SODIUM CHLORIDE- sodium chloride injection, solution
Fresenius Kabi USA, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sodium Chloride Injection USP

14.6% (2.5 mEq/mL)

CONCENTRATED SOLUTIONS FOR USE ONLY AFTER DILUTION WITH COMPATIBLE IV FLUIDS TO CORRECT SODIUM DEFICIENCY WHEN ORAL REPLACEMENT IS NOT FEASIBLE.

DESCRIPTION

Sodium Chloride Injection, USP is a sterile, nonpyrogenic, concentrated solution for intravenous administration ONLY AFTER DILUTION to replenish electrolytes. The preparation contains 2.5 mEq/mL (14.6%) sodium chloride, in Water for Injection. The solution contains no bacteriostat, antimicrobial agent or added buffer; pH of the solution ranges from 4.5 to 7.0. Each mL contains: Sodium chloride 146 mg; Water for Injection q.s. pH may have been adjusted with hydrochloric acid. The osmolar concentration of the 2.5 mEq/mL solution is 5 mOsmol/mL. Sodium chloride is chemically designated NaCI, a white crystalline compound freely soluble in water.

CLINICAL PHARMACOLOGY

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (CI^-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

Sodium is the principal cation of extracellular fluid. It comprises more than 90% of the total cations at its normal plasma concentration of approximately 142 mEq/L. While the sodium ion can diffuse across cell membranes, intracellular sodium is maintained at a much lower concentration than extracellular sodium through the expenditure of energy by the cell (so-called ‘‘sodium cation pump’’). Loss of intracellular potassium ion is usually accompanied by an increase in intracellular sodium ion.

When serum sodium concentration is low, the secretion of antidiuretic hormone (ADH) by the pituitary is inhibited, thereby preventing water reabsorption by the distal renal tubules. On the other hand, adrenal secretion of aldosterone increases renal tubular reabsorption of sodium in an effort to reestablish normal serum sodium concentration.

Chloride (CI^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells.

The distribution and excretion of sodium (Na^+) and chloride (CI^-) are largely under the control of the kidney which maintains a balance between intake and output.

INDICATIONS AND USAGE

Sodium Chloride Injection, USP is indicated for parenteral restoration of sodium ion in patients with restricted oral intake. Sodium replacement is specifically indicated in patients with hyponatremia or low salt syndrome. Sodium chloride injection may also be added to compatible carbohydrate solutions such as dextrose in water to provide electrolytes.

CONTRAINDICATIONS

Sodium chloride injection is contraindicated in patients with hypernatremia or fluid retention.

WARNINGS

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

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 exists edema with sodium retention.

In patients with diminished renal function, administration of solutions containing sodium may result in sodium retention.

The intravenous administration of this solution (after appropriate dilution) can cause fluid and/or solute overloading resulting in dilution of other serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

Excessive administration of potassium free solutions may result in significant hypokalemia.

PRECAUTIONS

Do not use unless the solution is clear and seal is intact. Discard unused portion.

Sodium chloride injection must be diluted before infusion to avoid a sudden increase in the level of plasma sodium. Too rapid administration should be avoided.

Special caution should be used in administering sodium containing solutions to patients with severe renal impairment, cirrhosis of the liver, cardiac failure, or other edematous or sodium-retaining states.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.

Pregnancy

Teratogenic Effects: Pregnancy Category C—

Animal reproduction studies have not been conducted with sodium chloride. It is also not known whether sodium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium chloride should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

None known.

OVERDOSAGE

In the event of over hydration or solute overload, reevaluate the patient and institute appropriate corrective measures. (See **WARNINGS** and **PRECAUTIONS**.)

DOSAGE AND ADMINISTRATION

Sodium chloride injection is administered intravenously *only after addition to a larger volume of fluid*.

The dose, dilution and rate of injection are dependent upon the individual needs of each patient.

All or part of the contents of one or more additive containers may be added to an intravenous solution container. Concentrations of up to 5% sodium chloride have been administered.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. (See **PRECAUTIONS**.)

HOW SUPPLIED

Sodium Chloride Injection, USP is available in flip-top glass vials.

Product No.	NDC No.	% NaCl	Na^+ mEq/mL	Cl^- mEq/mL	mOsmol/mL	Fill Volume mL
13920	63323-139-20	14.6	2.5	2.5	5	20
13940	63323-139-40	14.6	2.5	2.5	5	40

These vials are Single Dose Vials; packaged 25 vials per tray.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not permit to freeze.

APP
APP Pharmaceuticals, LLC
Schaumburg, IL 60173

45873E

Revised: June 2008

PACKAGE LABEL - PRINCIPAL DISPLAY - Sodium Chloride 40 mL Vial Label

NDC 63323-139-40

13940

Sodium Chloride Injection, USP

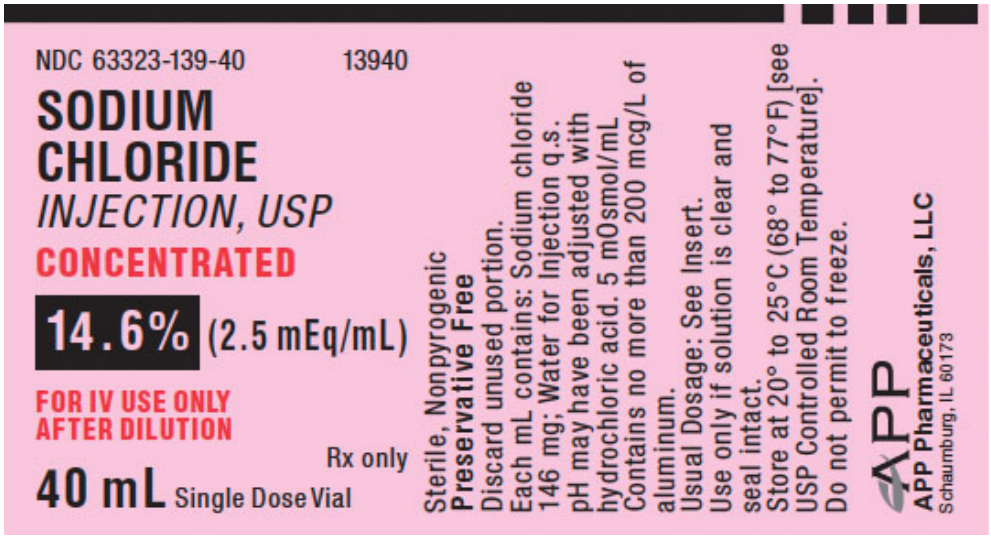
Concentrated

14.6% (2.5 mEq/mL)

For IV Use Only After Dilution

Rx only

40 mL Single Dose Vial



SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-139
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	146 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63323-139-40	25 in 1 TRAY	09/06/2000	
1		40 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/06/2000	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		023648251	manufacture(63323-139)

Revised: 10/2019 Fresenius Kabi USA, LLC