SODIUM CHLORIDE- sodium chloride injection, solution
Hospira, Inc.

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.

23.4%
Sodium Chloride Injection, USP

(4 mEq/mL)

CONCENTRATE
CAUTION: MUST BE DILUTED FOR I.V. USE.

Glass Fliptop Vials

Rx only

Pharmacy Bulk Package – Not for Direct Infusion

DESCRIPTION

23.4% Sodium Chloride Injection, USP is a sterile, nonpyrogenic, concentrated solution of sodium chloride in Water for Injection, USP.

Each mL contains sodium chloride, 234 mg (4 mEq/mL). The solution contains no bacteriostat, antimicrobial agent or added buffer. The specific gravity is 1.15, and the osmolarity is 8008 mOsmol/L (calc.). The additive may contain sodium hydroxide and/or hydrochloric acid for pH adjustment. The pH is 5.0 (4.5 to 7.0).

Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water. The molecular weight is 58.44.

The Pharmacy Bulk Package is a sterile dosage form which contains multiple single doses for preparation of admixtures for intravenous infusion (see DOSAGE AND ADMINISTRATION, Directions for Dispensing).

CLINICAL PHARMACOLOGY

Sodium chloride is an electrolyte replenisher. Sodium is the principal cation of extracellular fluid. With a normal plasma concentration of 142 mEq/L, sodium comprises more than 90% of the total plasma cations. While sodium can diffuse across membranes, the intracellular sodium concentration is maintained at a much lower level than extracellular concentrations-the so-called “sodium pump”. Compensation for loss of intracellular potassium occurs through an increase in intracellular sodium. Sodium is the principal ion that determines osmotic pressure of interstitial fluids and the degree of tissue hydration.

Adult serum chloride values typically range from 100 to 106 mEq/L. Serum chloride levels decrease in metabolic alkalosis, as serum bicarbonate levels generally increase. In parenteral nutrition when acidosis occurs, it is common practice to reduce chloride intake by substituting acetate salts in place of chloride salts.

Normal salt intake ranges from 5 g to 15 g/day, most of which is excreted by the kidneys. Control of

water and salt excretion is very intricate, involving filtration by the glomerulus and reabsorption by the tubules of approximately 99% of the filtered load. The actual quantities excreted depend upon the requirements prevailing at the moment. Finer adjustments of the tubular absorptive mechanisms are influenced by osmotic interrelationships between cell water, plasma and urine, and by certain steroid hormones influencing electrolyte excretion and the posterior pituitary hormone regulating water excretion. When food intake ceases or salt is withheld, the urine content of sodium chloride diminishes rapidly so that body stores are conserved. Similar renal retention of electrolytes occurs when salt is lost via vomiting. However, in other conditions, the kidneys fail to eliminate sufficient sodium. Examples include congestive heart failure, cirrhosis, nephritis, or hypersecretion of the adrenal cortical hormones. The result is retention of both salt and water, producing an excessive accumulation of extracellular fluid, which may be effectively treated by restricting salt intake and use of a diuretic.

Symptoms of sodium chloride deficiency include nausea, vomiting, and increased muscle irritability manifested by cramps, and possibly convulsions. It is recognized that excessive sweating can cause “heat cramps”–muscle cramps in the abdomen and extremities, which can be relieved completely by ingestion of a weak salt solution. Other causes of salt depletion include overzealous treatment of fluid and sodium retention, diabetic acidosis, burns, excessive sweating with free drinking of water, repeated paracentesis for removal of ascitic fluid, adrenal cortical hypofunction and certain forms of nephritis, as well as abnormal loss of gastrointestinal secretions. Reduction in the osmotic pressure of extracellular fluid accompanies salt loss. Urine volume may be maintained, but urine is hypo-osmolar secondary to salt conservation by the renal tubules.

INDICATIONS AND USAGE

23.4% Sodium Chloride Injection, USP is indicated for use as an electrolyte replenisher in parenteral fluid therapy. It serves as an intravenous sodium supplement in hyponatremia or low salt syndrome, as an additive for total parenteral nutrition (TPN) and as an additive for carbohydrate-containing I.V. fluids.

Toxicity secondary to intestinal obstruction is usually accompanied by a marked reduction in serum chloride, and sodium chloride supplements can have a lifesaving effect. Symptoms of sodium chloride deficiency are very similar to those of Addison’s disease, and large doses of sodium chloride will produce temporary alleviation of symptoms. Other disorders where sodium chloride is of clinical benefit include extensive burns, failure of gastric secretion and postoperative intestinal paralysis.

CONTRAINDICATIONS

Sodium chloride supplements are contraindicated in hypernatremic and fluid retention syndromes. Surgical patients should seldom receive salt-containing solutions immediately following surgery unless factors producing salt depletion are present. Because renal retention of salt occurs during surgery, additional electrolytes given intravenously may result in fluid retention, edema and circulatory overload.

WARNINGS

23.4% Sodium Chloride Injection, USP is hypertonic and must be diluted prior to administration. Inadvertent direct injection or absorption of concentrated sodium chloride solution may give rise to sudden hypernatremia and such complications as cardiovascular shock, central nervous system disorders, extensive hemolysis, cortical necrosis of the kidneys and severe local tissue necrosis (if administered extravascularly).

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.

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.

PRECAUTIONS

General – Excessive amounts of sodium chloride by any route may cause hypokalemia and acidosis. Excessive amounts by the parenteral route may precipitate congestive heart failure and acute pulmonary edema, especially in patients with cardiovascular disease and in patients receiving corticosteroids or corticotropin or drugs that may give rise to sodium retention. Special caution should be used in administering sodium-containing solutions to patients with severe renal impairment, cirrhosis of the liver 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. Do not use unless the solution is clear and seal is intact.

Drug Interactions – Additives may be incompatible with the fluid dispensed from this container. Consult with pharmacist, if available. When compounding admixtures, use aseptic technique, mix thoroughly and do not store.

Pregnancy Category C – Animal reproduction studies have not been conducted with 23.4% Sodium Chloride Injection, USP. 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.

Nursing Mothers – It is not known whether 23.4% Sodium Chloride Injection, USP is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sodium chloride is administered to a nursing woman.

Pediatric Use – Safety and effectiveness of 23.4% Sodium Chloride Injection, USP have not been established in pediatric patients. Its limited use in pediatric patients has been inadequate to fully define proper dosage and limitations for use.

ADVERSE REACTIONS

Sodium overload can occur with intravenous infusion of excessive amounts of sodium-containing solutions. See WARNINGS and PRECAUTIONS.

Overzealous administration can result in edema and symptoms resembling congestive heart failure. Signs of postoperative salt intolerance include cellular dehydration, weakness, disorientation, anorexia, nausea, distention, deep respiration, oliguria and increased blood urea nitrogen.

OVERDOSAGE

Excessive administration of 23.4% Sodium Chloride Injection, USP may result in electrolyte imbalance

with water retention, edema, loss of potassium and aggravation of an existing acidosis.

Excessive sodium chloride intake is accompanied by excretion of crystalloids, in an attempt to maintain normal osmotic pressure. Increased excretion of potassium and bicarbonate can result in acidosis. There is also a rapid elimination of any foreign salt, such as iodide and bromide, being used therapeutically.

DOSAGE AND ADMINISTRATION

23.4% Sodium Chloride Injection, USP is administered intravenously, but only after dilution in a larger volume of fluid. Maintenance electrolyte solutions usually contain sodium at a concentration of 33 to 40 mEq/L, on the assumption the patient will receive two to three liters of fluid/day. A typical oral salt intake of 10 g/day is equivalent to 171 mEq/day. But intake can range from 5 to15 g of sodium chloride/day, and patients on a sodium-restricted diet may receive 1 to 2 g of sodium/day. The actual dose of sodium chloride administered depends upon specific patient requirements, which are usually determined by review of serial blood samples and clinical evaluation. In solutions for total parenteral nutrition (TPN), adults typically receive 120 mEq of sodium/day (range: 75-180 mEq/day), whereas preterm infants receive 3-4 mEq/kg/day.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless solution is clear and seal is intact. Discard unused portion.

Directions for Proper Use of Pharmacy Bulk Package

Use Aseptic Technique

1. For hanger application, peel off the paper liner from both ends of the tape hanger to expose 3/4 in. long adhesive portions. Adhere each end to the label on the bottle.
2. During use, container must be stored and all manipulations performed in an appropriate laminar flow hood.
3. Remove cover from container and cleanse closure with antiseptic.
4. Insert suitable sterile dispensing set or transfer device and suspend unit in a laminar flow hood. The closure should be entered only once and after initial entry, the withdrawal of container contents should be completed promptly in one continuous operation. Should this not be possible, a maximum time of 4 hours from initial closure puncture is permitted to complete fluid transfer operations; i.e., discard container no later than 4 hours after initial closure puncture.
5. Sequentially dispense aliquots of 23.4% Sodium Chloride Injection, USP into I.V. containers using appropriate transfer device. During fluid transfer operations, the Pharmacy Bulk Package should be maintained under the storage conditions recommended in the labeling.

HOW SUPPLIED

23.4% Sodium Chloride Injection, USP (4 mEq/mL) is supplied as follows:

List No.	Type Container	Size	Concentration
1141	Pharmacy Bulk Package – glass, Fliptop Vial	100 mL	4mEq/mL

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

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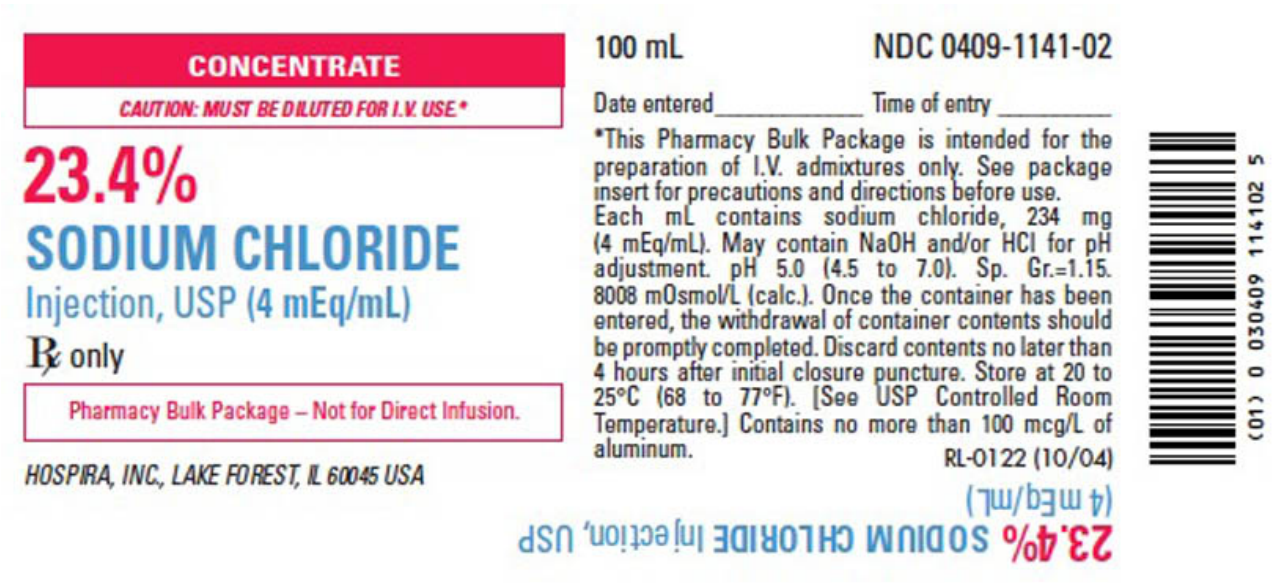

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-1141
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	234 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0409-1141-02	25 in 1 CASE		
1		100 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		04/30/2005	

Labeler - Hospira, Inc. (141588017)

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