IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0179/003/008
Case No: 2040155

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

0.45 %w/v Sodium Chloride and 2.5 %w/v Glucose Intravenous Infusion BP Solution for Infusion

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 **01/04/2008**.

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

0.45 %w/v Sodium Chloride and 2.5 %w/v Glucose Intravenous Infusion BP, Solution for Infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of solution contains:		
Sodium Chloride	4.50	g
Anhydrous Glucose as Glucose Monohydrate	25.00	g

Each litre provides:

Electrolytes:		
Sodium	77	mmol/l
Chloride	77	mmol/l

For a full list of exipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for infusion
A clear, colourless, sterile aqueous solution.

Calorific value:	418	kJ/l = 100 kcal/l
Theoretical osmolarity:	293	mOsm/l
Titration acidity (to pH 7.4):	< 0.5	mmol/l
pH:	3.5 – 5.5	

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use in prophylactic and replacement therapy requiring the use of dextrose and sodium chloride.

4.2 Posology and method of administration

4.2.1. Dosage

In accordance with fluid, electrolyte and energy requirements:
Not more than 40 ml/kg body weight per day, corresponding to 1 g glucose/kg body weight per day.

Infusion and drop rate:
Not more than 5 mg/kg body weight per hour, corresponding to 0.125 g glucose/kg body weight per hour or not more than 1.7 drops/kg body weight per min.

Notes concerning the carbohydrate intake:
The following dose limitations should be observed for the administration of glucose to adults:0.25 g glucose/kg body weight per hour and up to 6g/kg body weight per day.

Notes concerning fluid and electrolyte intake:
The basic substitution of the most important cations sodium and potassium amounts to ca. 1.5 – 3 mmol/kg body weight per day and 0.8 – 1.0 mmol/kg body weight per day respectively. The actual requirement during infusion therapy depends on appropriate determinations of the electrolyte balance and on the laboratory monitoring of the plasma concentrations.

4.2.2. Method and route of administration

Intravenous infusion.

4.3 Contraindications

0.45 % w/v Sodium Chloride and 2.5 % w/v Glucose Intravenous Infusion BP should not be used in cases of:
- Hyperhydration states.
- Hypotonic dehydration with hyponatraemia.
- Hypokalaemia.
- Impaired kidney function.

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

0.45 % w/v sodium chloride and 2.5 % w/v Glucose Intravenous Infusion BP should only be administered with caution in cases of insulin refractory hyperglycaemia necessitating the administration of more than 6 units of insulin/hour.

It is necessary to monitor the serum electrolytes and water balance.

In post-operative and post-traumatic conditions and in conditions of impaired glucose tolerance: only administer with monitoring of blood glucose level.

Special attention should be paid to regular monitoring of the serum potassium concentration.

4.5 Interaction with other medicinal products and other forms of interaction

The solution should not be administered through the same infusion equipment simultaneously, before or after an administration of blood because of the possibility of pseudo-agglutination.

4.6 Pregnancy and lactation

0.45 % w/v Sodium Chloride and 2.5 % w/v Glucose Intravenous Infusion BP 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 used in accordance with the instructions given.

4.9 Overdose

4.9.1. Symptoms

Overdose may result in overhydration with increased skin tension, venous congestion, oedema - possibly also lung or brain oedema, hypokalaemia and acid-base imbalances, and hyperglycaemia.
Clinical symptoms of water intoxication may also occur, such as nausea, vomiting, spasms.

4.9.2 Emergency treatment, antidotes

Immediate cessation of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances, administration of insulin if necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The solution contains equimolar proportions of sodium and chloride corresponding to half the physiological concentration in the plasma. In addition this solution also contains 2.5 % (w/v) of carbohydrate in the form of glucose. The solution is practically isotonic.

5.2 Pharmacokinetic properties

The total sodium content of the body is ca. 80 mmol/kg of which ca. 97 % is extracellular and ca. 3 % intracellular. The daily turnover is ca. 100 - 180 mmol (corresponding to 1.5 - 2.5 mmol/kg body weight).
Chloride is exchanged for hydrogen carbonate in the tubule system and is, thus, involved in the regulation of the acid base balance.
On infusion glucose is first distributed in the intravascular space and then is taken up into the intracellular space.
In glycolysis glucose is metabolised to pyruvate or to lactate. Lactate can be partially re-introduced into the glucose metabolism (Cori cycle). Under aerobic conditions pyruvate is completely oxidised 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

When mixing with other medicaments it should be remembered that 0.45% w/v Sodium Chloride and 2.5% w/v Glucose Intravenous Infusion BP has an acid pH which can cause precipitation in the mixture.

6.3 Shelf Life

Unopened: 3 years
Once opened: Use immediately, discard any unused contents.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Containers of low-density polyethylene with integral on-welded closure of the same material.
The closure contains a rubber diaphragm.

Contents: 500ml.

6.6 Special precautions for disposal and other handling

Single-dose container. Discard unused contents.
Solution is to be used immediately after breaking seal.
Only to be used if the solution is clear, free from visible solid particles and the container or its closure do not show visible signs of damage.

7 MARKETING AUTHORISATION HOLDER

B Braun Medical Limited
3 Naas Road Industrial Park
Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA 179/3/8

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

April 2008