

SODIUM CHLORIDE Injection, USP

Flexible Plastic Container

APPROVED

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DESCRIPTION

Sodium Chloride Injection, USP solutions are sterile and nonpyrogenic. They are parenteral solutions containing various concentrations of sodium chloride in water for injection intended for intravenous administration.

For 0.45% Sodium Chloride Injection, USP, each 100 mL contains 450 mg sodium chloride in water for injection. Electrolytes per 1000 mL: sodium 77 mEq; chloride 77 mEq. The osmolarity is 154 mOsmol/L (calc.).

For 0.9% Sodium Chloride Injection, USP, each 100 mL contains 900 mg sodium chloride in water for injection. Electrolytes per 1000 mL: sodium 154 mEq; chloride 154 mEq. The osmolarity is 308 mOsmol/L (calc.).

The pH for both concentrations in the 100 mL and smaller containers is 6.0; for the 250 mL and larger containers, the pH is 5.6. The pH range is 4.5 to 7.0 for all containers.

The solutions contain no bacteriostat, antimicrobial agent or added buffer and each is intended only as a single-dose injection. When smaller doses are required the unused portion should be discarded.

The solutions are parenteral fluid and electrolyte replenishers.

Sodium Chloride, USP is chemically designated NaCl, a white crystalline powder freely soluble in water.

Water for Injection, USP is chemically designated H₂O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials. Exposure to temperatures above 25°C (77°F) during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

When administered intravenously, these solutions provide a source of water and electrolytes.

Solutions which provide combinations of hypotonic or isotonic concentrations of sodium chloride are suitable for parenteral maintenance or replacement of water and electrolyte requirements.

Isotonic concentrations of sodium chloride are suitable for parenteral replacement of chloride losses that exceed or equal the sodium loss. Hypotonic concentrations of sodium chloride are suited for parenteral maintenance of water requirements when only small quantities of salt are desired. A hypertonic concentration of sodium chloride may be used to repair severe salt depletion syndrome.

Sodium chloride in water dissociates to provide sodium (Na⁺) and chloride (Cl⁻) ions. Sodium (Na⁺) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. 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.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirements range from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na⁺) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

Intravenous solutions containing sodium chloride are indicated for parenteral replenishment of fluid and sodium chloride as required by the clinical condition of the patient.

CONTRAINDICATIONS

None known.

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.

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

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

The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

PRECAUTIONS

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.

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies have not been performed with Sodium Chloride Injection, USP to evaluate the potential for carcinogenesis, mutagenesis or impairment of fertility.

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.

Nursing Mothers: Caution should be exercised when Sodium Chloride Injection, USP is administered to a nursing woman.

Pediatric Use: The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

DOSAGE AND ADMINISTRATION

The dose is dependent upon the age, weight and clinical condition of the patient.

Drug Interactions

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

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

INSTRUCTIONS FOR USE

To Open

Tear outer wrap at notch and remove solution container. If

supplemental medication is desired, follow directions below before preparing for administration. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

To Add Medication

1. Prepare additive port.
2. Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area, inner diaphragm and inject. Withdraw needle after injecting medication.
3. The additive port may be protected by covering with an additive cap.
4. Mix container contents thoroughly.

**Preparation for Administration
(Use aseptic technique)**

1. Close flow control clamp of administration set.
2. Remove cover from outlet port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated. **NOTE:** See full directions on administration set carton.
4. Suspend container from hanger.
5. Squeeze and release drip chamber to establish proper fluid level in chamber.
6. Open flow control clamp and clear air from set. Close clamp.
7. Attach set to venipuncture device. If device is not indwelling, prime and make venipuncture.
8. Regulate rate of administration with flow control clamp.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

Sodium Chloride Injection, USP is supplied in single-dose flexible plastic containers in various sizes and concentrations as shown in the accompanying Table.

| List No. | Product | Container size mL | | | | | |
|----------|---------------------------------|-------------------|----|-----|-----|-----|----------|
| | | 25 | 50 | 100 | 150 | 250 | 500 1000 |
| 7985 | 0.45% Sodium Chloride Inj., USP | | | | | X | X X |
| 7730* | 0.45% Sodium Chloride Inj., USP | X | X | X | | | |
| 7983 | 0.9% Sodium Chloride Inj., USP | | | | X | X X | X X |
| 7984* | 0.9% Sodium Chloride Inj., USP | X | X | X | | | |

*ADDS (Abbott Drug Delivery System) is the designation for the 25 mL, 50 mL and 100 mL diluent sizes of 0.9% Sodium Chloride Injection, USP, 0.45% Sodium Chloride Injection, USP and 5% Dextrose Injection, USP in plastic containers, which are used to administer supplemental drug admixtures intravenously.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C).