Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

0.9 % w/v Sodium Chloride Injection BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains
Sodium Chloride 9 mg

Electrolyte concentrations:
Sodium 154 mmol/l
Chloride 154 mmol/l

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless aqueous solution

Theoretical osmolarity 308 mOsm/l
Acidity (titration to pH 7.4) < 0.3 mmol/l
pH 4.5-7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Solvent or diluent for compatible medicinal products.

4.2 Posology and method of administration

Posology

Dosage, Route of administration and the duration of use depend on the instructions given for the medicinal product to be dissolved or diluted.

Method of administration
Intravenous, intramuscular or subcutaneous use.

For the use of this solution as solvent/diluent for compatible medicinal products, the instructions for use relating to the medicinal product to be added must be observed.

4.3 Contraindications

0.9% w/v Sodium Chloride Injection BP must not be administered to patients with

- severe hypernatraemia
- severe hyperchloraemia

4.4 Special warnings and precautions for use

0.9% w/v Sodium Chloride Injection BP should only be administered with caution in cases of:

- hypernatraemia

- hyperchloraemia

Clinical monitoring should include checks of the serum ionogram, the acid-base status and water balance.

Please note: The safety information of the additive provided by the respective manufacturer have to be taken into account.

4.5 Interaction with other medicinal products and other forms of interactions

Medicinal products causing sodium retention
The concomitant use of sodium-retaining drugs (e.g. corticosteroids, non-steroidal anti-inflammatory agents) may lead to oedema.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is a limited amount of data from the use of 0.9% w/v Sodium Chloride Injection BP in pregnant women. These data do not indicate direct or indirect harmful effects of 0.9% w/v Sodium Chloride Injection BP with respect to reproductive toxicity (see section 5.3). As the concentrations of sodium and chloride are similar to that in human body no harmful effects are to be expected if the product is used as indicated.
Therefore 0.9% w/v Sodium Chloride Injection BP can be used if indicated.

Breast-feeding
As the concentration of sodium and chloride are similar to that in human body no harmful effects are to be expected if the product is used as indicated. 0.9% w/v Sodium Chloride Injection BP can be used during breast-feeding, if required.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

0.9% w/v Sodium Chloride Injection BP has no influence on the ability to drive and use machines.

4.8 Undesirable effects

None to be expected if the product is used according to directions.

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

Symptoms

Overdose of 0.9% w/v Sodium Chloride Injection BP may result in hypernatraemia, hyperchloraemia, hyperhydration, hyperosmolarity of the serum and hyperchloraemic acidosis.
Treatment
Immediate stop of administration, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and diluting agents, including irrigating solutions
ATC Code: V07AB

Sodium is the primary cation of the extracellular space and together with various anions, regulates the size of this. Sodium and potassium are the major mediators of bioelectric processes within the body.

The sodium content and the liquid metabolism of the body are closely coupled to each other. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.

An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolality.

A 9 mg/ml sodium chloride Injection solution has the same osmolarity as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space. Therefore the haemodynamic effect of the solution is of short duration only.

Chloride is exchanged for hydrogen carbonate in the tubule system and is, thus, involved in the regulation of the acid base balance.

5.2 Pharmacokinetic properties

The kidneys are the major regulator of the sodium, chloride and fluid balances. In co-operation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and the hypothetical natriuretic hormone they are primarily responsible for keeping the volume of the extracellular space constant and regulating its fluid composition.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

When mixing with other medicinal products, possible incompatibilities should be considered.

6.3 Shelf life

- unopened 3 years

- after first opening The product must be used immediately after opening the container, see also section 6.6.
- after preparation of the ready-to-use mixture 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 dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Round or oval polyethylene ampoules Mini-Plasco; contents: 20 x 10 ml and 20 x 20 ml.

Polypropylene ampoules Mini-Plasco basic; contents: 100 x 10 ml and 100 x 20 ml, 50 x 10 ml, 50 x 20 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Containers are for single use only. Discard container and unused content after use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Solution should be used immediately after opening of the container or after preparation of the ready-to-use mixture.

Do not use if the solution is not clear and colourless or the container or its closure show visible signs of damage

7 MARKETING AUTHORISATION HOLDER

B. Braun Medical Limited
3 Naas Road Industrial Park
Dublin 12
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0179/002/013

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 1987

Date of last renewal: 8th April 2007

10 DATE OF REVISION OF THE TEXT

February 2020