

**SODIUM CHLORIDE- sodium chloride injection, solution**  
**Hospira, Inc.**

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**0.9% Sodium Chloride**

Injection, USP

**Carpject™ with Luer Lock**  
**Fliptop Plastic Vial**  
**LifeShield® Fliptop Plastic Vial**

*Preservative-Free*



Rx only

**DESCRIPTION**

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

0.9% Sodium Chloride Injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride and water for injection. Each mL contains sodium chloride 9 mg. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. 0.308 mOsmol/mL (calc.). 0.9% Sodium Chloride Injection, USP contains no preservatives. The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH 5.3 (4.5 to 7.0).

Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water.

The glass container is a Type I borosilicate glass and meets the requirements of the powdered glass test according to the USP standards.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

**CLINICAL PHARMACOLOGY**

Sodium chloride in water dissociates to provide sodium (Na<sup>+</sup>) and chloride (Cl<sup>-</sup>) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na<sup>+</sup>) and chloride (Cl<sup>-</sup>) are largely under the control of the kidney which maintains a balance between intake and output.

The small volume of fluid and amount of sodium chloride provided by 0.9% Sodium Chloride Injection, USP when used only as an isotonic vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in neonates and very small infants.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na<sup>+</sup>) plays a major role in maintaining physiologic equilibrium.

## **INDICATIONS AND USAGE**

This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

## **PRECAUTIONS**

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.

Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

*Pregnancy:* Animal reproduction studies have not been conducted with 0.9% Sodium Chloride Injection, USP. It is also not known whether sodium chloride injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium chloride injection containing additives should be given to a pregnant woman only if clearly needed.

*Pediatric Use:* The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

### **Drug Interactions**

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

When diluting or dissolving drugs, mix thoroughly and use promptly.

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers, discard unused portion.

## **ADVERSE REACTIONS**

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

## **OVERDOSAGE**

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of carbohydrate, sodium chloride or fluid overload except possibly in neonates or very small infants. In the event these should occur, re-evaluate the patient and institute appropriate corrective measures. See

**PRECAUTIONS** and **ADVERSE REACTIONS**.

## DOSAGE AND ADMINISTRATION

The volume of the preparation to be used for diluting or dissolving any drug for injection, is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer. This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

## HOW SUPPLIED

0.9% Sodium Chloride Injection, USP is supplied in the following:

Unit of Sale	Concentration
<b>NDC 0409-1918-32</b> Tub of 50 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System	0.9% (2 mL)
<b>NDC 0409-1918-33</b> Tub of 25 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System	0.9% (3 mL)
<b>NDC 0409-1918-35</b> Tub of 25 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System	0.9% (5 mL)
<b>NDC 0409-4888-10</b> Tray of 25 Single-dose Plastic Fliptop Vials	0.9% (10 mL)
<b>NDC 0409-4888-20</b> Tray of 25 Single-dose Plastic Fliptop Vials	0.9% (20 mL)
<b>NDC 0409-4888-50</b> Tray of 25 Single-dose Plastic Fliptop Vials	0.9% (50 mL)
<b>NDC 0409-4888-12</b> Tray of 25 Single-dose LifeShield® Plastic Fliptop Vials	0.9% (10 mL)

Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature.]

### Instructions for Use of the Syringe Systems

Instructions for using the Carpuject Syringe are available with the reusable Carpuject Holder, List 2049-02.

LIFESHIELD® is the trademark of ICU Medical, Inc. and is used under license.

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA



LAB-1097-2.0

10/2018

### PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

**10 mL** Single-dose

Rx only

**0.9% Sodium Chloride  
Injection, USP**

FOR USE AS A STERILE DILUENT.

**Hospira**

10 mL Single-dose Rx only

**0.9% Sodium Chloride  
Injection, USP**

FOR USE AS A STERILE DILUENT.



**PRESERVATIVE-FREE**

NDC 0409-4888-02

Each mL contains sodium chloride, 9 mg. May contain HCl and/or NaOH for pH adjustment. Sterile, nonpyrogenic. 0.308 mOsmol/mL (calc).

Hospira, Inc.  
Lake Forest, IL 60045 USA

RL-4492



**PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray**

10 mL Single-dose

**0.9% Sodium Chloride  
Injection, USP**

**FOR USE AS A STERILE DILUENT**

25 Units/NDC 0409-4888-10

Rx only

**Hospira**



**PRINCIPAL DISPLAY PANEL - 20 mL Vial Label**

**20 mL Single-dose**

**Rx only**

**PRESERVATIVE-FREE**

**0.9% Sodium Chloride Injection, USP**

**FOR USE AS A STERILE DILUENT.**

**Hospira**

20 mL Single-dose Rx only

**PRESERVATIVE-FREE**

NDC 0409-4888-03

# 0.9% Sodium Chloride Injection, USP

*FOR USE AS A STERILE DILUENT.*



Each mL contains sodium chloride,  
9 mg. May contain HCl and/or NaOH for  
pH adjustment. Sterile, nonpyrogenic.  
0.308 mOsmol/mL (calc).

Hospira, Inc.  
Lake Forest, IL 60045 USA RL-4493



## PRINCIPAL DISPLAY PANEL - 20 mL Vial Tray

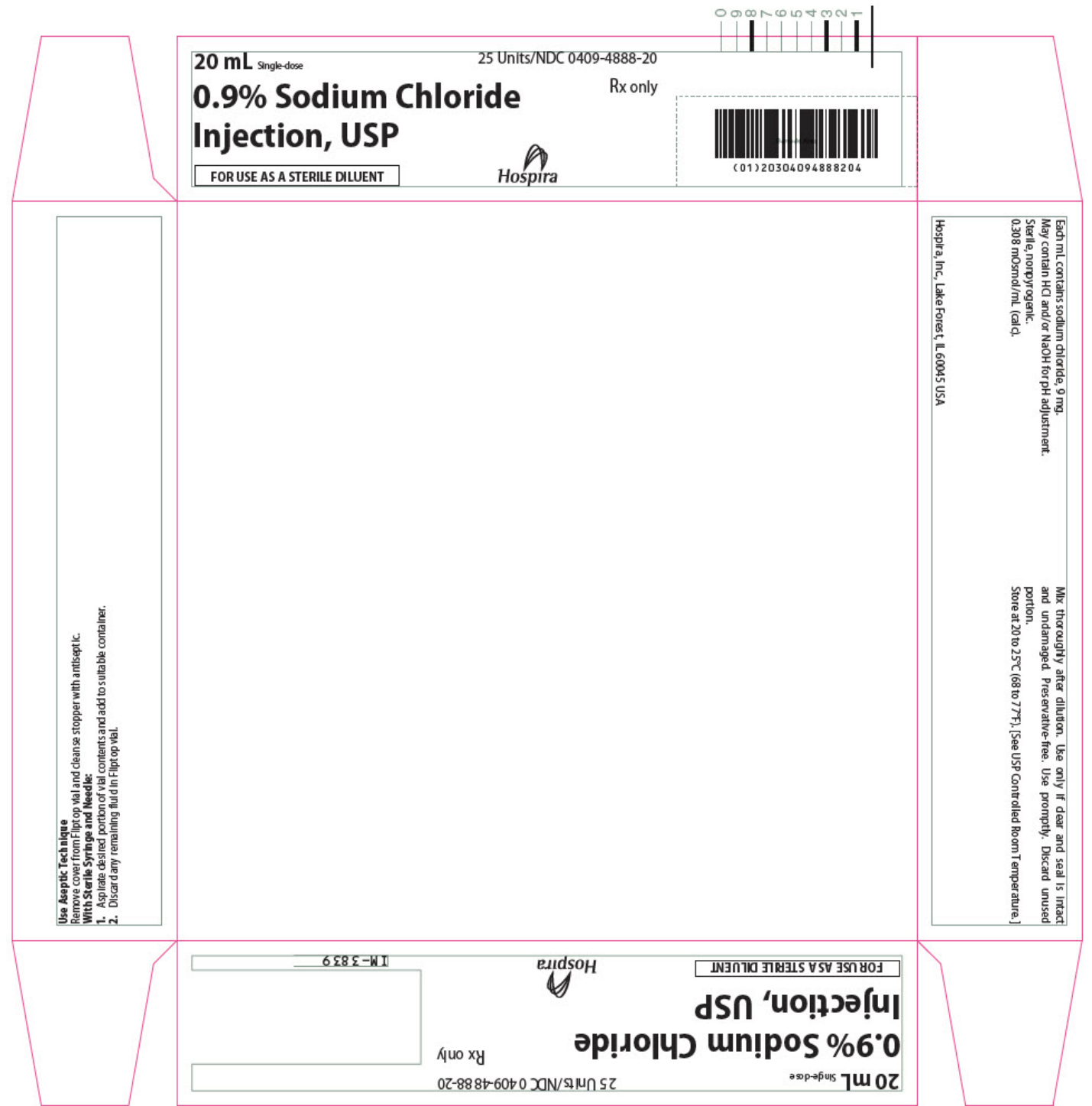
20 mL Single-dose  
25 Units/NDC 0409-4888-20

**0.9% Sodium Chloride  
Injection, USP**

Rx only

**FOR USE AS A STERILE DILUENT**

*Hospira*



**PRINCIPAL DISPLAY PANEL - 50 mL Vial Label**

50 mL Single-dose

Rx only

PRESERVATIVE-FREE

**0.9% Sodium Chloride  
Injection, USP**

*FOR USE AS A STERILE DILUENT.*

**Hospira**

50 mL Single-dose Rx only

**PRESERVATIVE-FREE**

NDC 0409-4888-06

# 0.9% Sodium Chloride Injection, USP

*FOR USE AS A STERILE DILUENT.*



Each mL contains sodium chloride, 9 mg. May contain HCl and/or NaOH for pH adjustment. Sterile, nonpyrogenic. 0.308 mOsmol/mL (calc).



Hospira, Inc.  
Lake Forest, IL 60045 USA RL-4494

## PRINCIPAL DISPLAY PANEL - 50 mL Vial Tray

50 mL Single-dose  
25 Units/NDC 0409-4888-50

### 0.9% Sodium Chloride Injection, USP

Rx only

FOR USE AS A STERILE DILUENT

*Hospira*





**PRINCIPAL DISPLAY PANEL - 10 mL Vial Label - LifeShield™**

**10 mL** Single-dose

Rx only

**LIFESHIELD™**

**Vial**

**0.9% Sodium Chloride**

**Injection, USP**

*FOR USE AS A STERILE DILUENT.*

**Hospira**

10 mL Single-dose Rx only

**PRESERVATIVE-FREE**

NDC 0409-4888-01

**LIFESHIELD™ Vial**  
**0.9% Sodium Chloride**  
**Injection, USP**

*FOR USE AS A STERILE DILUENT.*



Each mL contains sodium chloride,  
9 mg. May contain HCl and/or NaOH for  
pH adjustment. Sterile, nonpyrogenic.  
0.308 mOsmol/mL (calc).

Hospira, Inc.  
Lake Forest, IL 60045 USA      RL-4495



**PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray - LifeShield™**

10 mL Single-dose

**LIFESHIELD™**

**Vial**

**0.9% Sodium Chloride**

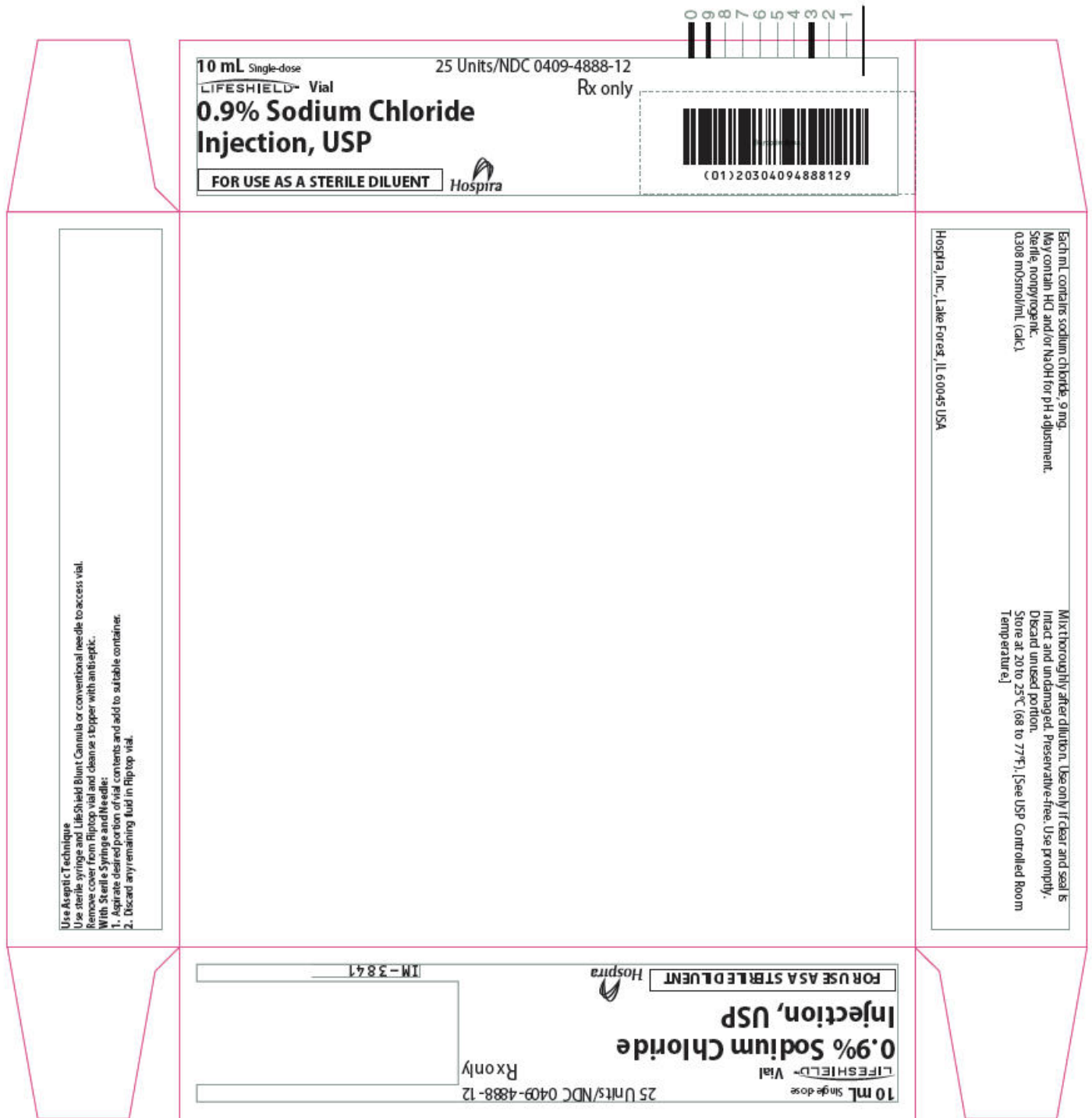
**Injection, USP**

**FOR USE AS A STERILE DILUENT**

25 Units/NDC 0409-4888-12

Rx only

*Hospira*



**PRINCIPAL DISPLAY PANEL - 2 mL Cartridge Label**

**2 mL Carpuject™  
 Sterile Cartridge Unit with Luer Lock**

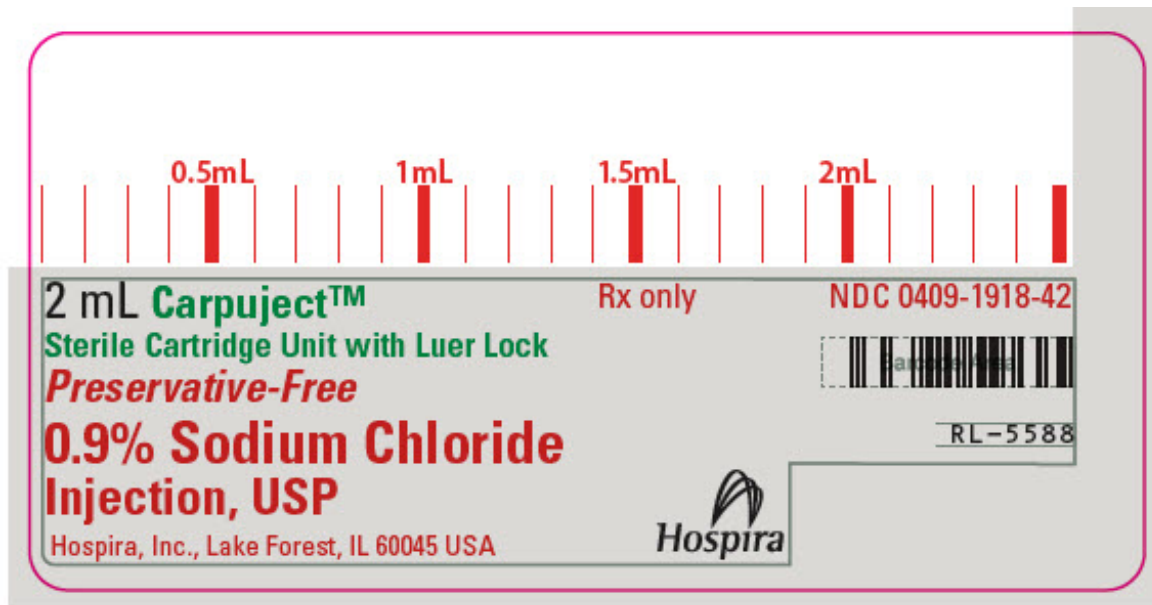
**Preservative-Free  
 0.9% Sodium Chloride  
 Injection, USP**

Hospira, Inc., Lake Forest, IL 60045 USA

Rx only  
 NDC 0409-1918-42

RL-5588

*Hospira*



**PRINCIPAL DISPLAY PANEL - 2 mL Cartridge Container Label**

2 mL

**Preservative-Free**

NDC 0409-1918-32

Rx only

**50 Carpuject™ Sterile Cartridge Units  
with Luer Lock**

Needle not included

**0.9% Sodium Chloride  
Injection, USP**

**Carpject Cartridges are to be used ONLY  
with Carpject Holders.**

Hospira, Inc., Lake Forest, IL 60045 USA

*Hospira*

2 mL Preservative-Free NDC 0409-1918-32  
Rx only

**50 Carpuject™** Sterile Cartridge Units

with Luer Lock

Needle not included

# 0.9% Sodium Chloride Injection, USP

**Carpuject Cartridges are to be used ONLY with Carpuject Holders.**

Each CARPUJECT Sterile Cartridge Unit contains 2 mL of a sterile isotonic solution of Sodium Chloride Injection, USP, 0.9%, and has a total osmolar concentration of 0.31 mOsmol/mL. Each mL contains 9 mg of sodium chloride. Do not use if solution is discolored or contains a precipitate. Sterile Aqueous Injection.

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Do not freeze.

RL-5055



(01)10304091918327

BREAK SEAL  
TO OPEN



BREAK SEAL  
TO OPEN

2 mL Preservative-Free NDC 0409-1918-32  
Rx only

**50 Carpuject™** Sterile Cartridge Units

with Luer Lock

Needle not included

# 0.9% Sodium Chloride Injection, USP

**Carpuject Cartridges are to be used ONLY with Carpuject Holders.**

Hospira, Inc., Lake Forest, IL 60045 USA



**PRINCIPAL DISPLAY PANEL - 3 mL Cartridge Label**

**3 mL Carpuject™  
Sterile Cartridge Unit with Luer Lock**

*Preservative-Free*

**0.9% Sodium  
Chloride  
Injection, USP**

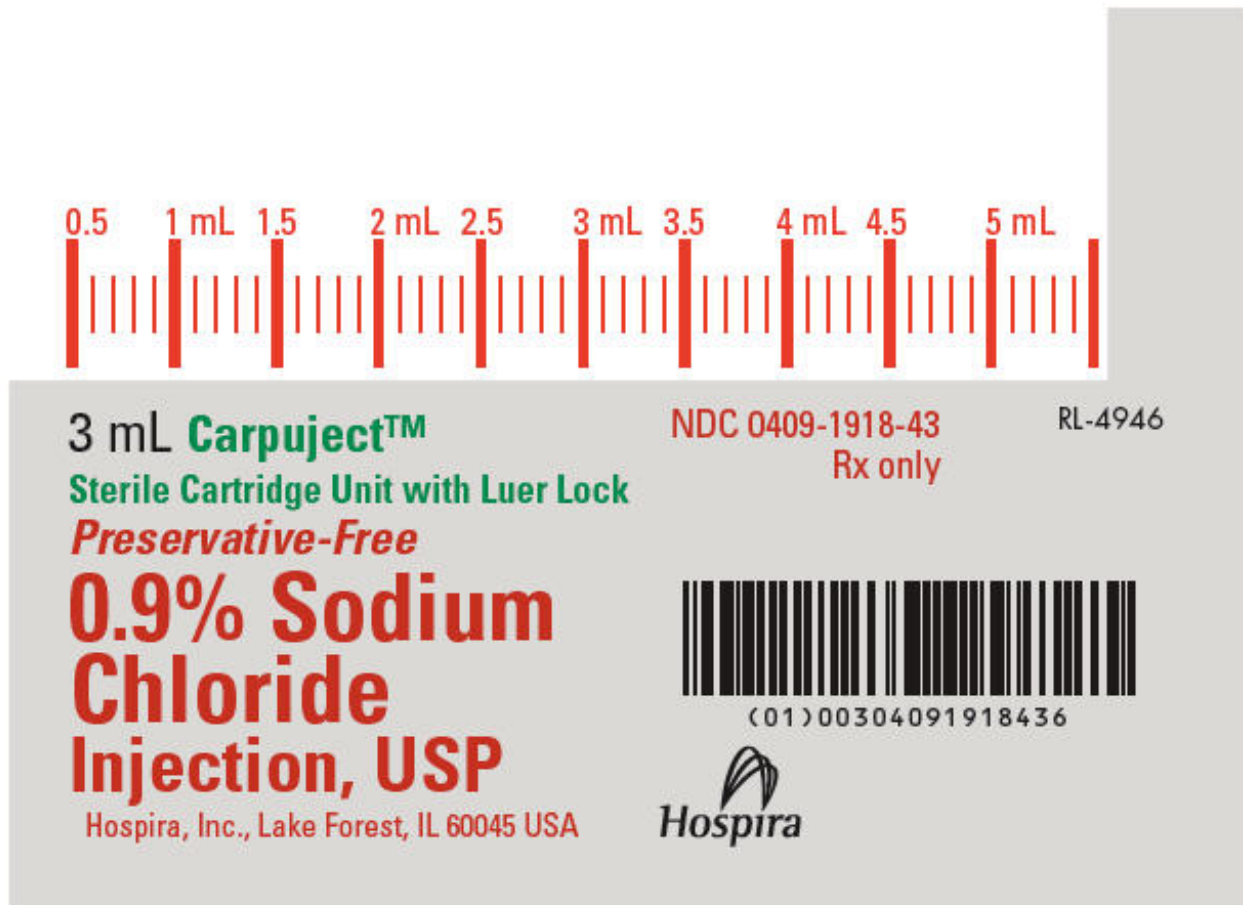
Hospira, Inc., Lake Forest, IL 60045 USA

NDC 0409-1918-43

Rx only

RL-4946

**Hospira**



**PRINCIPAL DISPLAY PANEL - 3 mL Cartridge Container Label**

3 mL

**Preservative-Free**

**25 Carpuject™ Sterile Cartridge Units  
with Luer Lock**

Needle not included

**0.9% Sodium Chloride  
Injection, USP**

**Carpuject Cartridges are to be used ONLY  
with Carpuject Holders.**

Hospira, Inc., Lake Forest, IL 60045 USA

NDC 0409-1918-33

Rx only

***Hospira***

3 mL Preservative-Free NDC 0409-1918-33

**25 Carpuject™** Sterile Cartridge Units  
with Luer Lock

Rx only

Needle not included

# 0.9% Sodium Chloride Injection, USP

**Carpject Cartridges are to be used ONLY with Carpuject Holders.**

Each CARPUJECT Sterile Cartridge Unit contains 3 mL of a sterile isotonic solution of Sodium Chloride Injection, USP, 0.9%, and has a total osmolar concentration of 0.31 mOsmol/mL. Each mL contains 9 mg of sodium chloride.

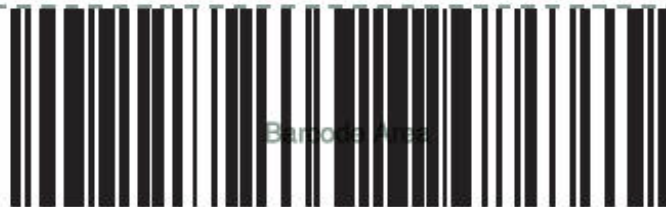
Do not use if solution is discolored or contains a precipitate.

Sterile Aqueous Injection.

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

**Do not freeze.**

RL-5056



(01)10304091918334

BREAK SEAL

BREAK SEAL



TO OPEN

TO OPEN

3 mL Preservative-Free NDC 0409-1918-33  
**25 Carpuject™** Sterile Cartridge Units Rx only  
with Luer Lock

Needle not included

**0.9% Sodium Chloride  
Injection, USP**

**Carpject Cartridges are to be used ONLY  
with Carpuject Holders.**

Hospira, Inc., Lake Forest, IL 60045 USA



**PRINCIPAL DISPLAY PANEL - 5 mL Cartridge Label**

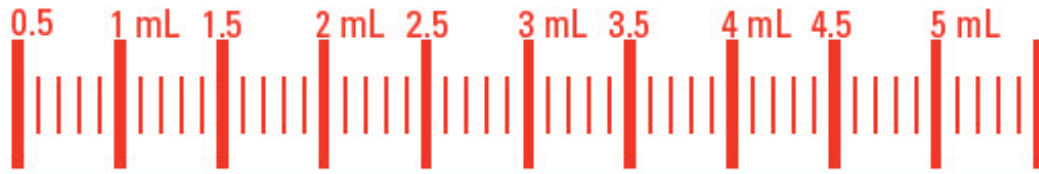
5 mL Carpuject™  
Sterile Cartridge Unit with Luer Lock

NDC 0409-1918-45  
Rx only  
RL-4947

**Preservative-Free  
0.9% Sodium  
Chloride  
Injection, USP**

Hospira, Inc., Lake Forest, IL 60045 USA

**Hospira**



5 mL **Carpujet™**  
**Sterile Cartridge Unit with Luer Lock**  
**Preservative-Free**  
**0.9% Sodium Chloride Injection, USP**

Hospira, Inc., Lake Forest, IL 60045 USA

NDC 0409-1918-45  
Rx only

RL-4947



(01)00304091918450



## PRINCIPAL DISPLAY PANEL - 5 mL Cartridge Container Label

5 mL

**Preservative-Free**

NDC 0409-1918-35

Rx only

**25 Carpujet™ Sterile Cartridge Units**

**with Luer Lock**

Needle not included

**0.9% Sodium Chloride**

**Injection, USP**

**Carpujet Cartridges are to be used ONLY  
with Carpujet Holders.**

Hospira, Inc., Lake Forest, IL 60045 USA

**Hospira**

5 mL Preservative-Free NDC 0409-1918-35  
Rx only

**25 Carpuject™** Sterile Cartridge Units  
with Luer Lock

Needle not included

# 0.9% Sodium Chloride Injection, USP

**Carpuject Cartridges are to be used ONLY with Carpuject Holders.**

Each CARPUJECT Sterile Cartridge Unit contains 5 mL of a sterile isotonic solution of Sodium Chloride Injection, USP, 0.9%, and has a total osmolar concentration of 0.31 mOsmol/mL. Each mL contains 9 mg of sodium chloride. Do not use if solution is discolored or contains a precipitate. Sterile Aqueous Injection.

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Do not freeze.

RL-5057



BREAK SEAL  
TO OPEN



BREAK SEAL  
TO OPEN

5 mL Preservative-Free NDC 0409-1918-35  
Rx only

**25 Carpuject™** Sterile Cartridge Units  
with Luer Lock

Needle not included

# 0.9% Sodium Chloride Injection, USP

**Carpuject Cartridges are to be used ONLY with Carpuject Holders.**

Hospira, Inc., Lake Forest, IL 60045 USA



## SODIUM CHLORIDE

sodium chloride injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0409-4888
<b>Route of Administration</b>	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:L4R4M0NH37)	SODIUM CHLORIDE	9 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4888-10	25 in 1 TRAY	04/30/2005	
1	NDC:0409-4888-02	10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:0409-4888-20	25 in 1 TRAY	02/28/2005	
2	NDC:0409-4888-03	20 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
3	NDC:0409-4888-50	25 in 1 TRAY	02/28/2005	
3	NDC:0409-4888-06	50 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
4	NDC:0409-4888-12	25 in 1 TRAY	07/14/2005	
4	NDC:0409-4888-01	10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018803	02/28/2005	

## SODIUM CHLORIDE

sodium chloride injection, solution

### Product Information

Item Code NDC:0409

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0409-1918
<b>Route of Administration</b>	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:L4YR4M0NH37)	SODIUM CHLORIDE	9 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-1918-32	50 in 1 CONTAINER	11/21/2005	
1	NDC:0409-1918-42	2 mL in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		
2	NDC:0409-1918-33	25 in 1 CONTAINER	02/28/2005	
2	NDC:0409-1918-43	3 mL in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		
3	NDC:0409-1918-35	25 in 1 CONTAINER	04/30/2005	
3	NDC:0409-1918-45	5 mL in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018803	02/28/2005	

**Labeler** - Hospira, Inc. (141588017)

### Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0409-4888) , LABEL(0409-4888) , MANUFACTURE(0409-4888) , PACK(0409-4888)

### Establishment

Name	Address	ID/FEI	Business Operations
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Hospira, Inc. | 030606222 | ANALYSIS(0409-1918) , LABEL(0409-1918) , MANUFACTURE(0409-1918) , PACK(0409-1918)

## Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Healthcare India Private Limited		860037912	ANALYSIS(0409-4888) , LABEL(0409-4888) , MANUFACTURE(0409-4888) , PACK(0409-4888)

Revised: 11/2018

Hospira, Inc.