1.6 Product Information:

1.6.1 Prescribing Information (summary of product characteristics):

1. Name of the medicinal product

SODIUM CHLORIDE INTRAVENOUS INFUSION BP 0.9 % W/V

2. Qualitative and quantitative composition

Each 100 mL contains:

Sodium Chloride BP	0.9 gm
Water For Injection BP	q.s.

3. Pharmaceutical form

Solution for infusion

A clear, colorless solution essentially free from visible particles.

4. Clinical particulars

4.1 Therapeutic indications

4.1 Therapeutic indications

Sodium Chloride Intravenous Infusion BP 0.9% w/v is of value as a source of water and electrolytes and is indicated for replenishing fluid and for restoring and maintaining the concentrations of sodium and chloride ions.

It is also of value in the treatment of poisoning, by aiding excretion.

It may also be used as a vehicle for the reconstitution and administration of intravenous medications.

4.2 Posology and method of administration

Posology

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).

The dosage, rate and duration of administration is to be individualised as determined by several factors including age, weight, clinical condition, concomitant treatment and in particular the patient's hydration state, clinical and laboratory response to treatment.

Fluid balance and plasma electrolyte concentrations must be monitored during treatment.

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 dose of medicinal product to be administered.

When Sodium Chloride 0.9 % 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.

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 bag maintains the sterility of the solution. Administer immediately following the insertion of infusion set.

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration. Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Additives may be introduced before infusion or during infusion through the injection site.

4.3 Contraindications

This product must be used with caution in patients with an impaired ability to handle sodium such as organic heart disease especially with a history of congestive heart failure, patients with renal insufficiency, cirrhosis of the liver, cardiopulmonary diseases or patients receiving salt retaining steroids.

When used in conjunction with cell separator procedures, the solution is contraindicated in those patients where adequate anticoagulation cannot be achieved.

4.4 Special warnings and precautions for use Fluid balance/renal function

Use in patients with (severe) renal impairment

Sodium Chloride 0.9% should be administered with particular caution to patients with or at risk of severe renal impairment. In such patients administration of Sodium Chloride 0.9% may result in sodium retention. (See "Use in patients at risk for sodium retention, fluid overload and oedema" below, for additional considerations.)

Risk of fluid and/or solute overload and electrolyte disturbances

Depending on the volume and rate of infusion, intravenous administration of Sodium Chloride 0.9% 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 0.9% 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 0.9% 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 or whenever the condition of the patient or the rate of administration warrants such evaluation.

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

Sodium Chloride 0.9% should be used with particular caution, if at all, in patients with or at risk for:

• Hypernatraemia. Rapidly correcting hypernatremia 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, especially in patients with renal impairment.

• Hypervolemia such as congestive heart failure and pulmonary oedema may be precipitated, particularly in patients with cardiovascular disease.

• Iatrogenic hyperchloremic metabolic acidosis (e.g., during intravenous volume resuscitation)

• Conditions that may cause sodium retention, fluid overload and oedema (central and peripheral), such as patients with

o primary hyperaldosteronism,

o 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 0.9 %. 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 hypernatremia is potentially dangerous (risk of serious neurologic complications). See section "*Hyponatraemia/hypernatraemia*" above.

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.

For information on preparation of the product and additives, please see section 6.6.

As with any prolonged intravenous infusion, venous irritation and thrombophlebitis may occur at the injection site.

When used in conjunction with cell separator procedures, there is a risk of air embolism or haemolysis. A donor should not be subjected to this procedure more frequently than once in a 48 hour period, twice in 7 days or 24 times a year.

4.5 Interaction with other medicinal products and other forms of interaction

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Sodium Chloride 0.9%. Administration of Sodium Chloride 0.9% may result in decreased lithium levels.

Corticoids/Steroids and carbenoxolone, are associated with the retention of sodium and water (with oedema and hypertension). See Section 4.4 Special warnings and precautions for use.

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of Sodium Chloride 0.9% in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride 0.9%.

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

No studies have been conducted on the influence of Sodium Chloride 0.9% on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

The following adverse reactions have been reported in post-marketing experience. The frequency of the adverse drug reactions listed in this section cannot be estimated from the available data.

System Organ Class (SOC)	**Adverse reactions (Preferred Term)**	**Frequency**
Nervous system disorders	Tremor	Not known
Vascular disorders	Hypotension	Not known
Skin and subcutaneous tissue disorders	Urticaria Rash Pruritus	Not known
General disorders and administration site conditions:	Infusion site reactions, such as • Infusion site erythema, • Injection site streaking, Burning sensation, • Infusion site urticaria • Pyrexia • Chills	Not known

The following adverse reactions have not been reported with this product but may occur:

• Hypernatraemia (eg. when administered to patients with nephrogenic diabetes insipidus or high nasogastric output)

• Hyperchloremic metabolic acidosis

• Hyponatraemia, which may be symptomatic. Hyponatraemia may occur when normal free water excretion is impaired. (eg SIADH or postoperative)

General adverse effects of sodium excess are described in section 4.9 Overdose.

Additives

When Sodium Chloride 0.9% is used as a diluent for injectable preparations of other drugs, the nature of additives will determine the likelihood of any other undesirable effect.

If an adverse event occurs the patient should be evaluated and appropriate counter measures be started, if needed the infusion should be stopped. The remaining part of the solution should be kept for investigation if deemed necessary.

When used in conjunction with cell separator procedures, reactions commonly experienced in routine blood collection such as syncope, vomiting and hyperventilation may occur. Individuals donating for the first time may be predisposed to these symptoms due to psychological factors. Reactions unique to apheresis collection procedures may also occur.

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 0.9% 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 specialised physician.

Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.

When Sodium Chloride 0.9% 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. Pharmacological properties

5.1 Pharmacodynamic properties
Not applicable.

5.2 Pharmacokinetic properties
Not applicable.

5.3 Preclinical safety data
Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Chloride
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

3 years.

6.4 Special precautions for storage

Keep container in the outer carton in order to protect from light.

6.5 Nature and contents of container

500 ml Bottle.

6.6 Special precautions for disposal and other handling

Do not store above 30°C. Do not refrigerate or freeze.

7. Marketing authorization holder

REALCADE LIFESCIENCE PVT. LTD.,
Address:
Survey No. 891-892, Y - Junction, At Narmada Canal, Karannagar, Ta.: Kadi, Kadi, Gujarat - 382715, India
Email Address : field.realcade@gmail.com

8. Marketing authorisation number(s)

Not Applicable.

9. Date of first authorisation/renewal of the authorisation

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10. Date of revision of the text

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