IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0179/001/036
Case No: 2040927

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

B. Braun Medical Limited

3 Naas Road Industrial Park, **Dublin 12**, **Ireland**

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

Glucose Intravenous Infusion BP 50% w/v, Solution for infusion (500 ml)

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 **27/03/2008**.

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 50% w/v, solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains 0.5 g anhydrous glucose, as glucose monohydrate.

	1000 ml of solution contain	500 ml of solution contain
Anhydrous glucose (as glucose monohydrate)	500.0 g	250.0 g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless or slightly yellowish aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Parenteral nutrition;
High-caloric carbohydrate therapy, especially when fluid intake is restricted, as for example in renal insufficiency;
Hypoglycaemia.

4.2 Posology and method of administration

Dosage

Adults (70 kg patient):

Max. dosage: 14 ml/kg body weight/day.
Drop rate: up to 23 drops/min = 70 ml/hour.

In the case of reduced glucose tolerance dosage and drop rate are to be adjusted to the prevailing clinical situation (blood sugar control).

Children:

In paediatrics the use of glucose infusions of up to 30 % w/v is recommended.

Method and route of administration

Intravenous infusion via a central venous catheter.

4.3 Contraindications

Diabetes mellitus (with the exception of hypoglycaemic conditions);
Glucose intolerance;
Hypotonic dehydration if lacking electrolytes are not replaced;
Hyperhydration;
Hypokalaemia;
Hyperosmolar coma;
Acidosis.

This container contains a significant volume of air. To avoid risk of air embolism, this product must not be administered by pressure infusion.

4.4 Special warnings and precautions for use

Special warnings

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

Special precautions for use

Blood glucose, serum electrolytes, and water balance should be monitored regularly.
Electrolytes are to be supplemented as required.
The compatibility of any additives to this solution should be checked before use.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Glucose Intravenous Infusion BP 50 % w/v can be given in these situations.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

In case of reduced glucose tolerance hyperglycaemia and renal losses may occur. These manifestations can be prevented by either restricting the dosage or giving insulin. A sudden interruption of large-dose or rapid glucose infusions may give rise to rebound hypoglycaemia. This occurrence is avoided by reducing the dose. Overdose may provoke rises of bilirubin and lactate.

4.9 Overdose

In case of reduced glucose tolerance hyperglycaemia and renal losses may occur. These manifestations can be prevented by either restricting the dosage or giving insulin. Overdose may provoke rises of bilirubin and lactate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Glucose is utilised as an energy source in the organism.

5.2 Pharmacokinetic properties

Exogenously administered glucose is indiscernibly mixed with the body's endogenous substrate pools. Specific pharmacokinetic data are not provided.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already stated in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Concentrated Hydrochloric acid
Water for Injections

6.2 Incompatibilities

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

6.3 Shelf Life

Unopened: 3 years.
Once opened, use immediately.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Containers of glass, type II (Ph.Eur) fitted with a chlarobutyl rubber stopper.

Contents: 500 ml, available in packs of 10 bottles.

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

No special requirements.
Single-dose container. Discard unused contents.

Only to be used if the solution is clear and the container or its closure do not show visible signs of damage.

7 MARKETING AUTHORISATION HOLDER

B Braun Medical Ltd.
3, Naas Road Industrial Park
Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA 179/1/36

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 August 1992

Date of last renewal: 17 August 2007

10 DATE OF REVISION OF THE TEXT

March 2008