Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion, Ecobag

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of solution contain

Sodium chloride	9.00	g

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 infusion.
A clear, colourless sterile, aqueous solution.

Theoretical osmolarity:	308 mOsm/1
Acidity (titration to pH 7.4):	< 0.3 mmol/l
pH:	4.5 - 7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- Fluid and electrolyte substitution in hypochloraemic alkalosis,
- Chloride losses,
- Short-term intravascular volume substitution,
- Hypotonic dehydration or isotonic dehydration,
- Vehicle solution for compatible electrolyte concentrates and medicinal products,
- Externally for wound irrigation and for moistening of wound tamponades and dressings.

4.2 Posology and method of administration

Posology
Adults
The dose is adjusted according to the actual requirements of water and electrolytes.

Maximum daily dose:
Up to 40 ml per kg body weight per day, corresponding to 6 mmol of sodium per kg body weight.
Any additional losses (due to e.g. fever, diarrhoea, vomiting, etc.) should be substituted according to the volume and composition of the lost fluids.

In the management of acute volume deficiency, i.e. imminent or manifest hypovolaemic shock, higher doses may be applied, e.g. by pressure infusion.

Infusion rate:
The infusion rate will depend on the conditions of the individual patient (see section 4.4).

Elderly population
Basically the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age.

Paediatric population
The dose has to be adjusted according to the individual need of water and electrolytes as well as the patient`s age, weight and clinical condition.
In case of severe dehydration a bolus of 20 ml/kg body weight is recommended for the first hour of treatment.
When administering this solution the total daily fluid intake should be taken into account.

Vehicle solution
When Sodium Chloride Intravenous Infusion BP 0.9% w/v is used as vehicle solution, the dosage and the infusion rate will be principally guided by the nature and the dosage regimen of the additive.

Wound irrigation
The amount of solution to be used for wound irrigation or moistening depends on actual requirements.

Method of administration

Intravenous use or irrigation and moistening.

When performing pressure infusion, using solution packed in a flexible container, all air must be expelled from the container and the giving set prior to starting the infusion to avoid the risk of air embolism.

4.3 Contraindications

Sodium Chloride Intravenous Infusion BP 0.9% w/v must not be administered to patients in states of:

- hyperhydration
- severe hypernatraemia
- severe hyperchloraemia

4.4 Special warnings and precautions for use

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

- Hypokalaemia
- Hypernatraemia
- Hyperchloraemia
- disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalised oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency.

To prevent development of the osmotic demyelination syndrome the increase of the serum sodium level should not exceed 9 mmol/l/day. As a general recommendation a correction rate of 4 to 6 mmol/l/day is reasonable in most cases, depending on patient condition and concomitant risk factors.

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

Carefully monitoring of cardiovascular and respiratory status should be performed if a rapid infusion of 0.9% NaCl is necessary.

Please note: If this solution is used as vehicle solution the safety information of the additive provided by the respective manufacturer have to be taken into account.

Paediatric population
Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusion of sodium chloride should therefore only be given after determination of the serum sodium level.

4.5 Interaction with other medicinal products and other forms of interaction

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 Sodium Chloride Intravenous Infusion BP 0.9% w/v in pregnant women. These data do not indicate direct or indirect harmful effects of Sodium Chloride Intravenous Infusion BP 0.9% w/v 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, Sodium Chloride Intravenous Infusion BP 0.9% w/v can be used as indicated.

Nevertheless, caution has to be exercised in the presence of eclampsia (see section 4.4).

Lactation
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.
Sodium Chloride Intravenous Infusion BP 0.9% w/v can be used during breast-feeding, if required.

Fertility
No data available

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

None known if used according to the instructions given.

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 Sodium Chloride Intravenous Infusion BP 0.9% w/v may result in hypernatraemia, hyperchloraemia, hyperhydration, acute volume overload, oedema, hyperosmolarity of the serum and hyperchloraemic acidosis.

Rapid increase of the serum sodium level in patients with chronic hyponatraemia may lead to the osmotic demyelination syndrome (see section 4.4).

First sign of overdose can be thirst, confusion, sweating, headache, weakness, somnolence or tachycardia. In case of severe hypernatraemia hypertension or hypotension, respiratory failure or coma can occur.

Treatment
Depending on the severity of the disorders immediate stop of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances.

In severe cases of overdose or in case of oligo- or anuria dialysis may become necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions affecting the electrolyte balance, electrolytes
ATC-code: B05B B01

Mechanism of action
Sodium is the primary cation of the extracellular space and together with various anions, regulates the size of this. Sodium is one of the major mediators of bioelectric processes within the body.
Chloride is the principal osmotic active anion in the extracellular space.

An increase of the serum chloride level leads to enhanced renal excretion of bicarbonate. Thus an acidifying effect is induced by chloride administration.

Pharmacodynamic effects
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 0.9 per cent sodium chloride 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.

5.2 Pharmacokinetic properties

Absorption
As the solution is administered by intravenous infusion the bioavailability of the solution is 100%.

Distribution
The total sodium content of the body is ca. 80 mmol/kg (5600 mmol); of this 300 mmol are in the intracellular fluid in a concentration of 2 mmol/l and 2500 mmol are sequestered in bone. About 2 mol are in the ECF at a concentration of about 135-145 mmol/l (3.1-3.3 g/l). The total body chloride in adults is about 33 mmol/kg body weight. Serum chloride is maintained at 98 – 108 mmol/l.

Biotransformation
Although sodium and chloride is absorbed, distributed, and excreted, there is no metabolism in the strict sense.
The kidneys are the major regulator of the sodium and water 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.

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

Elimination
Sodium and chloride ions are excreted via sweat, urine and gastrointestinal tract.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and toxicity to reproduction and development.
Since the components of Sodium Chloride Intravenous Infusion BP 0.9% w/v are physiologically present in human body, no harmful effects are to be expected with respect to genotoxicity and carcinogenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

When mixing with other medicaments, possible incompatibilities should be considered.

6.3 Shelf life

Unopened
2 years (as packed for sale)

After first opening
The product should be used immediately after first opening (see also section 6.6).

After dilution or admixture of additives
Unless chemical and physical stability of dilutions and mixtures with compatible solutions has been established (see section 6.2) the resulting mixture should be used immediately after preparation.

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

Do not store above 25^{o}C.

6.5 Nature and contents of container

Plastic bags (Ecobag) with butyl rubber stoppers and outer protective bags. The primary bag consists of a three layer plastic laminate with a polypropylene inner bag and a polyamide outer layer. Contents: 20 x 500ml, 10 x 1000ml.

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

No special requirements for disposal.

Containers are for single-use only.

Discard container and any unused contents after use.

Solution is to be used immediately after breaking the seal.

Only to be used if the solution is clear, free from visible solid particles and the container or its closure do not show visible signs of damage.

7 MARKETING AUTHORISATION HOLDER

B Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
Republic of Ireland

8 MARKETING AUTHORISATION NUMBER

PA0179/002/031

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 30th March 2007

Date of Last Renewal: 30th March 2012

10 DATE OF REVISION OF THE TEXT

July 2018