SODIUM CHLORIDE- sodium chloride injection, solution
Baxter Healthcare Corporation

3% and 5% Sodium Chloride Injection, USP

DESCRIPTION

3% and 5% Sodium Chloride Injection, USP is a sterile, nonpyrogenic, hypertonic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. The pH may have been adjusted with hydrochloric acid. It contains no antimicrobial agents. Composition, ionic concentration, osmolarity, and pH are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)	Ionic Concentration (mEq/L)		*Osmolarity (mOsmol/L) (calc)	pH
		Sodium Chloride, USP (NaCl)	Sodium	Chloride		
3% Sodium Chloride Injection, USP	500	30	513	513	1027	5.0 (4.5 to 7.0)
5% Sodium Chloride Injection, USP	500	50	856	856	1711	5.0 (4.5 to 7.0)

* Normal physiological osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

3% and 5% Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

3% and 5% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

CONTRAINDICATIONS

None known

WARNINGS

3% and 5% Sodium Chloride Injection, USP is strongly hypertonic and may cause vein damage.

3% and 5% 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 exists edema with sodium retention.

In patients with diminished renal function, administration of 3% and 5% Sodium Chloride Injection, USP may result in sodium retention.

GENERAL 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 3% and 5% Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with 3% and 5% Sodium Chloride Injection, USP. It is also not known whether 3% and 5% Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 3% and 5% Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of 3% and 5% Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of sodium chloride 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

Clinical studies of 3% and 5% Sodium Chloride Injection, USP, did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the 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 known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug 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.

Do not administer unless solution is clear and seal is intact.

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.

HOW SUPPLIED

3% and 5% Sodium Chloride Injection, USP in VIAFLEX plastic container is available as follows:

Code	Size (mL)	NDC	Product Name
2b1353	500	0338-0054-03	3% Sodium Chloride Injection, USP
2B1373	500	0338-0056-03	5% Sodium Chloride Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of VIAFLEX Plastic Container

Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open

Tear overwrap down side at slit and remove solution container. 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. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by 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.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0054
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Chloride (UNII: 451W47IQ8X) (Sodium Chloride - UNII:451W47IQ8X)		3 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0338-0054-03	500 mL in 1 BAG		

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0056
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Chloride (UNII: 451W47IQ8X) (Sodium Chloride - UNII:451W47IQ8X)		5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0056-03	500 mL in 1 BAG		

Labeler - Baxter Healthcare Corporation

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