(Summary of Product Characteristics)

1. Name of the Medicinal Product

R-SALINE NS Sodium Chloride Injection USP 0.9% w/v

2. Qualitative and quantitative

Sodium Chloride: 0.9% w/v

3. Pharmaceutical form

Solution for Infusion.

A clear colourless solution

The pH of the solution between 4.5 to 7.0.

4. Clinical particulars

4.1. Therapeutic indications R-Saline NS

is indicated for:

- Treatment of isotonic extracellular dehydration.
- Treatment of sodium depletion
- Vehicle or diluent of compatible drugs for parenteral administration.
- In the reconstitution, dilution and making up of certain drugs.
- Management of diabetic ketoacidosis
- As a priming fluid for haemodialysis procedures and to initiate and terminate bloodtransfusions.

4.2. Posology and method of administration

Adults, older people and children:

Doses may be expressed in terms of mEq or mmol of sodium, mass of sodium, or mass of sodium salt (1 g NaCl = 394 mg, 17.1 mEq or 17.1 mmol of Na and Cl).

Fluid balance, serum electrolytes and acid-base balance should be monitored before and during administration, with particular attention to serum sodium in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia. Monitoring of serum sodium is particularly important for hypotonic fluids.

Sodium Chloride Injection has a tonicity of 308 mOsm/l (approx.).

The infusion rate and volume depend on age, weight, clinical condition (e.g. burns, surgery, head-injury, infections), and concomitant therapy should be determined by the consulting physician experienced in intravenous fluid therapy.

Recommended dosage

The recommended dosage for treatment of isotonic extracellular dehydration and sodium

depletion is:

- For adults : 500 ml to 3 litres/24h
- For babies and children: 20 to 100 ml per 24h and per kg of body weight, depending of the age and the total body mass.

The recommended dosage when used as a vehicle or diluent ranges from 50 to 250 ml per doseof medicinal product to be administered.

When Sodium Chloride Injection is used as a diluent for injectable preparations of other drugs, the dosage and the infusion rate will also be dictated by the nature and the dose regimen of the prescribed drug.

Management of diabetic ketoacidosis (to restore circulating volume if systolic blood pressure is below 90mmHg and adjusted for age, sex, and medication as appropriate)

▶ Adult: 500 ml, sodium chloride 0.9% to be given over 10–15 minutes, repeat if blood pressure remains below 90mmHg and seek senior medical advice, when blood pressure is over 90 mmHg, sodium chloride 0.9% should be given by intravenous infusion at a rate that replaces deficit and provides maintenance, management regimen also includes administration of potassium chloride, soluble insulin, long acting insulin analogues and glucose 10% solution

Method of administration

The solution is for administration by intravenous infusion through a sterile and non-pyrogenic administration set, using aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

The product should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless solution is clear, free from visible particles and the seal is intact.

Do not remove unit from overwrap until ready for use. The inner container maintains the sterility of the solution. Administer immediately following the insertion of infusion set.

4.3. Contraindications

The solution is contra-indicated in patient presenting hypernatraemia or hyperchloraemia.The contra-indications related to the added medicinal product should be considered.

4.4. Special warnings and special precautions for use

With intravenous use Avoid excessive administration, cardiac failure, dilutional hyponatraemia especially in the elderly, hypertension, peripheral oedema, pulmonary, oedema, restrict intake in impaired renal function, toxaemia of pregnancy.

Fluid balance/renal function

Use in patients with (severe) renal impairment

Sodium Chloride Injection should be administered with particular caution to patients with or at risk of severe renal impairment. In such patients, administration of Sodium Chloride Injection may result in sodium retention.

Risk of fluid and/or solute overload and electrolyte disturbances

Depending on the volume and rate of infusion, intravenous administration of Sodium Chloride Injection can cause:

- Fluid and/or solute overload resulting in overhydration/hypervolemia and, for example, congested states, including central and peripheral oedema.
- Clinically relevant electrolyte disturbances and acid-base imbalance.

In general, the risk of dilutional states (retention of water relative to sodium) is inversely proportional to the electrolyte concentrations of Sodium Chloride Injection and its additions. Conversely, the risk of solute overload causing congested states (retention of solute relative to water) is directly proportional to the electrolyte concentrations of Sodium Chloride Injection and its additions.

Special clinical monitoring is required at the beginning of any intravenous infusion. Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy orwhenever the condition of the patient or the rate of administration warrants such evaluation.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia.

Hyponatraemia

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart, liver- and kidney diseases and patients exposed to vasopressin agonists are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, cerebral contusion and brain oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Use in patients at risk for sodium retention, fluid overload and oedema

Sodium Chloride Injection should be used with particular caution, if at all, in patients with or at risk for:

- Hypernatraemia. Rapidly correcting hypernatraemia once adaptation has occurred may lead to cerebral oedema, potentially resulting in seizures, permanent brain damage, or death.
- Hyperchloraemia
- Metabolic acidosis, which may be worsened by prolonged use of this product, especiallyin patients with renal impairment.
- Hypervolaemia such as congestive heart failure and pulmonary oedema may be precipitated, particularly in patients with cardiovascular disease.
- Iatrogenic hyperchloraemic metabolic acidosis (e.g., during intravenous volume resuscitation)
- Conditions that may cause sodium retention, fluid overload and oedema (central andperipheral), such as patients with
  - ✓ primary hyperaldosteronism,
  - ✓ secondary hyperaldosteronism, associated with, for example,

    -hypertension,

    -congestive heart failure,

    -liver disease (including cirrhosis),

    -renal disease (including renal artery stenosis, nephrosclerosis) or pre-eclampsia. Medications that may increase the risk of sodium and fluid retention, such as corticosteroids.

Infusion reactions

Symptoms of unknown aetiology which can appear to be hypersensitivity reactions have been

reported very rarely in association with infusion of Sodium Chloride Injection. These have been characterized as hypotension, pyrexia, tremor, chills, urticaria, rash and pruritus. Stop the infusion immediately if signs or symptoms of these reactions develop. Appropriate therapeutic countermeasures should be instituted as clinically indicated.

Specific patient groups

The consulting physician should be experienced in this product's use and safety in these special populations that are especially sensitive to rapid changes in serum sodium levels.

Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurologic complications).

Paediatric population

Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes. Repeated infusions of sodium chloride should therefore only be given after determination of the serum sodium level.

Geriatric population

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

4.5. Interaction with other FPPs and other forms of interaction

Drugs leading to an increased vasopressin effect

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids.

- ✓ Drugs stimulating vasopressin release include: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, and narcotics.
- ✓ Drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs, and cyclophosphamide.
- ✓ Vasopressin analogues include: Desmopressin, oxytocin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Sodium Chloride Injection. Administration of Sodium Chloride Injection may result in decreased lithium levels.

Corticoids/Steroids and carbenoxolone, are associated with the retention of sodium and water (with oedema and hypertension).

4.6. Use in Pregnancy and lactation

There are no adequate data from the use of Sodium Chloride Injection in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride Injection.
Sodium Chloride Injection should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin.
Caution is advised with patients with pre-eclampsia.
When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation has to be considered separately.

4.7. Effects on ability to drive and use machines

Not known.

4.8. Undesirable effects

With intravenous use Chills, fever, hypervolaemia, hypotension, local reaction, localized pain, paraesthesia, skin reactions, tremor, vascular irritation, venous thrombosis.
The administration of large doses may give rise to sodium accumulation, oedema, and hyperchloremic acidosis.

4.9. Overdose

General adverse effects of sodium excess in the body include nausea, vomiting, diarrhea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma,and death.
An excessive volume of Sodium Chloride Injection may lead to hypernatraemia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema and death) and sodium overload (which can lead to central and/or peripheral oedema) and should be treated by an attending specialized physician.
Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.
When Sodium Chloride Injection is used as a diluent for injectable preparations of other drugs, the signs and symptoms of over infusion will be related to the nature of the additives being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.

5. P h a r m a c o l o g i c a l properties Pharmacodynamic properties

Pharmacotherapeutic group: Other IV Solution Additives, Electrolytes
ATC code: B05XX
Mechanism of action:

Sodium and chloride-major electrolytes of the fluid compartment outside of cells (i.e., extracellular)-work together to control extracellular volume and blood pressure. Disturbances in sodium concentrations in the extracellular fluid are associated with disorders of water balance.

Pharmacodynamic effects

Sodium Chloride Injection is an isotonic solution, with an approximate osmolarity of 308 mOsm/l.

The pharmacodynamic properties of the solution are those of the sodium and chloride ions in maintaining the fluid and electrolyte balance. Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

Pharmacokinetic properties

Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption.Small amounts of sodium are lost in the faeces and sweat.

5.3 Preclinical safety data

The safety of sodium chloride in animals is not relevant in view of its presence as a normal component in animal and human plasma.

6. Pharmaceutical particulars

6.1. List of excipients

Water for Injections.

6.2. Incompatibilities

As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition. In the absence of compatibility studies, this solution must not be mixed with other medicinal products. Those additives known to be incompatible should not be used.

6.3 Shelf life

36 months from date of manufacture.

From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4. Special precautions for storage

Store below 30°C. Protect from light. Do not refrigerate or freeze.

5. Nature and contents of container

The product is packed as 500 ml in FFS (Form Fill and Seal) impermeable LDPE Containers. Each labeled container has a dust cap, and is further packed in a poly pouch and such 25 poly pouches are packed in a corrugated box.

6. Special precautions for disposal and other handling

Discard after single use. Discard any unused portion.

Do not remove unit from overwrap until ready for use. The container maintains the sterility of the product.

7. MARKETING AUTHORIZATION HOLDER

R. K. Laboratories Pvt. Ltd.

V.P.O. – Manpura, Tehsil- Nalagarh,
Distt. - Solan (Himachal Pradesh)-174101
India.

8. MARKETING AUTHORIZATION NUMBER

TAN 22 HM 0409

9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION

21/09/2022

10. DATE OF REVISION OF THE TEXT

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