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.

Pregnancy - 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.

Geriatric Use - An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

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. See WARNINGS.

DOSAGE AND ADMINISTRATION

23.4% Sodium Chloride Injection, USP Additive Solution 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. In solutions for total parenteral nutrition (TPN), 120 mEq of sodium/day (range: 75-180 mEq/day) is the recommended adult dosage, whereas the recommended dosage is 3-4 mEq/kg/day for preterm infants.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard unused portion.

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

Directions for Proper Use of Pharmacy Bulk Package

Use Aseptic Technique

1. During use, container must be stored and all manipulations performed in an appropriate laminar flow hood.
2. To hang the bottle use plastic hanger.
3. Remove fliptop cap from vial 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 intravenous containers using appropriate transfer device. During fluid transfer operations, the Pharmacy Bulk Package should be maintained under the storage conditions recommended in the labeling.
6. Inspect solution after admixing. Discard if the solution is discolored or particulates are observed.

HOW SUPPLIED

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

Product Code	Unit of Sale	Strength/ Concentration	Each
918961	NDC 63323-095-61 Unit of 20	400 mEq/100 mL (4 mEq/mL)	NDC 63323-095-02 100 mL fill in a 100 mL Plastic Fliptop Vial Pharmacy Bulk Package

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

Preservative Free.

The container closure is not made with natural rubber latex.

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Maxivial®

Rx only

23.4% Sodium Chloride Injection, USP

400 mEq (4 mEq/mL)

Additive Solution

Plastic Fliptop Vials

PHARMACY BULK PACKAGE-
Not For Direct Infusion

CONCENTRATE

CAUTION: MUST BE DILUTED FOR I.V. USE

Concentrated Solution - For use only after dilution with compatible intravenous fluids to correct sodium deficiency when oral replacement is not feasible.

DESCRIPTION

23.4% Sodium Chloride Injection, USP Additive Solution is a sterile, nonpyrogenic, concentrated solution for intravenous administration ONLY AFTER DILUTION to replenish electrolytes. The preparations contain 23.4 g of sodium chloride (400 mEq each of Na^+ and Cl^-) in Water for Injection, USP.

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

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

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).

CLINICAL PHARMACOLOGY

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) 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, the 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. Sodium is the principal ion that determines osmotic pressure of interstitial fluids and the degree of tissue hydration.

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 re-establish normal serum sodium concentration.

Chloride (Cl^-) 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 (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

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 additive for total parenteral nutrition (TPN) and as an additive for carbohydrate containing I.V. fluids.

CONTRAINDICATIONS

23.4% Sodium Chloride Injection, USP Additive Solution is contraindicated in patients with hypernatremia or fluid retention.

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, specifically osmotic demyelination syndrome, 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