## Summary of Product Characteristics

**1. Name of the medicinal product**

**Sodium Chloride MONICO 3% solution for infusion**

**2. Qualitative and quantitative composition**

**Each ml contains 30mg sodium chloride.**

Each 1000 mL of solution contains:

| | | **3%** |
|---|---|---|
| | sodium chloride | 30.0 g |
| mEq/L: | $Na^+$ | 513 |
| | $Cl^-$ | 513 |
| Theoretical osmolarity (mOsm/L): | | 1026 |
| pH: | | 4.5 ÷ 7.0 |

1 g NaCl = 394 mg of Na+ or 17.1 mEq or 17.1 mmol of Na+ and Cl-
1 mmol Na+ = 23 mg of Na+

For the full list of excipients, see section 6.1.

**3. Pharmaceutical form**

Solution for infusion.
Clear, colorless and free from foreign particles.

**4. Clinical particulars**

**4.1 Therapeutic indications**

Reintegration of fluids and sodium chloride.

**4.2 Posology and method of administration**

The medicine must be administered by intravenous infusion.

**Treatment of sodium deficiency**
The dose depends on the age, weight, clinical conditions, electrolytic framework and osmolarity and is related to the calculated sodium deficiency. The theoretical sodium deficiency can be calculated with the following formula:

*DEFICIT (mEq)=(140-P)x V*

P = plasma sodium concentration (mEq/L)
V = volume of body water (equal to 60% of body weight for children and adult males, 50% for adult women, 50% and 45% respectively for elderly men and women)

Using Sodium chloride monico 3%, administer half dose in the first 8 hours up to a maximum of 100 mL/hour; subsequently administer the remaining dose to reach a plasma sodium concentration equal to 130 mEq/L or until the symptoms improve.
In the case of severe sodium depletion and in the treatment of severe symptoms related to chronic hyponatraemia, administer Sodium chloride monico 3% so as to increase the plasma sodium concentration by 1-2 mmol/L/hr. Make sure the correction does not exceed 10-12 mmol/L in 24 hours and 18 mmol/L in 48 hours.

The infusion rate and the volume will depend on the age, weight and clinical conditions of the patient (e.g. burns, surgery, head injuries, infections) and, **In the case of treatment of paediatric patients**, the concomitant therapy must be determined by a physician with experience in paediatric therapy with solutions for intravenous administration (see sections 4.4 and 4.8).

**4.3 Contraindications**

Hypernatraemia.
Plethora hydrosaline.

**4.4 Special warnings and precautions for use**

Sodium salts must be administered with caution in patients with hypertension, cardiac insufficiency, peripheral or pulmonary oedema, reduced renal function, pre-eclampsia, or other conditions associated with sodium retention (see section 4.5).

Solutions with a concentration exceeding 0.9% (hypertonic solutions) must be used with precaution, at a controlled infusion rate and only in cases in which they are specifically prescribed.
Use with great caution in patients with congestive heart failure, severe renal insufficiency, and in clinical states where there exists an oedema with saline retention; in patients under treatment with corticosteroid or corticotropin containing medicines.
Continuous administration without addition of potassium can cause hypokalemia.
Use with caution in children.
During the infusion it is good practice to monitor the fluid balance, the electrolytes, the plasma osmolarity and the acid-base balance.
The solution must be clear, colourless and free from foreign particles. Use immediately after opening the container. The container is intended for a single and uninterrupted administration and any residue must not be used.

**4.5 Interaction with other medicinal products and other forms of interaction**

Corticosteroids are associated with sodium and water retention, with consequent oedema and hypertension: it is therefore necessary to use caution in the simultaneous administration of sodium salts and corticosteroids (see section 4.4).

Although sodium chloride might be compatible

with a large number of medicines, it is advisable to check the compatibility in the SmPC of the medicinal product that you want to administer.

**4.6 Pregnancy and lactation**

Although no effects on foetal development have been reported, this medicine should be administered only in case of actual need and only after having assessed the risk/benefit ratio.
This medicine is compatible with lactation.

**4.7 Effects on the ability to drive and use machines**

This medicine does not alter the ability to drive or use machines.

**4.8 Undesirable effects**

The undesirable effects of sodium chloride, organized according to the MedDRA system organ classes, are listed below. The data available is inadequate to establish the frequency of the single effects listed below.

*Disorders of the hydric and electrolytic balance*
Hypernatraemia, hypervolemia, hyperchloremia (which can cause loss of bicarbonates with consequent acidosis).

*Diseases of the nervous system*
Headache, dizziness, restlessness, fever, irritability, weakness, muscle stiffness, convulsions, coma, death.

*Psychiatric disorders*
Drowsiness, confusional states.

*Respiratory, thoracic and mediastinal diseases*
Dyspnea, respiratory arrest.

*Gastrointestinal diseases*
Thirst, reduced salivation, nausea, vomiting, diarrhea, abdominal pains.

*Cardiac pathologies*
Tachycardia.

*Eye diseases*
Reduced lacrimation.

*Renal and urinary diseases*
Renal insufficiency.

*Vascular pathologies*
Hypotension, hypertension, pulmonary and peripheral oedema.

*Systemic diseases and conditions relating to the administration site*
Infection at the infusion site, local pain or reaction, venous irritation, venous thrombosis or phlebitis that extends from the infusion site, extravasation.

**Reporting of suspected adverse reactions**
Reporting suspected adverse reactions after authorization 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*
The administration of excessive doses of hypertonic solutions of sodium chloride can lead, depending on the clinical condition of the patient, to hypernatraemia, hyperchloremia and/or hypervolemia.
Hypernatremia (associated mainly with the administration of hypertonic solutions) and excessive sodium retention, where there is a defective sodium excretion at renal level, determines the dehydration of the internal organs, especially of the brain, and the accumulation of extracellular fluids with oedemas that can affect cerebral, pulmonary and peripheral circulation with appearance of pulmonary and peripheral oedema.
The accumulation of chloride ions causes a reduction in the concentration of the bicarbonate ions which leads to acidosis.

*Treatment*
In the event of excessive accidental infusion, treatment must be discontinued and the patient must be kept under observation to evaluate the appearance of any signs and symptoms related to the medicine administered, guaranteeing the patient symptomatic and supportive measures according to their need.
In the event of overdose, the therapy must be aimed at restoring the physiological sodium ion concentrations.
In these cases the intravenous administration of 5% glucose or of hypotonic or isotonic solutions of sodium chloride is recommended (since they are hypotonic for the hypernatraemic patient).
In the event of high natraemia you can use loop diuretics.
Natraemia exceeding 200 mmol/L may require the use of dialysis.

**5. Pharmacological properties**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Solutions that affect the electrolytic balance - ATC code: B05BB01.
Sodium is the main extracellular cation, while chloride is the main anion. The sodium concentration is generally responsible for the volume of the extracellular fluids.
Sodium is important for the maintenance of the fluid osmolarity, of the transmembrane potential and of the acid-base balance.
Ions, such as sodium, circulate through the cell membrane using different transport mechanisms, including the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and in the cardiac electrophysiology, and also in its renal metabolism.
Chloride is a predominantly extracellular anion. Intracellular chloride is present in high concentrations in the red blood cells and in the gastric mucosa. Chloride reabsorption follows that of sodium.

**5.2 Pharmacokinetic properties**

After the administration, the sodium is distributed in the liquids and tissues of the organism; it concentrates in the bone tissue.
The kidney maintains the sodium concentration in extracellular fluids within a range between 0.5% and 10% of the amount filtered. Sodium homoeostasis is regulated by the renin-angiotensin-aldosterone system. In conditions of volume depletion, the amount of sodium that arrives at the kidney is inferior and this stimulates the release of renin from the cells of the juxtaglomerular system. Renin converts angiotensinogen into angiotensin I, which is in turn converted into angiotensin II by the converting enzyme (ACE). Angiotensin II determines an increase of sodium reabsorption, and therefore, by osmotic effect, of water in the proximal tubule. Angiotensin II also stimulates the release of aldosterone from the adrenal cortex; aldosterone increases the direct reabsorption of sodium at the level of the loop of Henle, the distal tubule and the collecting duct. Sodium is also eliminated in a small part through perspiration and faeces in amount of about 7% of the amount introduced.

**5.3 Preclinical safety data**

Preclinical data are scarcely important in the clinical framework in the light of the extensive experience acquired through human use of the medicine.

**6. Pharmaceutical particulars**

**6.1 List of excipients**

Water for Injection.

**6.2 Incompatibilities**

Incompatibility of the medicinal product to be added to the solution must be assessed before addition. Those additives known to be incompatible should not be used.

**6.3 Shelf life**

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

Use immediately after the opening of the container.

The container is intended for a single and uninterrupted administration and any residue may not be used.

**6.4 Special precautions for storage**

Do not refrigerate or freeze. Store below 25ºC.

**6.5 Nature and contents of container**

500 ml Polypropylene bag with two necks.

**6.6 Special precautions for disposal and other handling**

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

**7. Marketing authorisation holder and Importer**

RAZ PHARMACEUTICS LTD, ISRAEL
31 GESHER HAETZ ST., INDUSTRIAL PARK, EMEK HEFER, 3877701, ISRAEL

**8. Marketing authorisation number(s)**

**175-40-37163-99**

**Approved in November 2024.**

RAZS0518-00