Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride: 0.9% w/v

Each ml contains 9 mg sodium chloride.

Each 1ml of sterile solution for injection contains 0.15 millimoles of Na^+ and Cl^- ions.
Each 2ml of sterile solution for injection contains 0.3 millimoles of Na^+ and Cl^- ions.
Each 5ml of sterile solution for injection contains 0.75 millimoles 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^- per litre)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection. (Injection)
A clear colourless sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use in prophylactic and replacement therapy requiring the use of sodium chloride. Also for reconstitution and dilution of certain drugs and as an irrigant.

4.2 Posology and method of administration

For intravenous administration, or as appropriate to the reconstituted drug. In prophylaxis or replacement therapy of extracellular fluid deficits, the intravenous route should be used and the dose is dependent upon the age, weight, clinical state and degree of deficiency of the patient, and must be determined on an individual basis.

4.3 Contraindications

Administration in congestive heart failure, in conditions of severe impairment of renal function or in oedema with sodium retention.

4.4 Special warnings and precautions for use

Administration should be carried out under regular and careful supervision and should be discontinued if adverse reaction occurs.
No other medication or substance should be added to this solution unless compatibility is known.
The solution should not be administered unless it 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 Fertility, 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 section 4.9, Overdosage)*.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

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. Do not add any other agent to this solution unless compatibility is known.

6.3 Shelf life

Unopened: 5 years.
Once opened: Use immediately. Discard any unused contents.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the ampoule in the outer carton in order to protect from light.

6.5 Nature and contents of container

2 ml, 5 ml and 10 ml clear glass ampoules, glass type I Ph. Eur.
Pack sizes: 10 x 2 ml; 10 x 5 ml; 10 x 10 ml.

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

Solutions containing visible solid particles should not be used.
The solution should not be used if the ampoule is damaged or if the contents are discoloured.
Single use only.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals (Ireland) Ltd
4045 Kingswood Road
Citywest Business Park
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 0073/105/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 June 1988

Date of last renewal: 01 June 2008

10 DATE OF REVISION OF THE TEXT

July 2015