SODIUM CHLORIDE- sodium chloride injection, solution
B. Braun Medical Inc.

0.9% Sodium Chloride Injection USP

DESCRIPTION

Each 100 mL of **0.9% Sodium Chloride Injection USP** contains:

Sodium Chloride USP 0.9 g; Water for Injection USP qs

pH: 5.6 (4.5-7.0)

Calculated Osmolarity: 308 mOsmol/liter

pH adjusted with Hydrochloric Acid NF

Concentration of Electrolytes (mEq/liter): Sodium 154; Chloride 154

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

The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Sodium Chloride USP	NaCl	58.44

Not made with natural rubber latex, PVC, or DEHP.

The plastic container is made from a homogenous blend of polypropylene and thermoplastic modifier specifically developed for parenteral drugs. The container is nontoxic and biologically inert. The container is a closed system and is not dependent upon entry of external air during administration.

Addition of medication should be accomplished using complete aseptic technique.

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

CLINICAL PHARMACOLOGY

Sodium Chloride Injection USP provides electrolytes and is a source of water for hydration. It is 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.

INDICATIONS AND USAGE

This intravenous solution is indicated for use in adults and pediatric patients as a source of electrolytes and water for hydration.

0.9% Sodium Chloride Injection USP is indicated for extracellular fluid replacement, treatment of metabolic alkalosis in the presence of fluid loss and mild sodium depletion.

0.9% Sodium Chloride Injection USP is also indicated for use as a priming solution in hemodialysis procedures and may be used to initiate and terminate blood transfusions without hemolyzing red blood cells.

Sodium Chloride Injection USP is also indicated as a pharmaceutic aid and diluent for the infusion of compatible drug additives. Refer to prescribing information accompanying additive drugs.

CONTRAINDICATIONS

This solution is contraindicated where the administration of sodium or chloride could be clinically detrimental.

WARNINGS

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.

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

Infusion of isotonic (0.9%) sodium chloride during or immediately after surgery may result in excessive sodium retention. Use the patient’s circulatory system status as a guide.

PRECAUTIONS

General

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.

This solution 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.

Infusion of more than one liter of isotonic (0.9%) sodium chloride per day may supply more sodium and chloride than normally found in serum, and can exceed normal tolerance, resulting in hypernatremia; this may also cause a loss of bicarbonate ions, resulting in an acidifying effect.

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.

Do not use plastic container 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.

This solution 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Sodium Chloride Injection USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy

- Teratogenic Effects

Animal reproduction studies have not been conducted with Sodium Chloride Injection USP. It is also not known whether Sodium Chloride Injection USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection USP should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Chloride Injection USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of sodium chloride injections 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.

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 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

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.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

This solution is for intravenous use only.

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.

In the average adult, daily requirements of sodium and chloride are met by the infusion of one liter of 0.9% sodium chloride (154 mEq each of sodium and chloride).

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 **PRECAUTIONS, *Pediatric Use.***)

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

0.9% Sodium Chloride Injection USP may also be administered intravascularly as a priming fluid in hemodialysis procedures.

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

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

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

HOW SUPPLIED

Sodium Chloride Injection USP is supplied sterile and nonpyrogenic in Plastic Containers packaged 12 per case.

NDC	REF	Size
0264-7800-09	E8000	1000 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.]

Directions for Use of Plastic Container

Caution: Do not use plastic container in series connection.

To Open

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.

To Add Medication Before Solution Administration

1. Prepare medication site by removing the additive port closure. Swab the exposed medication site before puncturing.
2. Using syringe with 18-22 Ga. 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 by removing the additive port closure. Swab the exposed medication site before puncturing.
3. Using syringe with 18-22 Ga. 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.

Revised: December 2022

LD-436-4 Y36-003-070

Package Insert

Rx only

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

PRINCIPAL DISPLAY PANEL

0.9% Sodium Chloride Injection USP

REF E8000
NDC 0264-7800-09

1000 mL

Each 100 mL contains:
Sodium Chloride USP 0.9 g
Water for Injection USP qs

pH adjusted with HCl NF
pH: 5.6 (4.5-7.0)

Calc. Osmolarity: 308 mOsmol/liter
Electrolytes (mEq/liter): Na^+ 154 Cl^- 154
Sterile. Single dose container.
For intravenous use only.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Avoid excessive heat. Protect from freezing. See Package Insert.

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

Not made with natural rubber latex, DEHP, or PVC.

Rx only

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

Y38-000-073 LD-362-7

ADD SET

LOT

EXP

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-7800
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.9 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0264-7800-09	12 in 1 CASE	12/31/2013	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019635	12/31/2013	

Labeler - B. Braun Medical Inc. (002397347)

Establishment

Name	Address	ID/FEI	Business Operations
B. Braun US Pharmaceutical Manufacturing LLC		037425308	label(0264-7800) , manufacture(0264-7800) , pack(0264-7800)

Revised: 5/2024 B. Braun Medical Inc.