IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0073/105/005A
Case No: 2080418

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

Antigen Pharmaceuticals Ltd

Chandler House, **Castle Street**, **Roscrea**, **Co Tipperary**, **Ireland**

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

Sodium Chloride 0.9% w/v Solution for Injection

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 **29/03/2010**.

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

Sodium Chloride 0.9% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains 9mg of Sodium Chloride (0.9% w/v)
Each 1 ml of sterile solution for injection contains 0.15 millimoles of Na^+ and Cl^-ions
Each 5ml of sterile solution for injection contains 0.75 millimetres of Na^+ and Cl^-ions
Each 10ml of sterile solution for injection contains 1.5 millimoles of Na^+ and Cl^-ions.
(equivalent to 150 millimoles of Na^+ and Cl^-ions per litre)

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Solution for Injection (injection)
Clear, colourless, sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

1. For use in prophylactic and replacement therapy requiring the use of isotonic saline solution.
2. In the reconstitution, dilution and making up of certain drugs.
3. As a saline irrigant.

4.2 Posology and method of administration

Route of administration: For intravenous administration, or as appropriate to the reconstituted drug.
In prophylaxis or replacement therapy of extracellular fluid deficits, the dosage of Sodium Chloride 0.9% w/v Solution for Injection is dependent on the age, weight, clinical state and degree of deficiency, and must be determined on an individual basis.

4.3 Contraindications

There are no absolute contraindications to the use of Sodium Chloride 0.9% w/v Solution for Injection.

4.4 Special warnings and precautions for use

Sodium Chloride 0.9% w/v Solution for Injection should be administered with caution to patients with congestive cardiac failure, pre-eclampsia, impaired renal function or oedema with sodium retention. Care is also required when administering this solution to the very young or to elderly patients.
Administration should be carried out under regular and careful surveillance.
No other medication or substance should be added to this fluid unless compatability is known.
Discontinue if adverse reaction occurs.
Do not administer unless the solution is clear and the container is undamaged.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration of other sodium salts may contribute to the sodium load.

4.6 Pregnancy and lactation

The solution is physiological saline and may be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

As the solution is physiological saline, adverse effects may be expected to occur only in the event of an excess of sodium or chloride in the body (see Overdosage below).

4.9 Overdose

Because the infusion is iso-osmotic with plasma, administration of an excessive volume of Sodium Chloride 0.9% w/v Solution for Injection produces an isotonic expansion of the extracellular fluid compartment which may result in oedema. The concentration of sodium in plasma is usually normal. Hypernatraemia may occur when patients who are dependent on parenteral fluids are given isotonic saline without free water to replace daily water loss through the skin. Irritability, lethargy and weakness are early neurologic signs of acute hypernatraemia. Osmotically-induced water shifts decrease the intracellular fluid volume and result in dehydration of internal organs; cerebral dehydration may provoke convulsive activity and may lead to coma and death. With judicious use of intravenous saline therapy, these effects can be avoided

Diuretics may be used to treat oedema resulting from isotonic expansion, and appropriate replacement therapy should be employed to avoid fluid and electrolyte imbalance. Treatment of hypervolaemic hypernatraemia requires removal of sodium in excess of water and can be achieved by replacing diuretic-induced sodium and water losses with only water. The basic aim of therapy is to restore the volume and composition of the body fluids to normal.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium Chloride 0.9% w/v Solution for Injection is a sterile solution of physiological saline containing approximately 150 mmol of sodium and chloride per litre.

5.2 Pharmacokinetic properties

Sodium chloride is well absorbed from the gastro-intestinal tract. Sodium is predominantly excreted via the kidneys and renal reabsorption of sodium is extensive. Small amounts of sodium are excreted in the faeces and in sweat.

5.3 Preclinical safety data

No relevant information other than that which is shown in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dilute hydrochloric acid (for pH adjustment)

Water for injections.

6.2 Incompatibilities

The addition of sodium chloride to mannitol 20% or 25% may cause precipitation of the mannitol.

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

6.3 Shelf Life

3 years.

This product should be used immediately after opening.

6.4 Special precautions for storage

Do not store above 25^{o}C

Keep the ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

5ml or 10ml hermetically sealed translucent plastic ampoules, polypropylene Ph. Eur. packed in cardboard cartons to contain 10, 20, 50 or 100 ampoules.

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

For I.V. Injection.

For single use only.

Solutions containing visible solid particles should not be used. If only part of the ampoule is used, discard the remaining solution.

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Limited
Chandler House
Castle Street
Roscrea
Co. Tipperary.

8 MARKETING AUTHORISATION NUMBER

PA0073/105/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th August 1991

Date of next renewal : 8th August 2006

10 DATE OF REVISION OF THE TEXT

March 2010