PRESCRIBING INFORMATION

Sodium Chloride Injection, USP

Sterile Solution

Electrolyte Replenisher

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PRESCRIBING INFORMATION

Sodium Chloride Injection, USP

4000 mmol / L 4 mmol / mL

8008 mOsmol / L 8 mOsmol / mL

Not for multiple-dose use. Do not inject without dilution. Use only if solution is clear. No preservative added; the contents of the vial should be promptly used.

DESCRIPTION

Sodium Chloride Injection, USP is a sterile, nonpyrogenic, concentrated solution for intravenous administration **only after dilution** to replenish electrolytes. The preparation contains 4 mEq / mL (23.4%) 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 234 mg; Water for Injection q.s. pH may have been adjusted with hydrochloric acid. The osmolar concentration of the 4 mEq / mL solution is 8 mOsmol / mL (calculated). Sodium chloride is chemically designated NaCl, a white crystalline compound freely soluble in water.

A Pharmacy Bulk Package is a sterile dosage form containing many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion.

ACTIONS AND INDICATIONS

Sodium Chloride Injection, USP 4 mmol / mL, is indicated as an additive in parenteral fluid therapy for use in patients who have special problems of sodium electrolyte intake or excretion. It is intended to meet the specific requirement of the patient with unusual fluid and electrolyte needs. After available clinical and laboratory information is considered and correlated, the appropriate number of millimoles of Sodium Chloride Injection, USP is taken and diluted for use.

CONTRAINDICATIONS

Sodium Chloride Injection, USP is contraindicated in patients with hypernatremia or fluid retention.

WARNINGS

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.

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 per kg per day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration of TPN products and of the lock-flush solutions used in their administration.

PRECAUTIONS

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

Sodium Chloride Injection, USP 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:
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 overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. (See WARNINGS and PRECAUTIONS.)

DOSAGE AND ADMINISTRATION

The dosage of Sodium Chloride Injection, USP 4 mmol / mL, as an additive in parenteral fluid therapy is predicated on the specific requirements of the patient after necessary clinical and laboratory information is considered and correlated. The appropriate volume is then withdrawn for proper dilution. Having determined the milliequivalents of sodium chloride to be added, divide by four to calculate the number of milliliters (mL) of Sodium Chloride Injection, USP 4 mmol / mL, to be used. Withdraw this volume aseptically and transfer this additive solution into appropriate intravenous solutions such as 5% dextrose injection. The final solution should be used in its entirety within four hours. The properly diluted solutions may be given intravenously or subcutaneously.

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

AVAILABILITY OF DOSAGE FORMS

Sodium Chloride Injection, USP is supplied in single use, flip-top vials, in boxes of 25, and in Maxivial® Pharmacy Bulk Packages.

Single-dose Vial:

Product No.	Vial Size	NaCl / mL
C918930	30 mL	234 mg

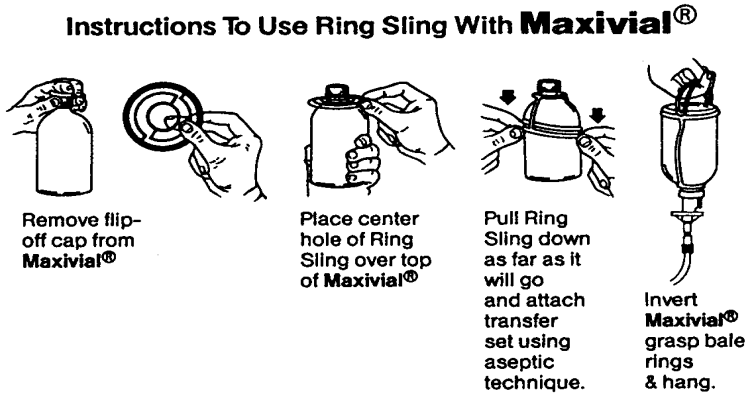
Maxivials® (Pharmacy Bulk Packages):

Product No.	Vial Size	NaCl / mL
C88B1	100 mL	234 mg
C88B2	200 mL	234 mg

Store at 15 °C to 30 °C. Protect from freezing.

DIRECTIONS FOR DISPENSING FROM MAXIVIAL® (Pharmacy Bulk Package – Not for Direct Infusion):

Pharmacy Bulk Package is a **single use** vial for pharmacy use only. Maxivial® should be inserted into the ring sling (plastic hanging device) provided, and suspended as a unit in a laminar flow hood. Entry into the vial must be made with a sterile transfer set or other sterile dispensing device and contents dispensed in aliquots using aseptic technique (see DOSAGE AND ADMINISTRATION). Use of syringe/needle is not recommended as it may cause leakage. **Any unused portion should be discarded within 24 hours after initial entry.** See graphic illustration below:



This Prescribing Information is prepared by:

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