IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0167/050/009A
Case No: 2040988

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

Sodium Chloride 0.9% w/v and Glucose 5% w/v Solution for Infusion BP.

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 **23/03/2009**.

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

Sodium Chloride 0.9% w/v and Glucose 5% w/v Solution for Infusion BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride:	9.0 g/l
Glucose (as anhydrous or monohydrate):	50.0 g/l

Each ml contains 50 mg glucose and 9.0 mg sodium chloride.

mmol/l: Na^+: 154 Cl^-:154

mEq/l: Na^+: 154 Cl^-:154

For a full list of excipients: see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.
Clear solution, free from visible particles
585 mOsm/l (approx) pH: 3.5 to 6.5

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Dosage

The dosage is dependant upon the age, weight and clinical condition of the patients.

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

Administration should be carried out under surveillance. The fluid should only be administered with great care to patients with diabetes mellitus or renal insufficiency.

4.5 Interaction with other medicinal products and other forms of interaction

None specified.

4.6 Pregnancy and lactation

None specified.

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
Hydrochloric acid, concentrated (for pH adjustment)

6.2 Incompatibilities

Incompatibility of the medicinal product to be added with the solution in Viaflex container must be assessed before addition.

In the absence of compatibility studies, this solution must not be mixed with other medicinal products.

The Instructions for Use of the medicinal product to be added must be consulted.
Before adding a drug, verify it is soluble and stable in water at the pH of Sodium Chloride 0.9% w/v and Glucose 5% w/v solution (see section 3).

As a guidance, the following medications are incompatible with the Sodium Chloride 0.9 % w/v & Glucose 5% w/v solution (non-exhaustive listing):

- Ampicillin sodium
- Mitomycin
- Amphotericin B
- Erythromycin lactobionate

Those additives known to be incompatible should not be used.
Because of the presence of glucose, "Sodium chloride 0.9% w/v and Glucose 5% w/v solution" should not be administered through the same infusion equipment as whole blood as hemolysis and clumping can occur.

6.3 Shelf Life

Unopened: 2 years

In-use shelf life: Chemical and physical stability of any additive at the pH of the Sodium Chloride 0.9 % w/v & Glucose 5 % w/v solution in the Viaflex container should be established prior to use.

From a microbiological 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 has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

A clear, collapsible Viaflex infusion bag composed of plasticised Poly (vinyl chloride) (PVC), effectively sealed into a high density polyethylene or polypropylene overpouch and containing 500ml of solution.
Not all pack sizes may be marketed.

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

The solution should be visually inspected prior to use.
Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.
Do not remove unit from overpouch until ready for use.
The inner bag maintains the sterility of the product.
Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.
The solution should be administered with sterile equipment using an aseptic technique.
The equipment should be primed with the solution in order to prevent air entering the system.
Additives may be introduced before infusion or during infusion through the injection site.
When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.
Discard after single use.
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 0167/050/009A

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

March 2009