1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name: Sodium Chloride Intravenous Infusion BP (0.9 % w/v)
1.2 Strength: 0.9 %w/v
1.3 Pharmaceutical Dosage Form: Solution for Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Composition:

Each 100ml contains:
Sodium Chloride BP
Water for Injections BP

Quantitative Composition:

Each 100ml contains:

Sodium Chloride BP	0.9 gm
Water for Injections BP	q.s.

3. PHARMACEUTICAL FORM

Solution for Infusion

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

Sodium Chloride Intravenous Infusion is use as Pharmaceutical aid (tonicity adjusting agent), fluid and electrolyte replenisher.

1. When alkalosis is present along with fluid loss, normal saline is indicated.
2. In case of severe salt depletion when rapid electrolyte restoration is essential normal saline is of particular value.

In the treatment of low salt syndrome which may occur in presence of heart failure, renal impairment, during surgery, etc. In these cases chloride loss frequently exceeds sodium loss.

In severe salt depletion resulting from excessive fluid loss due to sweating,diarrhoea, vomiting, etc.

4.2 Posology and Method of Administration:

1 lit /day in average adult

- **AVERAGE DOSE RANGE FOR ADULTS AND CHILDREN:-**
- **Adults and Children over 12 years of age:-**

In the average adult, daily requirements of sodium and chloride are met by the infusion of one liter of 0.9% sodium chloride (154 mEq each of sodium and chloride).

- **Children below 12 years of age:-**

There is no specific pediatric dose. The dose is dependent on weight, clinical condition and laboratory results.

Route of administration: Parenteral Route

Condition of administration: Intravenous Only

4.3 Contraindications:

Cautious use or avoid in hypertensive and in patients with oedema due to congestive heart failure, renal failure, renal diseases and cirrhosis.
Dehydration with severe Hypokalaemia: with deficit of potassium so infusion of isotonic saline, without additional potassium supplementation, will aggravate electrolyte imbalance of ICF.
Normal saline solution is inadequate for repairing electrolyte deficit involving intracellular fluid because it may increase intracellular deficits e.g. the main electrolyte of intracellular fluid is potassium. Now, if normal saline is given to a potassium-depleted patient, the lost potassium is replaced by sodium, which again disturbs the electrolyte balance in intracellular fluid. Here a solution providing both intracellular and extracellular electrolytes should be used.

4.4 Special Warning and Precautions for use:

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration.
The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there is sodium retention with edema. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.
Infusion of isotonic (0.9%) sodium chloride during or immediately after surgery may result in excessive sodium retention. Use the patient's circulatory system status as a guide.
Sodium salt should be used with caution in patients with

- Hypertension,
- Heart failure,
- Peripheral or pulmonary oedema,
- Renal impairment, pre-eclampsia, or other condition associated with sodium retention.

Sodium chloride solution should not be used to induce emesis

4.5 Interaction with other Medicinal Products and other form 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).

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%.

4.7 Side effects

Electrolyte imbalance.

- Retention of excess sodium in the body usually occurs when there is a defective renal sodium excretion. This lead to accumulation of extracellular fluid to maintain normal plasma osmolarity, which may lead to pulmonary and peripheral oedema.
- Hypernatraemia (a rise in plasma osmolarity) (after I.V administration of hypertonic saline).
- The most serious effect o Hypernatraemia is dehydration of the brain, which causes somnolence and confusion progressing to convulsion, coma, respiratory failure and death. Other symptoms include thirst, reduced salivation and lachrymation, fever, sweating, tachycardia, hypertension or hypotension, headache, dizziness, restlessness, irritability, weakness, and muscular twitching and rigidity.
- Excessive use of chloride salts may cause a loss of bicarbonate with an acidifying effect.

4.8 Undesirable effects

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- Retention of excess sodium in the body usually occurs when there is a defective renal sodium excretion. This lead to accumulation of extracellular fluid to maintain normal plasma osmolarity, which may lead to pulmonary and peripheral oedema.
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- Excessive use of chloride salts may cause a loss of bicarbonate with an acidifying effect.

4.9 Overdose

Symptoms:

- General gastrointestinal effects: Nausea, Vomiting, diarrhoea and cramps.
- Salivation and lacrimation are reduced, whilst thirst and swelling are increased.
- Possible other symptoms: Hypertension, Tachycardia, renal failure, Peripheral and pulmonary oedema and respiratory arrest.
- CNS: headache, dizziness, irritability, restlessness, weakness, muscle twitching or rigidity, convulsion, coma and death.

Treatment:

Normal plasma sodium concentrations should be restored at no more than 10-15 mmol/day with IV hypotonic saline. Dialysis may be required if there is renal impairment, if plasma sodium level are greater than 200 mmol/L of the patient is moribund. Convulsions should be treated with diazepam.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties:

Pharmacotherapeutic group: "Other IV Solution Additives"

ATC code: B05XX

Sodium Chloride 0.9% intravenous infusion 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.

5.2 Pharmacokinetic Properties:

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

6.2 Shelf Life:

36 Months from the date of manufacture

6.3 Precaution for Storage:

Store below 30°C.

6.4 Nature and Contents of Container:

The solution is filled in 500 ml & 1000ml Plastic bottle.

7.0 Marketing Authorization Holder:

Aculife Healthcare Pvt. Ltd.
Village: Sachana
Taluka: Viramgam
District: Ahmedabad – 382150
Gujarat, India.

8.0 Marketing Authorization Number:

9.0 Date of first Authorization/Renewal of Authorization:

10.0 Date of last revision: ----