SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

Product Name: Sodium Chloride Intravenous Infusion BP (0.9%w/v)

Strength: 0.9gm / 100ml

Pharmaceutical Dosage Form: Intravenous Infusion

2. Qualitative and Quantitative Composition Qualitative

Composition: Sodium Chloride BP

Water for injections BP

Quantitative Composition: Sodium Chloride BP – 0.9%w/v

Water for injections BP – q.s

3. Pharmaceutical Form

A clear colorless solution filled in 100 ml Non – PVC bag. Sealed the bag with HMHD Pouch and such 60 bags packed in one corrugated box with plate partition.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

Sodium Chloride Injection is use as Pharmaceutical aid (tonicity adjusting agent),Fluid and electrolyte Replenisher.

When alkalosis is present along with fluid loss, normal saline is indicated.

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, diarrhea, vomiting, etc.

4.2 Posology and Method of Administration:

Dose: 1 Lt / day in average adult.

Rate: Normal saline is usually given at the rate of 400 M/hr. in adult.

In case of shock treatment 2000 ml/hr may be given.

Route of Administration: Intravenous

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:

Precautions: sodium salt should be use 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.

The use of hyper osmotic dextrose solution is contraindicated in-patient with

- Anuria
- Intracranial or intraspinal haemorrhage
- Delirium tremens where there is dehydration.

4.5 Interaction with other Medicinal Products and other form of Interaction:

Drugs leading to an increased vasopressin effect

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte freewater 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, narcotics
- Drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs,

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 0.9%. Administration of Sodium Chloride0.9% 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 Pregnancy and Lactation:

It is not known whether it can cause fetal harm administered to a pregnant woman or can affect reproductive capacity. It should only be given to pregnant woman if the benefits overweight the risk.

4.7 Effects on ability to drive and use machine

This preparation is intended for use only in emergencies.

4.8 Undesirable 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.

4.9 Overdose:

Symptoms of overdose may include: swelling, trouble breathing. If overdose is suspected,

contact your local poison control center or emergency room immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynemic Properties:

ATC code: B05XX

Sodium chloride is an electrolysis supplement agent; sodium and chloride are important electrolysis for the human body and mainly exist in extracellular fluid, which play an important role in maintaining normal volume of blood and extracellular fluid and osmosis pressure. Normal serum sodium concentration is about 135~145mmol/L, with a 92 percent of the plasmacation and a 90 percent of total osmosis pressure, so the quantity of plasma sodium play a decisive role for the osmosis pressure; normal serum chloride concentration is about 98~106mmol/L; sodium and chloride in human body are mainly adjusted by hypothalamus, lobus posterior hypophyseos and kindney so as to maintain the stability of body fluid volume and osmosis pressure.

5.2 Pharmacokinetic Properties:

Sodium chloride enter the blood circulation directly after injected by intravenous, and distribute widely in the human body, and mainly exist in extracellular fluid. Both sodium and chloride can be filtrated by glomerule, and partially be absorbed by renal tubules. Sodium chloride is mainly excreted through urine by kindney, some is excreted through sweat.

5.3 Preclinical safety Data

Not applicable since Sodium Chloride has been used in clinical practice for many years and itseffects in man are well known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:

Water for Injections
Sodium Hydroxide
Hydrochloric Acid

6.2 Incompatibilities

The addition of sodium chloride to mannitol 20 or 25% may cause precipitation of the mannitol.

6.3 Shelf Life:

36 Months

6.4 Special Precaution for Storage:

Store below 30°C.

6.5 Nature and Contents of Container:

100 ml Non – PVC bag with spike port.

6.6 Special precautions for disposal and other handling
Use as directed by a physician.

7.0 Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Marketing authorisation holder
Aculife Healthcare Private Limited,
Commerce House-V, Besides Vodafone House,
Prahlad Nagar Corporate Road,
Ahmedabad, Gujarat, India, Pin 380051
Website: www.aculife.co.in

7.2 Manufacturer
Aculife Healthcare Pvt. Ltd.,
Village Sachana, Taluka: Viramgam,
Ahmedabad-382150,
Gujarat, India.
Tel: +91 079 26839100
Fax: +91 079 26839108
Email: sumitripathi@aculife.co.in

8.0 Marketing Authorization Number

TAN 21 HM 0177

9.0 Date of first registration/ Renewal of the registration

Date of first registration: 29/03/2021

10. Date of Revision of the Text

March 2021