnings and 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.

Hypertonic solution for central vein administration only.

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 contraindicated.

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 additive compatibilities before use.

6.3 Shelf Life

The shelf life is 15 months providing the unit has not been opened.

From a microbial 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 than 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 solution is contained in a 500 ml or 1000 ml Viaflex container.

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 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.

Discard any unused portion.

Do not reconnect partially used bags.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 167/9/18

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th January 1987

Date of last renewal: 26th January 2007

10 DATE OF REVISION OF THE TEXT

May 2009