SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SODIUM CHLORIDE S.A.L.F. 0.9%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1,000 mL solution for injection contain: Sodium chloride 9.0 g

Electrolytes
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 and colourless solution
Theoretical osmolarity 308 mOsm/L
pH 4.5 – 7.0

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Short - term intravascular volume substitution.
Hypotonic dehydration or isotonic dehydration.
Vehicle solution for supplementary medication.
Fluid and electrolyte replacement, hypochloremic alkalosis and chloride losses. Externally for wound irrigation and moistening of wound tamponade dressings.

4.2 Posology and method of administration

Dosage
The dosage guideline for adults: Average dose: 1000 ml per day.
Flow rate: Up to 180 drops/min, corresponding to 550 ml/h.
Maximum recommended dosage: 40 ml per KG body weight and per day, not more than 2000 ml per day.
Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determination.

Route of administration
I.V., S.C., I.M. – in use as dissolvent and carrier; External.
When administering a solution packed in a flexible container via a pressure infusion, all air must be removed from the container and infusion system prior to administering the infusion.

4.3 Contraindications

Sodium chloride S.A.L.F. 0.9 % may not be used in the event of

- hyperhydration
- severe hypernatraemia
- severe hyperchloraemia

4.4 Special warnings and precautions for use

Sodium chloride S.A.L.F. 0.9 % should be used with caution only in

- hypokalaemia
- hypernatraemia
- hyperchloraemia
- Conditions requiring a restricted intake of sodium, such as heart failure, generalised oedema, pulmonary oedema, hypertension, eclampsia and severe renal failure.

In order to prevent osmotic demyelination syndrome from developing, serum sodium concentrations should not exceed 9 mmol/L/day. As a general recommendation, a rate of correction of 4 to 6 mmol/L/day is considered appropriate in the majority of cases, depending on the patient's conditions and associated risk factors.
Clinical monitoring should include checks of the serum ionogram, water balance and the acid-base balance.
If the rapid infusion of 0.9 % NaCl is required, the cardiovascular and respiratory status should be monitored closely.
Please note: if this solution is being used as a carrier solution, the safety information on the additive provided by the respective manufacturer is to be taken into account.

Children and adolescents
Premature or newborn babies may develop excess sodium levels due to immature kidney function. Therefore, repeated sodium chloride infusions should only be administered after serum sodium levels have been determined.

4.5 Interactions with other medicinal products and other forms of interaction

Medicinal products leading to sodium retention
The simultaneous use of sodium-retaining medicinal products (e.g. corticosteroids, non-steroidal anti- inflammatory drugs) can lead to oedema.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data from the use of Sodium chloride S.A.L.F 0.9 % in pregnant women. Similarly, animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Given that the concentrations of sodium and chloride are similar to those found in the human body, no harmful effects are to be expected when the product is used correctly.
Sodium chloride S.A.L.F. 0.9 % may therefore be used as stated.
Caution must be exercised, however, in the event of eclampsia (see section 4.4).
Lactation
Sodium chloride is excreted in human milk. Given that the concentrations of sodium and chloride are similar to those found in the human body, no harmful effects are to be expected when the product is used correctly.
Sodium chloride S.A.L.F. 0.9 % may be used during lactation if required.
Fertility
No data are available.

4.7 Effects on ability to drive and use machines
Sodium chloride S.A.L.F. 0.9 % has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
None known if used correctly.
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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il.

4.9 Overdose
Symptoms
An overdose of Sodium chloride S.A.L.F. 0.9 % can lead to hypernatraemia, hyperchloraemia, hyperhydration, acute volume overload, oedema, serum hyperosmolality and hyperchloraemic acidosis.
In patients with chronic hyponatraemia, a rapid rise in the serum sodium concentration can lead to osmotic demyelination syndrome (see section 4.4).
The first signs of overdose may be thirst, confusion, sweating, headache, weakness, drowsiness or tachycardia. Hypertension or hypotension, respiratory failure or coma may occur in the event of severe hypernatraemia.

Management
Depending on the severity of the symptoms, immediate stopping of the infusion and administration of diuretics whilst constantly monitoring serum electrolytes, and correction of electrolyte and acid-base imbalances.
Dialysis may be required in the event of major overdosage or oliguria or anuria.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: solutions affecting electrolyte balance, electrolytes, ATC code: B05XA03
Mechanism of action
Sodium is the primary cation in the extracellular space and, together with various anions, regulates the size of the latter. Sodium is one of the major mediators of bioelectric processes within the body. Chloride is the main osmotically active anion in the extracellular space.

A rise in the serum chloride concentration leads to increased renal bicarbonate excretion. An acidifying effect is therefore induced through the administration of chloride.
Pharmacodynamic properties
The sodium content and fluid metabolism in the body are closely connected. Each deviation in plasma sodium from the physiological concentration simultaneously affects the body's fluid status.
Independently of serum osmolality, a rise in the sodium content within the body also means a drop in free body water.
An 0.9 % solution of sodium chloride has the same osmolarity as plasma. Administration of this solution leads primarily to filling of the interstitial space, which represents roughly 2/3 of the whole extracellular space. Only 1/3 of the volume administered remains in the intravasal space. The haemodynamic effect of the solution is therefore only short-lasting.

5.2 Pharmacokinetic properties
Absorption
As the solution is administered as an intravenous infusion, the bioavailability of the solution is 100 %.
Distribution
The body's total sodium content is approximately 80 mmol/kg (5600 mmol), of which 300 mmol can be found in intracellular fluid in a concentration of 2 mmol/L and 2500 mmol of which are bound in bones. Approximately 2 mol can be found in extracellular fluid in a concentration of 135-145 mmol/L (3.1-3.3 g/L).

The total chloride content in the body is approximately 33 mmol/kg bodyweight. Serum chloride ranges from 98 to 108 mmol/L.

Biotransformation

Although sodium and chloride are absorbed, distributed and excreted, they are not metabolised in the strict sense.

The kidneys are the main regulators of sodium and fluid balance. Together with hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and with the hypothetical natriuretic hormone, they are chiefly responsible for keeping the volume of the extracellular space constant and for its fluid composition.

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

Elimination

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

5.3 Preclinical safety data

No preclinical studies have been conducted with Sodium chloride S.A.L.F. 0.9 %.

Given that sodium and chloride ions are major elements of the human body, Sodium chloride S.A.L.F. 0.9 % is not expected to have any toxic effects when used correctly.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Possible incompatibilities are to be borne in mind when mixed with other medicinal products.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store in its original package tightly closed below 25°C.

Do not freeze or refrigerate.

6.5 Nature and contents of container

Bag sizes:

PVC free bag of 100ml, 250ml, 500ml, 1,000ml and 2,000ml.

Bottle sizes:

PP bottles of 100ml, 250ml and 500ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The containers are intended for single use only. After administration, the container and any remaining solution are to be discarded.

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

7. MARKETING AUTHORISATION HOLDER and IMPORTER

RAZ PHARMACEUTICS LTD.,
31 Gesher Haetz, Industrial Park, Emek Hefer, Israel

8. MARKETING AUTHORISATION NUMBER

163-93-35433-00

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