Sodium Chloride Injection, USP
Flexible Plastic Container

DESCRIPTION
Sodium Chloride Injection, USP solutions are sterile and nonpyrogenic. These solutions consist of crystalline 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 (NaCl); for 0.9% Sodium Chloride Injection, USP, each 100 mL contains 900 mg sodium chloride (NaCl) in water for injection. Solutions for percutaneous use contain 154 mEq sodium chloride (NaCl) in 1000 mL; 158 mEq sodium chloride (NaCl) in 1500 mL; and 208.8 mEq sodium chloride (NaCl) in 2000 mL. The pH for both concentrations in the 100 mL and smaller containers is 5.8, while the pH for the 1500 mL to 2000 mL containers is 5.5. The injection is clear and colorless.

The solutions are parenteral fluid and electrolyte replenishers. The solutions are 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 plastic container may leach out certain chemicals 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. Sodium chloride injection solutions are isotonic, or hypotonic, when compared to plasma. Potassium chloride solutions are hypotonic with respect to plasma. Sodium chloride injection solutions are isotonic to plasma; however, they are hypotonic with respect to extracellular fluid. Sodium chloride injection solutions provide a source of sodium and chloride ions, and potassium chloride injection solutions provide a source of potassium ions.

The osmolarity of the solutions is 154 mOsmol/L (calc.) for 0.9% Sodium Chloride Injection, USP and 136 mOsmol/L (calc.) for 0.45% Sodium Chloride Injection, USP. The pH for both concentrations in the 100 mL and smaller containers is 6.0; in the larger containers, the pH is 5.8.

The pH of dilution is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload and osmotic diuresis is directly proportional to the electrolyte concentrations of the injections. In patients with described renal failure, administration of Sodium Chloride Injection, USP may result in sodium retention.

WARNINGS
Sodium Chloride Injection, USP should be used with great care (at all) in patients with cardiovascular insufficiency, severe renal insufficiency, or in clinical states in which there exists edema with sodium retention. The intravenous administration of Sodium Chloride Injection, USP can cause fluid and/or solute overload resulting in dilution of serum sodium concentrations, overhydration, congested states or pulmonary edema.

The risk of dilution is inversely proportional to the electrolyte concentration of the parent. The risk of solute overload may be decreased by dilution with a larger volume of fluid but should be proportionally decreased with the electrolyte concentration of the injections. In patients with described renal failure, administration of Sodium Chloride Injection, USP may result in sodium retention.

PRECAUTIONS
General
Do not use plastic containers in series connections. Such use will result in an endotoxin because of residual air drawn from the primary container into the secondary container is completed. Preventing intravenous solutions contained in flexible plastic containers to remove flow rates can result in an embolus if the residual air in the container is not removed.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets and the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests
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.

DRUG INTERACTIONS
Cautions must be exercised in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropins.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies have not been performed in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropins.

Pregnancy
No specific studies have been performed in the administration of Sodium Chloride Injection, USP. Sodium Chloride Injection, USP is not likely to be teratogenic.

Nursing Mothers
Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP. It is not known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity of the male. For male patients, the use of spermicides is recommended in women who are pregnant or may become pregnant, or are breast feeding. For female patients, the use of oral contraceptives is recommended. It is not likely to be teratogenic.

Other reported clinical experience has not identified differences in responses 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 drug therapy. This drug is not appreciably excreted by the kidney, and the risk of toxic reactions to its drugs may be greater in patients with impaired renal function. 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. 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 drug therapy.

Overdosage
The intravenous administration of Sodium Chloride Injection, USP can lead to dilutional states and in severe cases to pulmonary edema. The risk of dilution is inversely proportional to the electrolyte concentration of the injection. The risk of solute overload may be decreased by dilution with a large volume of fluid but should be proportionally decreased with the electrolyte concentration of the injection. The risk of dilution is inversely proportional to the electrolyte concentration of the injections.

In addition to the above listed adverse reactions hyponatremia has been reported for 0.45% Sodium Chloride Injection, USP (see Pediatric Use section).

OVERDOSAGE
In the event of overexposure 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, as well as the results of laboratory tests. It should be noted that the administration of hypotonic solutions tends to dilute the patient's electrolyte concentrations.

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

Preparation for Administration
(Use aseptic technique)
1. Close flow 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 container.
4. Suspend container from holder.
5. Square each and release滴速器 to establish proper fluid flow in chamber.
7. Attach set to venouspuncture device if device is not indwelling, prime with necessary amount of solution.
8. Regulate rate of administration with flow control clamp.

WARNING: Do not use flexible container in series connections. This drug is isotonic or hypotonic to plasma and blood. (See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.)

INDICATIONS AND USAGE
Sodium Chloride Injection, USP is indicated for parenteral replenishment of fluid and sodium chloride as required by the clinical condition of the patient.

CONTRAINDICATIONS
None known.

Pediatric Use
The use of Sodium Chloride Injection, USP in pediatric patients is based on the following considerations.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids (2.4% Sodium Chloride Injection, USP) together with the non-cumulative secretions of ADH may result in hypotonic edema in infants with acute acid-base disturbances. Hypotonic edema may also occur in adult patients with congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections. The risk of solute overload may be decreased by dilution with a large volume of fluid but should be proportionally decreased with the electrolyte concentration of the injection. In addition to the above listed adverse reactions hyponatremia has been reported for 0.45% Sodium Chloride Injection, USP (see Pediatric Use section).

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