

**SODIUM CHLORIDE- sodium chloride injection, solution**  
**Baxter Healthcare Corporation**

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**Sodium Chloride Injection, USP**  
**in AVIVA 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 5.5 (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 flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See **DIRECTIONS FOR USE**). The primary function of the overwrap is to protect the container from the physical environment.

**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/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.

Depending on the volume and rate of infusion, the intravenous administration of Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration/hypervolemia, congested states, pulmonary edema, or acid-base imbalance. The risk of dilutive states is inversely proportional to the electrolyte concentration of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Administer with 0.9% Sodium Chloride Injection, USP with particular caution to patients with or at risk for hyponatremia, hyperchloremia, or metabolic acidosis.

The infusion of solutions with 0.45% Sodium Chloride Injection, USP may result in hyponatremia. Close clinical monitoring may be warranted. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death. The risk for hyponatremia is increased, for example, in children, elderly, women, postoperatively, in persons with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as certain antiepileptic and psychotropic medications). The risk for developing hyponatremic encephalopathy is increased, for example, in pediatric patients ( $\leq 16$  years of age), women (in particular pre-menopausal women), in patients with hypoxemia, and in patients with underlying central nervous system disease. Acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Administer Sodium Chloride Injection, USP with particular caution to patients with or at risk for hypervolemia or with conditions that may cause sodium retention, fluid overload and edema; such as patients with primary hyperaldosteronism, or secondary hyperaldosteronism [e.g., associated with hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis) or pre-eclampsia]. Certain medications may increase risk of sodium and fluid retention, see DRUG INTERACTIONS.

ADMINISTER Sodium Chloride Injection, USP with particular caution to patients with severe renal impairment. In such patients, administration of Sodium Chloride Injection, USP may result in sodium retention.

## **PRECAUTIONS**

### **General**

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air

embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Do not mix or administer 0.45% Sodium Chloride Injection, USP through the same administration set with whole blood or cellular blood components.

Rapid correction of hypo- and hypernatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in intravenous fluid therapy.

### **Drug Interactions**

Caution must be exercised in the administration of Sodium Chloride Injection, USP to patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be decreased in the presence of hyponatremia. Administration of 0.45% Sodium Chloride Injection, USP may result in increased lithium levels.

Renal sodium and lithium clearance may be increased during administration of 0.9% Sodium Chloride Injection, USP. Administration of 0.9% Sodium Chloride Injection, USP, may result in decreased lithium levels.

### **Pregnancy**

Pregnancy Category C

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 **DOSAGE AND ADMINISTRATION**).

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 (0.45% Sodium Chloride Injection, USP) together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

### **Geriatric Use**

Clinical studies of 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 the 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 other 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.

## **ADVERSE REACTIONS**

### **Post-Marketing Adverse Reactions**

The following adverse reactions have been identified during postapproval 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 0.9% Sodium Chloride Injection, USP and include the following: hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, pruritus.

Also reported are: infusion site reactions, such as infusion site erythema, injection site streaking, burning sensation, and infusion site urticarial.

The following adverse reactions have not been reported with 0.9% Sodium Chloride Injection, USP but may occur: hypernatremia, hyperchloremic metabolic acidosis, and hyponatremia, which may be symptomatic.

Hyponatremia has been reported for 0.45% Sodium Chloride Injection, USP (see **Pediatric Use** section).

The following adverse reactions have not been reported with 0.45% Sodium Chloride Injection, USP but may occur: hyperchloremic metabolic acidosis, hypersensitivity/infusion reaction (including hypotension, pyrexia, tremor, chills, urticaria, rash and pruritus), and infusion site reactions (such as infusion site erythema, injection site streaking, burning sensation, infusion site urticaria).

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 may lead to hypo- and hypernatremia, while excessive administration of 0.9% Sodium Chloride Injection, USP may lead to hypernatremia. Both hypo- and hypernatremia can lead to CNS manifestations, including seizures, coma, cerebral edema and death.

Excessive administration of Sodium Chloride Injection, USP may lead to sodium overload (which can lead to central and/or peripheral edema).

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.

## **DOSAGE AND ADMINISTRATION**

All injections in AVIVA plastic containers are intended for intravenous administration using sterile and nonpyrogenic equipment.

As directed by a physician. Dosage, rate, and duration of administration are to be individualized and depend upon the indication for use, the patient's age, weight, clinical condition, concomitant treatment, and on the patient's clinical and laboratory response to treatment.

When other electrolytes or medicines are added to this solution, the dosage and the infusion rate will also be dictated by the dose regimen of the additions.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible.

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

Additives may be incompatible with Sodium Chloride Injection, USP. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Sodium Chloride Injection, USP is appropriate. After addition, check for unexpected color changes and/or the appearance of precipitates, insoluble complexes or crystals.

The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible must not be used. When introducing additives to Sodium Chloride Injection, USP, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion. Do not reconnect any partially used containers. Discard any unused portion.

## HOW SUPPLIED

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

Code	Size (mL)	NDC	Product Name
6E1313	500	0338-6333-03	0.45% Sodium Chloride Injection, USP
6E1314	1000	0338-6333-04	
6E1356	250	0338-6333-02	
6E1322	250	0338-6304-02	0.9% Sodium Chloride Injection, USP
6E1323	500	0338-6304-03	
6E1324	1000	0338-6304-04	

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 AVIVA PLASTIC CONTAINER

For Information on Risk of Air Embolism – see **PRECAUTIONS**.

### 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.

### **Baxter Healthcare Corporation**

Deerfield, IL 60015 USA

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Mississauga, ON L5N 0C2

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For Product Information  
1-800-933-0303

**PACKAGE LABEL - PRINCIPAL DISPLAY PANEL**

LOT

EXP



**6E1324** **1**  
 NDC 0338-6304-04  
**1000 mL** **2**  
**0.9%**  
**Sodium Chloride** **3**  
**Injection USP**

EACH 100 mL CONTAINS 900 mg SODIUM **4**  
 CHLORIDE USP pH 5.5 (4.5 TO 7.0) mEq/L  
 SODIUM 154 CHLORIDE 154 OSMOLARITY 308  
 mOsmol/L (CALC) STERILE NONPYROGENIC  
 SINGLE DOSE CONTAINER ADDITIVES MAY BE **5**  
 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 **6**  
 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 AT ROOM TEMPERATURE **7**  
 (25°C/77°F) UNTIL READY TO USE AVOID  
 EXCESSIVE HEAT SEE INSERT

**Baxter**

**BAXTER HEALTHCARE CORPORATION**  
DEERFIELD IL 60015 USA  
MADE IN USA

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FOR PRODUCT INFORMATION **8**  
1-800-933-0303



**9**

LOT EXP

6E1324

NDC 0338-6304-04

1000 mL

0.9% Sodium Chloride Injection USP

EACH 100 mL CONTAINS 900 mg SODIUM  
 CHLORIDE USP pH 5.5 (4.5 TO 7.0) mEq/L  
 SODIUM 154 CHLORIDE 154 OSMOLARITY 308  
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BAXTER  
BAXTER HEALTHCARE CORPORATION  
DEERFIELD IL 60015 USA  
MADE IN USA

FOR PRODUCT INFORMATION  
1-800-933-0303

*AVIVA Logo* CONTAINER

PVC  
SOLUTION CONTACT

LATEX

DEHP  
SOLUTION  
CONTACT

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9



6E-13-24

15-1000 ML

AVIVA CONTAINER

0.9% SODIUM CHLORIDE  
INJECTION, USP

EXP  
XXXXX

SECONDARY BAR CODE

(17) YYMM00 (10) XXXXX

LOT  
XXXXX

PRIMARY BAR CODE

(01) 50303386304041

6E-13-24

15-1000 ML

AVIVA CONTAINER

0.9% SODIUM CHLORIDE  
INJECTION, USP

EXP  
XXXXX

SECONDARY BAR CODE  
(17) YYMM00 (10) XXXXX

LOT  
XXXXX

PRIMARY BAR CODE  
(01) 50303386304041

LOT

EXP

6E1314  
NDC 0338-6333-04

1000 mL

**0.45%**

# Sodium Chloride Injection USP

EACH 100 mL CONTAINS 450 mg SODIUM CHLORIDE USP pH 5.5 (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 AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT

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DEERFIELD IL 60015 USA

MADE IN USA

FOR PRODUCT INFORMATION  
1-800-933-0303

AVIVA CONTAINER



1

2

3

4

5

6

7

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9

LOT EXP

6E1314

NDC 0338-6333-04

**1000 mL**  
**0.45%**  
**Sodium Chloride**  
**Injection USP**

EACH 100 mL CONTAINS 450 mg SODIUM  
CHLORIDE USP pH 5.5 (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 AT ROOM  
TEMPERATURE (25°C/77°F) UNTIL READY TO USE  
AVOID EXCESSIVE HEAT SEE INSERT

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DEERFIELD IL 60015 USA

MADE IN USA

FOR PRODUCT INFORMATION  
1-800-933-0303

***AVIVA Logo*** CONTAINER

PVC  
SOLUTION CONTACT

LATEX

DEHP  
SOLUTION  
CONTACT

1  
2  
3  
4  
5  
6  
7  
8  
9

6E1314

15-1000 ML

AVIVA CONTAINER

0.45% SODIUM CHLORIDE  
INJECTION, USP

EXP  
XXXXX

SECONDARY BAR CODE

(17) YYMM00 (10) XXXXX

LOT  
XXXXX

PRIMARY BAR CODE

(01) 50303386333041

6E1314  
15-1000 ML  
AVIVA CONTAINER  
0.45% SODIUM CHLORIDE  
INJECTION, USP

EXP  
XXXXX

SECONDARY BAR CODE  
(17) YYMM00 (10) XXXXX

LOT  
XXXXX

PRIMARY BAR CODE  
(01) 50303386333041

**SODIUM CHLORIDE**

sodium chloride injection, solution

**Product Information**

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:0338-6333

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	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:0338-6333-02	250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0338-6333-03	500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0338-6333-04	1000 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	NDA018016	02/02/1979	

## SODIUM CHLORIDE

sodium chloride injection, solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-6304
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	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:0338-6304-02	250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0338-6304-03	500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0338-6304-04	1000 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	

**Labeler** - Baxter Healthcare Corporation (005083209)

**Establishment**

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	ANALYSIS(0338-6333, 0338-6304) , LABEL(0338-6333, 0338-6304) , MANUFACTURE(0338-6333, 0338-6304) , PACK(0338-6333, 0338-6304) , STERILIZE(0338-6333, 0338-6304)

**Establishment**

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-6333, 0338-6304)

Revised: 12/2014

Baxter Healthcare Corporation