PRESCRIBING INFORMATION

0.45 % SODIUM CHLORIDE INJECTION USP

Solution, Intravenous

IV Fluid and Electrolyte Replenisher

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

0.45% Sodium Chloride Injection USP is indicated for use in adults and pediatric patients as sources of electrolytes and water for hydration.

0.45% Sodium Chloride Injection USP is also indicated as pharmaceutic aids and diluents for the infusion of compatible drug additives. Refer to prescribing information accompanying additive drugs.

0.45% Sodium Chloride Injection USP is primarily a hydrating solution and may be used to assess the status of the kidneys, since more water is provided than is required for excretion of salt. It may also be used in the treatment of hyperosmolar diabetes where the use of dextrose is inadvisable and there is a need for large amounts of fluid without an excess of sodium ions.

1.1 Pediatrics

Pediatrics (<16 years of age): For considerations of the safe use in pediatric patients, see **Warnings and Precautions, Special Populations, Pediatrics**.

1.2 Geriatrics

Geriatrics (>65 years of age): For considerations of the safe use in geriatric patients, see **Warnings and Precautions, Special Populations, Geriatrics**.

2 CONTRAINDICATIONS

0.45% Sodium Chloride Injection USP is contraindicated where the administration of sodium or chloride could be clinically detrimental.

0.45% Sodium Chloride Injection USP is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the **Dosage Form, Strengths, Composition and Packaging** section of the Prescribing Information.

3 DOSAGE AND ADMINISTRATION

0.45% Sodium Chloride Injection USP is for intravenous use only.

3.1 Dosing Considerations

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

3.2 Recommended Dose and Dosage Adjustment

There is no specific pediatric dose. The dose is dependent on weight, clinical condition and laboratory results. Follow recommendations of appropriate pediatric reference text. (See **Warnings and Precautions, Special Populations, Pediatrics**)

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

3.3 Administration

0.45% Sodium Chloride Injection USP is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact.

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

Administration with Additives
Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic technique. Mix thoroughly. **Do not store**.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

Directions for use of Excel Container

Caution: Do not use plastic containers in series connection.

To Open
Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

NOTE: Before use, perform the following checks:

- Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date.
- Invert container and carefully inspect the solution in good light for cloudiness, haze, or particulate matter. Any container, which is suspect, should not be used.
- Use only if solution is clear and container and seals are intact.

Preparation for Administration
1. Remove plastic protector from sterile set port at bottom of container.
2. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Some additives may be incompatible.

Addition of medication should be accomplished using complete aseptic technique.

To Add Medication before Solution Administration

1. Prepare medication site.
2. Using syringe with 18–22 gauge needle, puncture medication port and inner diaphragm and inject.
3. Squeeze and tap ports while ports are upright and mix solution and medication thoroughly.

To Add Medication during Solution Administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 18–22 gauge needle of appropriate length (at least 5/8 inch), puncture resealable medication port and inner diaphragm and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping and squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

4 OVERDOSAGE

In the event of a fluid or solute overload during parenteral therapy, reevaluate the patient's condition and institute appropriate corrective treatment.

5 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Each 100 mL of 0.45% Sodium Chloride Injection USP contains:

Sodium Chloride USP 0.45 g; Water for Injection USP qs

pH: 5.6 (4.5–7.0)

Calculated Osmolarity: 155 mOsmol / liter, hypotonic

pH adjusted with Hydrochloric Acid NF

Concentration of Electrolytes (mEq / liter): Sodium 77 Chloride 77

0.45% Sodium Chloride Injection USP is sterile, nonpyrogenic, isotonic and contains no bacteriostatic or antimicrobial agents.

Not made with natural rubber latex, PVC or DEHP.

The plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers and exhibits virtually no leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container solution unit is a closed system and is not dependent upon entry of external air during administration.

The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site. Refer to the **Directions for Use** of the container.

0.45% Sodium Chloride Injection USP is supplied in sterile and nonpyrogenic EXCEL Containers.

The 1000 mL container is packaged 12 per case; the 500 mL container is packaged 24 per case.

DIN	REF	SIZE
01927949	L8020-00	1000 mL
	L8021-00	500 mL

6 WARNINGS AND PRECAUTIONS

General

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

0.45% Sodium Chloride Injection USP 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 is sodium retention with edema.

0.45% Sodium Chloride Injection USP should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation.

Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.

Additional essential electrolytes, minerals and vitamins should be supplied as needed.

Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotropin, or to other salt-retaining patients. Care should be exercised in administering solutions containing sodium to patients with renal or cardiovascular insufficiency, with or without congestive heart failure, particularly if they are postoperative or elderly.

Do not use plastic containers in series connection.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result. If administration is not controlled by a pumping device, refrain from applying excessive pressure (>300mmHg) causing distortion to the container such as wringing or twisting. Such handling could result in breakage of the container.

Carcinogenesis and Mutagenesis
Studies with 0.45% Sodium Chloride Injection USP have not been performed to evaluate carcinogenic or mutagenic potential.

Monitoring and 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. Significant deviations from normal concentrations may require tailoring of the electrolyte pattern, in these or alternative solutions.

Renal
In patients with diminished renal function, administration of 0.45% Sodium Chloride Injection USP may result in sodium retention.

Sexual Health

Reproduction
Studies with 0.45% Sodium Chloride Injection USP have not been performed to evaluate effects on fertility.

6.1 Special Populations

6.1.1 Pregnant Women

There are no adequate data from the use of 0.45% Sodium Chloride Injection USP in pregnant women. Healthcare Practitioners should carefully consider the potential risks and benefits for each specific patient before administering of 0.45% Sodium Chloride Injection USP.

6.1.2 Breast-feeding

There are no adequate data from the use of 0.45% Sodium Chloride Injection USP in lactating women. Because many drugs are excreted in human milk, caution should be exercised when 0.45% Sodium Chloride Injection USP is administered with any other additives to a nursing woman.

6.1.3 Pediatrics

Safety and effectiveness of 0.45% Sodium Chloride Injection USP in pediatric patients have not been established by adequate and well controlled trials; however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

6.1.4 Geriatrics

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 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.

7 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.

The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted.

Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential.

Hypernatremia may be associated with edema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume.

If infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

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.

8 DRUG INTERACTIONS

When 0.45% Sodium Chloride Injection USP is used as a diluent for infusion of compatible drug additives, refer to dosage and administration information accompanying additive drugs.

9 ACTION AND CLINICAL PHARMACOLOGY

0.45% Sodium Chloride Injection USP provides electrolytes and is a source of water for hydration. They are capable of inducing diuresis depending on the clinical condition of the patient.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

10 STORAGE, STABILITY AND DISPOSAL

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); however, brief exposure up to 40°C does not adversely affect the product.

11 SPECIAL HANDLING INSTRUCTIONS

For single use only.

Discard any unused portion.

PART II: SCIENTIFIC INFORMATION

12 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Sodium Chloride

Chemical name: Sodium Chloride

Molecular formula and molecular mass: NaCl; 58.44

Structural formula: Na – Cl

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