

SODIUM CHLORIDE- sodium chloride injection, solution
Baxter Healthcare Corporation

Sodium Chloride Injection, USP
in VIAFLEX Plastic Container

DESCRIPTION

Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. The nominal pH is 5.0 (4.5 to 7.0). Composition, osmolarity, and ionic concentration are shown below:

0.45% Sodium Chloride Injection, USP contains 4.5 g/L Sodium Chloride, USP (NaCl) and is hypotonic with an osmolarity of 154 mOsmol/L (calc). It contains 77 mEq/L sodium and 77 mEq/L chloride.

0.9% Sodium Chloride Injection, USP contains 9 g/L Sodium Chloride, USP (NaCl) with an osmolarity of 308 mOsmol/L (calc). It contains 154 mEq/L sodium and 154 mEq/L chloride.

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

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

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

0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.

CONTRAINDICATIONS

None known.

WARNINGS

Hypersensitivity

Hypersensitivity and infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus have been reported with 0.9% Sodium Chloride Injection, USP and may occur with 0.45% Sodium Chloride Injection, USP.

Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Electrolyte Imbalances

Fluid Overload

Depending on the volume and rate of infusion, and the patient's underlying clinical condition, the intravenous administration of Sodium Chloride Injection, USP can cause fluid disturbances such as overhydration/hypervolemia and congested states, including pulmonary congestion and edema.

Avoid 0.9% Sodium Chloride Injection, USP in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations, and acid base balance, as needed and especially during prolonged use.

Hyponatremia

Sodium Chloride Injection, USP may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk of hospital-acquired hyponatremia is increased in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH) treated with high volume of Sodium Chloride Injection, USP.

The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). See **DRUG INTERACTIONS**.

Patients at increased risk for developing complications of hyponatremia such as hyponatremic encephalopathy, include pediatric patients, women (in particular premenopausal women), patients with hypoxemia, and patients with underlying central nervous system disease. Avoid Sodium Chloride Injection, USP in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications. Brain adaptations reducing risk of cerebral edema make the brain vulnerable to injury when chronic hyponatremia is too rapidly corrected, which is known as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

Hypernatremia

Hypernatremia may occur with Sodium Chloride Injection, USP. Conditions that may increase the risk of hypernatremia, fluid overload and edema (central and peripheral),

include patients with: primary hyperaldosteronism; secondary hyperaldosteronism associated with, for example, hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis); and pre-eclampsia.

Certain medications, such as corticosteroids or corticotropin, may also increase risk of sodium and fluid retention, see **DRUG INTERACTIONS**.

Avoid Sodium Chloride Injection, USP in patients with, or at risk for, hypernatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hypernatremia is potentially dangerous with risk of serious neurologic complications. Excessively rapid correction of hypernatremia is also associated with a risk for serious neurologic complications such as osmotic demyelination syndrome (ODS) with risk of seizures and cerebral edema.

PRECAUTIONS

Patients with Severe Renal Impairment

Administration of Sodium Chloride Injection, USP in patients with or at risk of severe renal impairment, may result in hypernatremia and/or fluid overload (see **WARNINGS**). Avoid Sodium Chloride Injection, USP in patients with severe renal impairment or conditions that may cause sodium and/or potassium retention, fluid overload, or edema. If use cannot be avoided, monitor patients with severe renal impairment for development of these adverse reactions.

Drug Interactions

Other Products that Affect Fluid and/or Electrolyte Balance

Administration of Sodium Chloride Injection, USP to patients treated concomitantly with drugs associated with sodium and fluid retention may increase the risk of hypernatremia and volume overload. Avoid use of Sodium Chloride Injection, USP in patients receiving such products, such as corticosteroids or corticotropin. If use cannot be avoided, monitor serum electrolytes, fluid balance and acid-base balance.

Lithium

Renal sodium and lithium clearance may be decreased during administration of 0.45% Sodium Chloride Injection, USP. Monitor serum lithium concentrations during concomitant use.

Renal sodium and lithium clearance may be increased during administration of 0.9% Sodium Chloride Injection, USP. Monitor serum lithium concentrations during concomitant use.

Other Drugs that Increase the Risk of Hyponatremia

Administration of Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with hyponatremia may increase the risk of developing hyponatremia.

Avoid use of Sodium Chloride Injection, USP in patients receiving products, such as

diuretics, and certain antiepileptic and psychotropic medications. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids. If use cannot be avoided, monitor serum sodium concentrations.

Pregnancy

There are no adequate and well controlled studies with Sodium Chloride Injection, USP in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman. Sodium Chloride Injection, USP should be given during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

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

Pediatric Use

The use of Sodium Chloride Injection, USP in pediatric patients is based on clinical practice. (See **DOSE AND ADMINISTRATION**).

Closely monitor plasma electrolyte concentrations in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Sodium Chloride Injection, USP may result in increased serum osmolality and risk of intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy.

Geriatric Use

Geriatric patients are at increased risk of developing electrolyte imbalances. Sodium Chloride Injection, USP 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. Therefore, 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. Consider monitoring renal function in elderly patients.

ADVERSE REACTIONS

Post-Marketing Adverse Reactions

The following adverse reactions have been identified during post approval use of Sodium Chloride Injection, USP. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been reported in the post-marketing experience

during use of Sodium Chloride Injection, USP and include the following:

General disorders and administration site conditions: Infusion site erythema, injection site streaking, burning sensation, and infusion site urticaria

Hypersensitivity reactions: Hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus.

Metabolism and nutrition disorders: Hypernatremia*, hyponatremia, hyperchloremic metabolic acidosis.

Nervous System Disorders: Hyponatremic encephalopathy

* Adverse reaction of hyponatremia is only related to 0.9% Sodium Chloride Injection, USP

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

Excessive administration of:

- 0.45% Sodium Chloride Injection, USP can cause hyponatremia and hypernatremia. Both hypo- and hypernatremia can lead to CNS manifestations, including seizures, coma, cerebral edema and death.
- 0.9% Sodium Chloride Injection, USP can cause hypernatremia.
- Sodium Chloride Injection, USP can cause fluid overload (which can lead to pulmonary and/or peripheral edema). See **WARNINGS and ADVERSE REACTIONS**.

When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment.

Interventions include discontinuation of Sodium Chloride Injection, USP administration, dose reduction, and other measures as indicated for the specific clinical constellation (e.g., monitoring of fluid balance, electrolyte concentrations and acid base balance).

DOSAGE AND ADMINISTRATION

Important Preparation and Administration Instructions

- Sodium Chloride Injection, USP is intended for intravenous administration using sterile equipment.
- Prior to infusion, visually inspect the solution for particulate matter and discoloration. The solution should be clear, and there should be no precipitates. Do not administer unless solution is clear, and container is undamaged.
- To reduce the risk of air embolism, adhere to the following preparation instructions for Lactated Ringer's Injection, USP:
 - o Use a non-vented infusion set or close the vent on a vented set.
 - o Use a dedicated line without any connections (do not connect flexible

- containers in series).
- o The use of pressure infusion is **not** recommended as a method to increase flow rates. However, if pressure infusion is required, ensure that any air within the bag is fully evacuated prior to initiation of infusion.
 - o If using a pumping device to administer Sodium Chloride Injection, turn off the pump before the container is empty.
 - o Do not mix or administer 0.45% Sodium Chloride Injection, USP through the same administration set with whole blood or cellular blood components.

Dosing Information

The choice of product, dosage, volume, rate, and duration of administration is dependent upon the age, weight and clinical condition of the patient and concomitant therapy, and administration should be determined by a physician experienced in intravenous fluid therapy.

Introduction of Additives

Additives may be incompatible.

Evaluate all additions to the plastic container for compatibility and stability of the resulting preparation. Consult with a pharmacist, if available.

If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Do not store solutions containing additives. Discard any unused portion.

HOW SUPPLIED

The available sizes of each injection in VIAFLEX plastic containers are shown below:

Code	Size (mL)	NDC	Product Name
2B1313	500	0338-0043-03	0.45% Sodium Chloride Injection, USP
2B1314	1000	0338-0043-04	
2B1300	25 Quad Pack	0338-0049-10	0.9% Sodium Chloride Injection, USP
	50		
2B1306	Single pack	0338-0049-41	
2B1301	Quad pack	0338-0049-11	
2B1308	Multi pack	0338-0049-31	
	100		
2B1307	Single pack	0338-0049-48	
2B1302	Quad pack	0338-0049-18	
2B1309	Multi pack	0338-0049-38	
2B1321	150	0338-0049-01	
2B1322	250	0338-0049-02	
2B1323	500	0338-0049-03	

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F); brief exposure up to 40°C/104°F does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

For Information on Risk of Air Embolism – see **DOSAGE AND ADMINISTRATION**.

To Open

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. 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 protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

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.

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PACKAGE LABELING - PRINCIPAL DISPLAY PANEL

LOT EXP

0.9% 2B1302
NDC 0338-0049-18

**Sodium Chloride
Injection USP**

100mL SINGLE DOSE CONTAINER
EACH 100 mL CONTAINS
900 mg SODIUM CHLORIDE USP
pH 5.0 (4.5 TO 7.0) mEq/100 mL
SODIUM 15 CHLORIDE 15 OSMOLARITY
308 mOsmol/L (CALC) STERILE
NONPYROGENIC READ PACKAGE INSERT
FOR FULL INFORMATION ADDITIVES MAY
BE INCOMPATIBLE DOSAGE
INTRAVENOUSLY AS DIRECTED BY A
PHYSICIAN CAUTIONS MUST NOT BE USED
IN SERIES CONNECTIONS DO NOT USE
UNLESS SOLUTION IS CLEAR **Rx ONLY**
VIAFLEX CONTAINER PL 146 PLASTIC
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BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

LOT
EXP

2B1302
NDC 0338-0049-18

0.9% Sodium Chloride Injection USP

100 mL

Single dose container
Each 100 mL contains
900 mg Sodium Chloride USP
pH 5.0 (4.5 to 7.0) mEq/100 mL
Sodium 15 Chloride 15 Osmolarity

308 mOsmol/L (calc) Sterile
Nonpyrogenic Read package insert
for full information Additives may
be incompatible Dosage
Intravenously as directed by a
physician Cautions Must not be used
in series connections Do not use
unless solution is clear **Rx Only**
VIAFLEX container
PL 146
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Baxter International Inc

Baxter
Baxter Healthcare Corporation
Deerfield IL 60015 USA
Made in USA

LOT

EXP

2B1313
NDC 0338-0043-03

0.45% Sodium Chloride Injection USP

500 mL

EACH 100 mL CONTAINS 450 mg SODIUM CHLORIDE USP
pH 5.0 (4.5 TO 7.0) mEq/L SODIUM 77 CHLORIDE 77
HYPOTONIC OSMOLARITY 154 mOsmol/L (CALC) STERILE
NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE
INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE
WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX
THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS
DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS
SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT
STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED
IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS
CLEAR Rx ONLY STORE UNIT IN MOISTURE BARRIER
OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY
TO USE AVOID EXCESSIVE HEAT SEE INSERT

VIAFLEX CONTAINER PL 146 PLASTIC

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FOR PRODUCT INFORMATION 1-800-933-0303

Baxter

BAXTER HEALTHCARE CORPORATION

DEERFIELD IL 60015 USA

MADE IN USA

07-25-34-139

LOT EXP

281313

NDC0338-0043-03

**0.45°/o Sodium Chloride
Injection USP**

500ml

EACH 100 mL CONTAINS 450 mg SODIUM CHLORIDE USP
pH 5.0 (4.5 TO 7.0) mEq/L SODIUM CHLORIDE 77
HYPOTONIC OSMOLARITY 154 mOsmol/L (CALC) STERILE
NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE
CONSULT WITH PHARMACIST IF AVAILABLE
WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX
THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS
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TO USE AVOID EXCESSIVE HEAT SEE INSERT

VIAFLEX CONTAINER PI 146 PLASTIC

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FOR PRODUCT INFORMATION 1-800-933-0303

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DEERFIELD IL 60015 USA

MADE IN USA

07-25-34-139

SODIUM CHLORIDE			
sodium chloride injection, solution			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-0049
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:Q32Z N48698)		SODIUM CHLORIDE	9 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0049-01	150 mL in 1 BAG; Type 0: Not a Combination Product	12/09/1970	09/30/2015
2	NDC:0338-0049-02	250 mL in 1 BAG; Type 0: Not a Combination Product	12/09/1970	
3	NDC:0338-0049-03	500 mL in 1 BAG; Type 0: Not a Combination Product	12/09/1970	
4	NDC:0338-0049-04	1000 mL in 1 BAG; Type 0: Not a Combination Product	12/09/1970	
5	NDC:0338-0049-10	4 in 1 PACKAGE	12/09/1970	
5		25 mL in 1 BAG; Type 0: Not a Combination Product		
6	NDC:0338-0049-41	1 in 1 PACKAGE	12/09/1970	
6		50 mL in 1 BAG; Type 0: Not a Combination Product		
7	NDC:0338-0049-11	4 in 1 PACKAGE	12/09/1970	
7		50 mL in 1 BAG; Type 0: Not a Combination Product		
8	NDC:0338-0049-31	16 in 1 PACKAGE	12/09/1970	
8		50 mL in 1 BAG; Type 0: Not a Combination Product		
9	NDC:0338-0049-48	1 in 1 PACKAGE	12/09/1970	
9		100 mL in 1 BAG; Type 0: Not a Combination Product		
10	NDC:0338-0049-18	4 in 1 PACKAGE	12/09/1970	
10		100 mL in 1 BAG; Type 0: Not a Combination Product		
11	NDC:0338-0049-38	16 in 1 PACKAGE	12/09/1970	
11		100 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016677	12/09/1970	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-0043
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:Q32Z N48698)	SODIUM CHLORIDE	4.5 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0043-03	500 mL in 1 BAG; Type 0: Not a Combination Product	02/02/1979	
2	NDC:0338-0043-04	1000 mL in 1 BAG; Type 0: Not a Combination Product	02/02/1979	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018016	02/02/1979	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	ANALYSIS(0338-0043, 0338-0049) , LABEL(0338-0043, 0338-0049) , MANUFACTURE(0338-0043, 0338-0049) , PACK(0338-0043, 0338-0049) , STERILIZE(0338-0043, 0338-0049)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		189326168	ANALYSIS(0338-0049, 0338-0043) , LABEL(0338-0049, 0338-0043) , MANUFACTURE(0338-0049, 0338-0043) , PACK(0338-0049, 0338-0043) , STERILIZE(0338-0049, 0338-0043)

Establishment

Name	Address	ID/FEI	Business Operations
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Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0043, 0338-0049)
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Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		091171389	ANALYSIS(0338-0049) , MANUFACTURE(0338-0049) , LABEL(0338-0049) , PACK(0338-0049) , STERILIZE(0338-0049)

Establishment

Name	Address	ID/FEI	Business Operations
Bieffe Medital SA		464755693	ANALYSIS(0338-0049) , LABEL(0338-0049) , MANUFACTURE(0338-0049) , PACK(0338-0049) , STERILIZE(0338-0049)

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Baxter Healthcare Corporation