Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% w/v Injection BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 9mg/mL or 0.9% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection and solvent for parenteral use.

A clear colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Sodium chloride injection is indicated as a pharmaceutical aid and diluent for the infusion of compatible drug additives and for diluting or dissolving drugs for parenteral administration.

Other indications for sodium chloride injection include flushing of IV catheters, as a priming solution in haemodialysis procedures and to initiate and terminate blood transfusions without haemolysing red blood cells. Sodium chloride injection may be added to compatible carbohydrate solutions such as dextrose in water to produce electrolytes

4.2 Posology and method of administration

Dosage:

The volume given and administration rate are dependent upon the additive.

Administration:

For parenteral use.

The directions for use of the additive will dictate the administration route

4.3 Contraindications

Hypernatremia, hyperchloremia and those contraindications related to the additive.

4.4 Special warnings and precautions for use

Newborn babies, both premature and at term, may exhibit excessively high sodium levels due to immaturity if renal function. As a result, in newborn babies, both premature and at term, repeated injections of sodium chloride may only be given after determining blood serum levels.

Sodium Chloride must be used with caution in patients with hypertension, heart failure, pulmonary or peripheral oedema, impaired renal function, pre-eclampsia, hypreraldosteronism, and other diseases and treatments (eg corticosteroids) associated with sodium retention.

4.5 Interaction with other medicinal products and other forms of interactions

1. Interaction

None known when used as a diluent or priming solution.

4.6 Fertility, pregnancy and lactation

This solution does not present any hazard to pregnant women, to the foetus or to the breast-fed child.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Unwanted reactions may be associated with the administration technique and consist of fever, infection at the injection site, local pain or reaction, venous irritation, venous thrombosis or ohlebitis spreading from the injection site, extravasation.

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

Administration of quantities which may have adverse effects is very unlikely as vials contain a maximum of 20mL.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: V07AB

Sodium chloride is the principal salt involved in the maintenance of plasma and other tissues tonicity. Solutions of sodium chloride closely approximate the composition of the extracellular fluid of the body; more than 90% of the cation of the extracellular fluid is sodium and more than 60% of the anion is chloride. Furthermore, a 0.98% solution of sodium chloride is approximately isotonic with body fluids. Thus, an injection of 0.9% sodium chloride will not appreciably affect the osmotic pressure of the body or the chemical composition of the extracellular fluid. A 0.9% solution of sodium chloride is therefore the choice of solvent for many drugs which have to be administered parenterally. The solution has the added advantage of being non-irritating to tissue.

5.2 Pharmacokinetic properties

Not appropriate.

5.3 Preclinical safety data

There is no preclinical data of relevance to the prescriber which are not included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections.

6.2 Incompatibilities

Compatibility should be checked when sodium chloride injection is used as a diluent or solvent.

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

6.3 Shelf life

5 years
Discard after single use, discard any unused portion.
From a microbiological point of view, the product should be used immediately after opening. 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 / dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Unopened product: This medicinal product does not require any special storage conditions.
Opened product: For storage conditions of the opened, reconstituted or diluted medicinal product, see section 6.3.

6.5 Nature and contents of container

Polypropylene ampoules of 5 mL, 10 mL or 20 mL. 5 mL ampoules are packed into cartons of 20 and 50 ampoules, 10mL are packed into cartons of 20, 50 and 100 ampoules, and 20mL are packed into a carton of 20 ampoules.

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

Use only if the solution is clear without visible particles.
Discard after single use.
Discard any unused portion

7 MARKETING AUTHORISATION HOLDER

Noridem Enterprises Ltd
Evagorou & Makariou
Mitsi Building 3, Office 115
1065 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER

PA1122/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 March 2008
Date of last renewal: 25 August 2009

10 DATE OF REVISION OF THE TEXT

September 2019