IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0179/001/027
Case No: 2042339

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

5% w/v Glucose Intravenous Infusion, Solution for Infusion (100ml)

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 **20/11/2007**.

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

5% w/v glucose Intravenous Infusion BP, solution for infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of solution contain

Anhydrous Glucose (as glucose monohydrate)	5.00g

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for infusion. (Infusion)

Clear, colourless aqueous solution.

100ml of solution contain:

Caloric value:	85 kJ/100 ml = 20 kcal/100 ml
Theoretical osmolarity:	278 mOsm/l
Titration acidity (to pH 7):	<0.5 mmol/l
pH:	3.5 - 5.5

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vehicle solution for compatible electrolyte concentrates and medicaments.

4.2 Posology and method of administration

Dosage
The quantity to be chosen depends on the desired concentration of the medicament to be dissolved.

Method and route of administration
Slow intravenous injection or addition to an intravenous infusion.

4.3 Contraindications

Hyperglycaemia;
Hypokalaemia;
Acidosis.

4.4 Special warnings and precautions for use

Special warnings
None

Special precautions for use
Patient monitoring should include regular checks of the blood glucose level.
Glucose solutions should not be administered through the same infusion equipment simultaneously, before or after an administration of blood because of the possibility of pseudo-agglutination.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Glucose Intravenous Infusion BP 5% w/v can be used as indicated.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None to be expected if indications, contraindications, dosage recommendations, and precautions are duly observed.

4.9 Overdose

Symptoms
Overdose may lead to hyperglycaemia.
Emergency treatment, antidotes
Depending on type and severity of the symptoms, the glucose input should be reduced and insulin should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Glucose solutions of low concentration are suitable as vehicle solutions because glucose is metabolised ubiquitously as the natural substrate of the cells of the body. Under physiological conditions glucose is the most important energy-supplying carbohydrate with a caloric value of ca. 16 kJ or 3.75 kcal/g. Nervous tissue, erythrocytes and medulla of the kidneys are amongst the tissues with an obligate requirement for glucose. The concentration of glucose in the blood is reported as 50-95 mg/100 ml, or 2.8-5.3 mmol/l (fasting).

Glucose utilization disturbances (glucose intolerance) can occur under conditions of pathological metabolism. These mainly include diabetes mellitus and states of metabolic stress (e.g. intra-, and postoperatively, severe disease, injury), hormonally mediated depression of glucose tolerance, which can even lead to hyperglycaemia without exogenic supply of the substrate. Hyperglycaemia can - depending on its severity - lead to osmotically mediated renal fluid losses with consecutive hypertonic dehydration, to hyperosmotic disorders up to and including hyperosmotic coma.

5.2 Pharmacokinetic properties

On infusion, glucose is first distributed in the intravascular space and then is taken up into the intracellular space.
In glycolysis glucose is metabolized to pyruvate or to lactate. Lactate can be partially re-introduced into the glucose metabolism (Cori cycle). Under aerobic conditions pyruvate is completely oxidized to carbon dioxide and water. The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water).

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

Water for injections.

6.2 Incompatibilities

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

6.3 Shelf Life

Unopened 3 years.
Once opened, the product should be used immediately.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Type II Glass bottles sealed with rubber stoppers, contents: 100 ml.

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 does not show visible signs of damage.

7 MARKETING AUTHORISATION HOLDER

B. Braun Medical Ltd
3 Naas Road Industrial Park
Dublin 12
Republic of Ireland

8 MARKETING AUTHORISATION NUMBER

PA 179/1/27

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

August 2007