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

0.9% Sodium Chloride

Injection, USP

Carpuject™ 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^+) and chloride (Cl^-) 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^+) and chloride (Cl^-) 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^+) 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
NDC 0409-1918-32 Tub of 50 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System	0.9% (2 mL)
NDC 0409-1918-33 Tub of 25 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System	0.9% (3 mL)
NDC 0409-1918-35 Tub of 25 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System	0.9% (5 mL)
NDC 0409-4888-90 Tray of 10 Single-dose Plastic Fliptop Vials	0.9% (10 mL)
NDC 0409-4888-10 Tray of 25 Single-dose Plastic Fliptop Vials	0.9% (10 mL)
NDC 0409-4888-20 Tray of 25 Single-dose Plastic Fliptop Vials	0.9% (20 mL)
NDC 0409-4888-50 Tray of 25 Single-dose Plastic Fliptop Vials	0.9% (50 mL)
NDC 0409-4888-12 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-1097-3.0

Revised: 08/2021

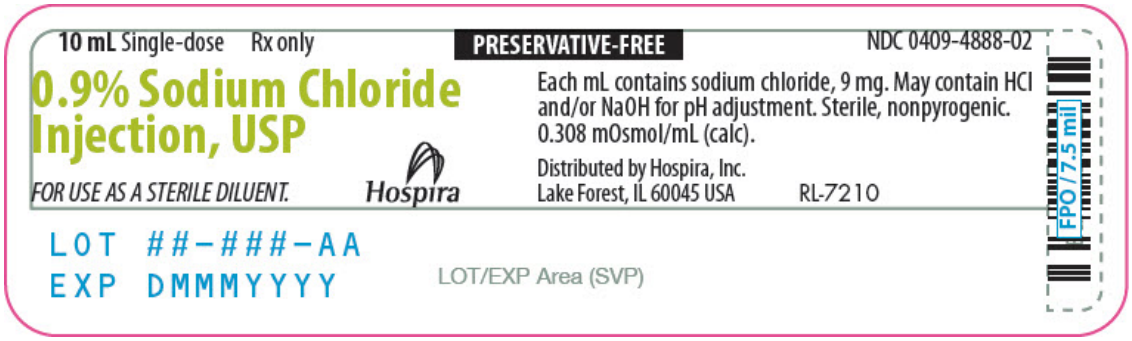
PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

10 mL Single-dose
Rx only

0.9% Sodium Chloride
Injection, USP

FOR USE AS A STERILE DILUENT.
Hospira

LOT ##-###-AA
EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray

10 mL Single-dose

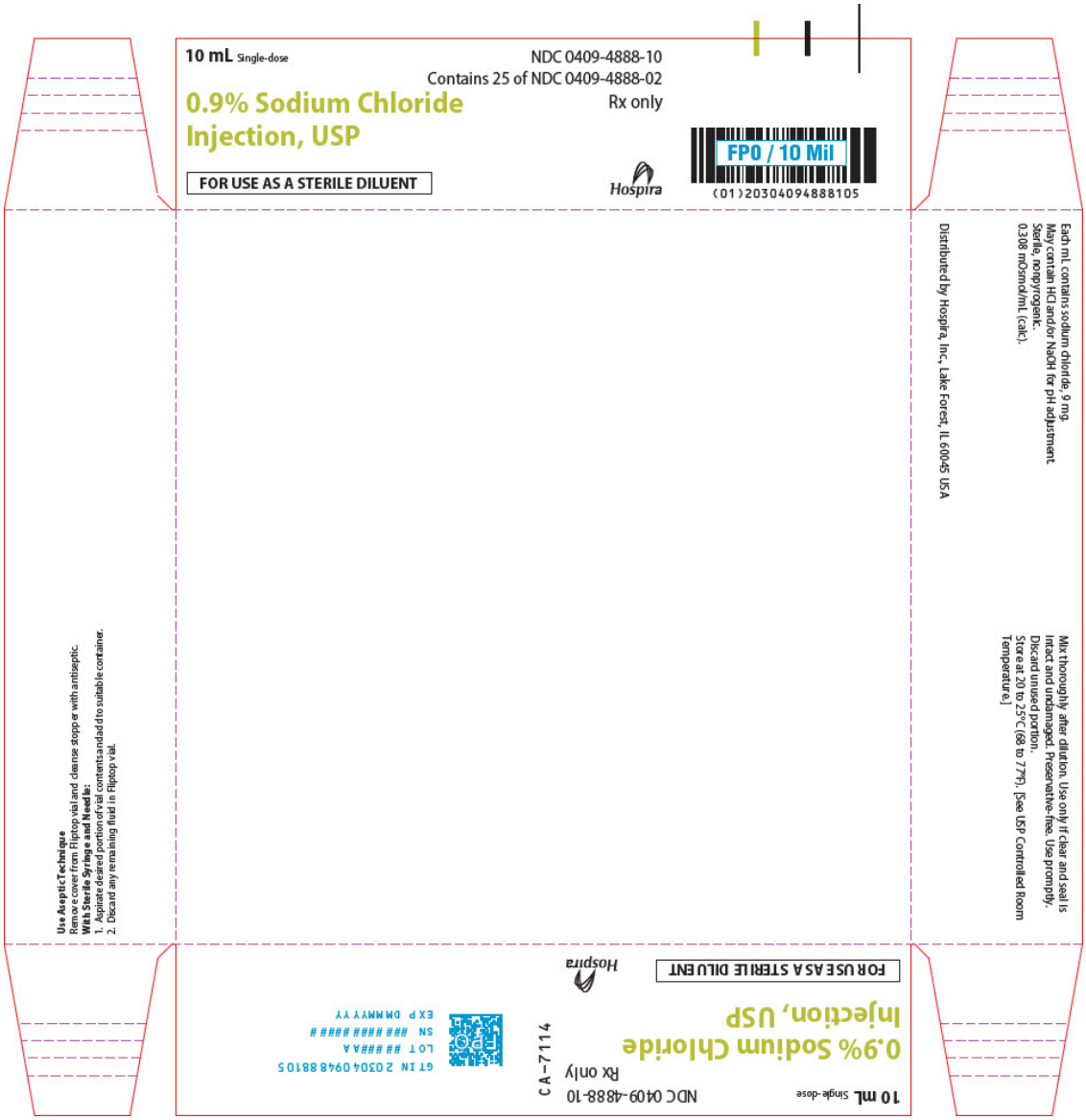
NDC 0409-4888-10
Contains 25 of NDC 0409-4888-02

Rx only

0.9% Sodium Chloride
Injection, USP

FOR USE AS A STERILE DILUENT

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

LOT ##-###-AA
EXP DMMMYYYY

PRINCIPAL DISPLAY PANEL - 20 mL Vial Tray

20 mL Single-dose

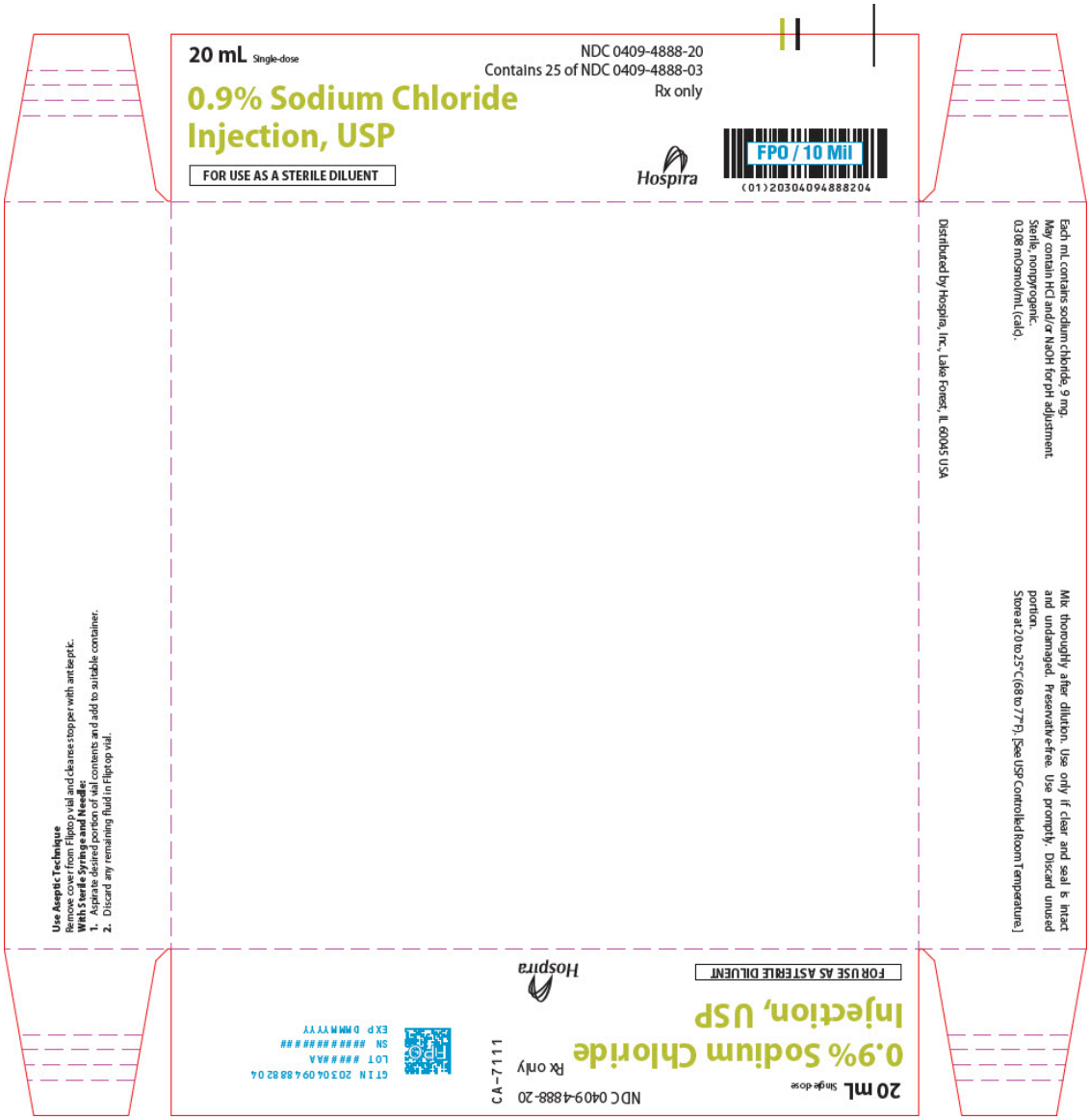
NDC 0409-4888-20
Contains 25 of NDC 0409-4888-03

Rx only

0.9% Sodium Chloride
Injection, USP

FOR USE AS A STERILE DILUENT

Hospira



PRINCIPAL DISPLAY PANEL - 50 mL Vial Label

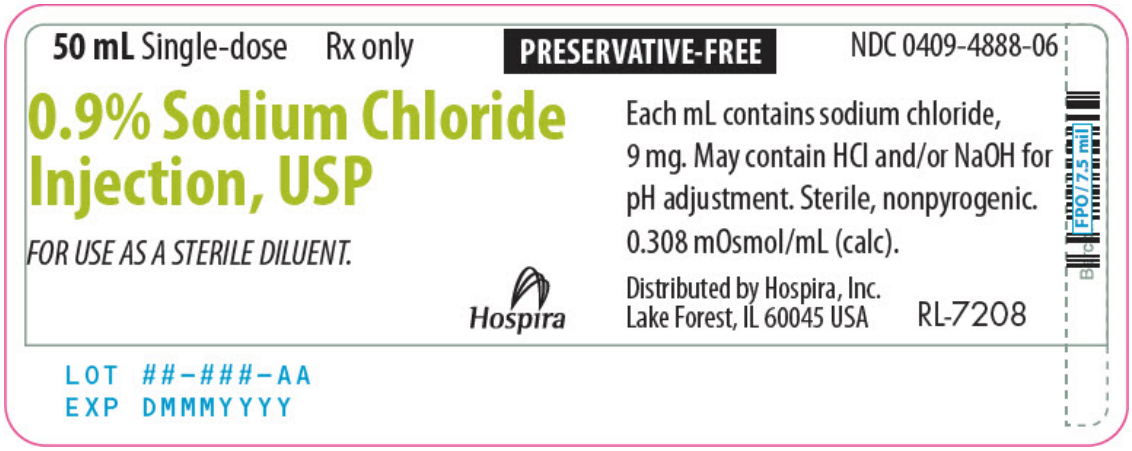
50 mL Single-dose
Rx only
PRESERVATIVE-FREE

0.9% Sodium Chloride
Injection, USP

FOR USE AS A STERILE DILUENT.

Hospira

LOT ##-###-AA
EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 50 mL Vial Tray

50 mL Single-dose

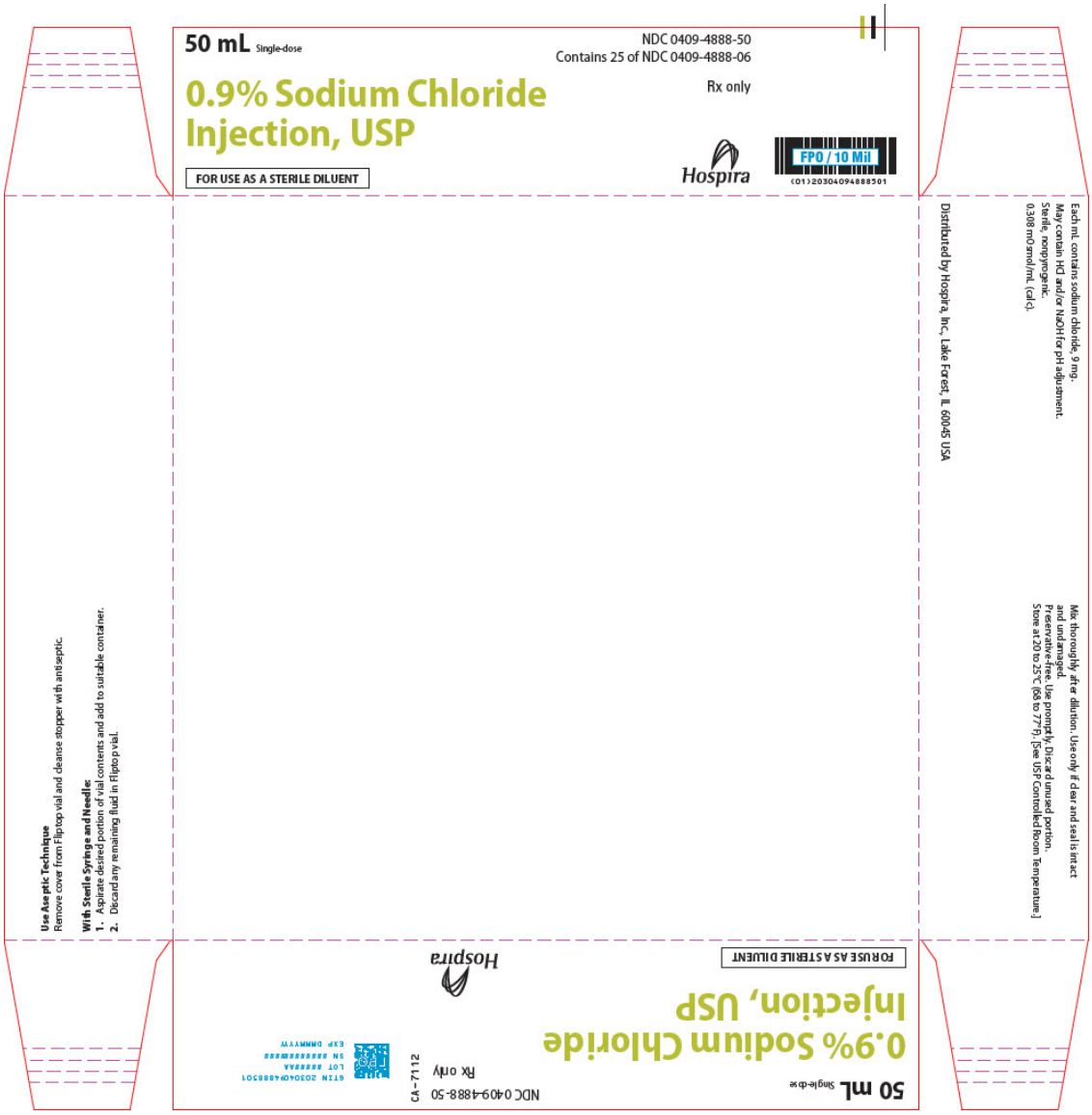
NDC 0409-4888-50
Contains 25 of NDC 0409-4888-06

Rx only

0.9% Sodium Chloride
Injection, USP

FOR USE AS A STERILE DILUENT

Hospira



PRINCIPAL DISPLAY PANEL - 10 mL Vial Label - LifeShield

10 mL Single-dose
Rx only
PRESERVATIVE-FREE

LIFESHIELD®
Vial

0.9% Sodium Chloride
Injection, USP

FOR USE AS A STERILE DILUENT.

Hospira

PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray - LifeShield

10 mL Single-dose
LIFESHIELD®
Vial

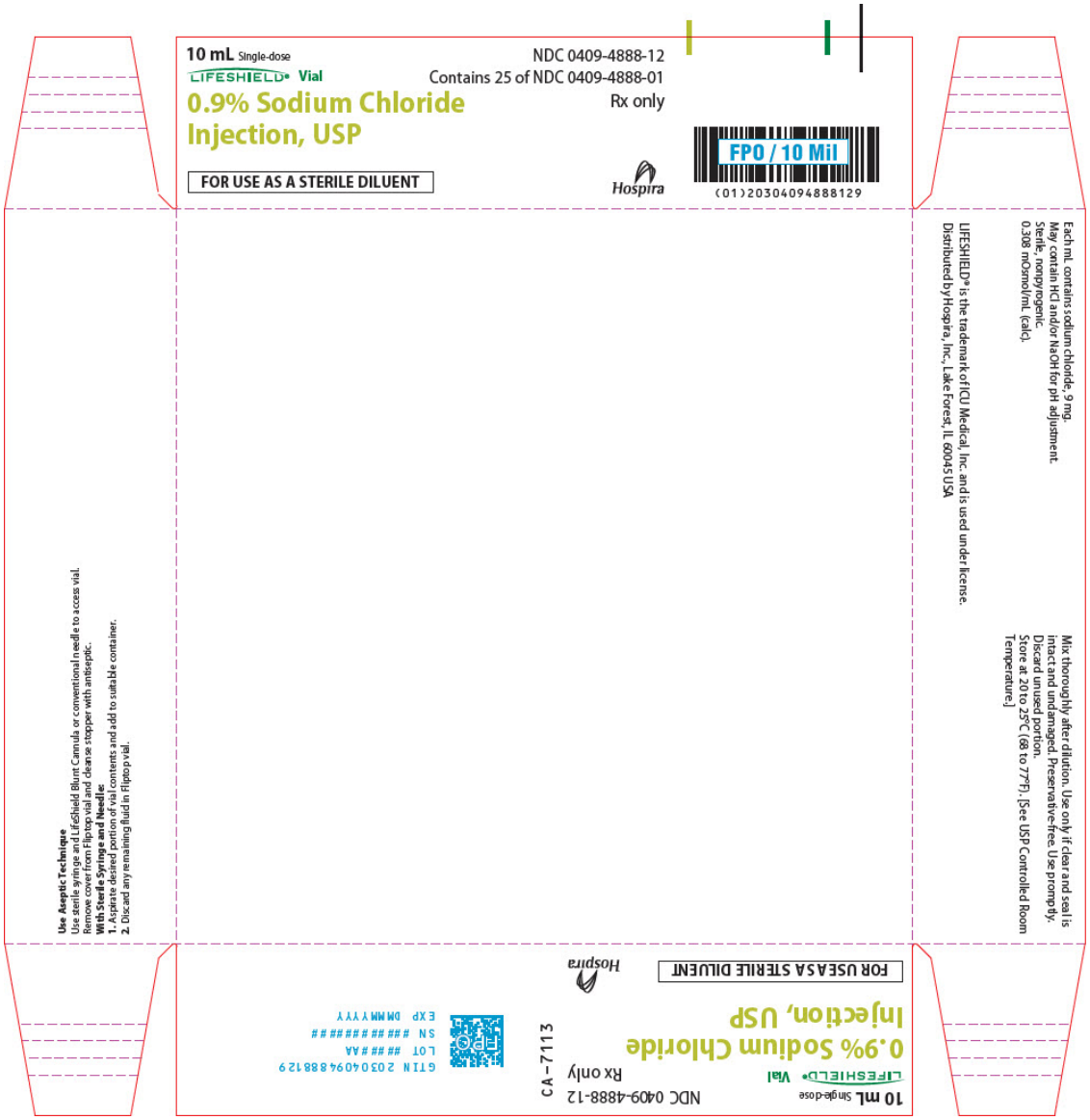
NDC 0409-4888-12
Contains 25 of NDC 0409-4888-01

Rx only

0.9% Sodium Chloride
Injection, USP

FOR USE AS A STERILE DILUENT

Hospira



PRINCIPAL DISPLAY PANEL - 2 mL Cartridge Label

2 mL Single-dose Carpuject™
Sterile Cartridge Unit with Luer Lock

Preservative-Free
0.9% Sodium Chloride
Injection, USP

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

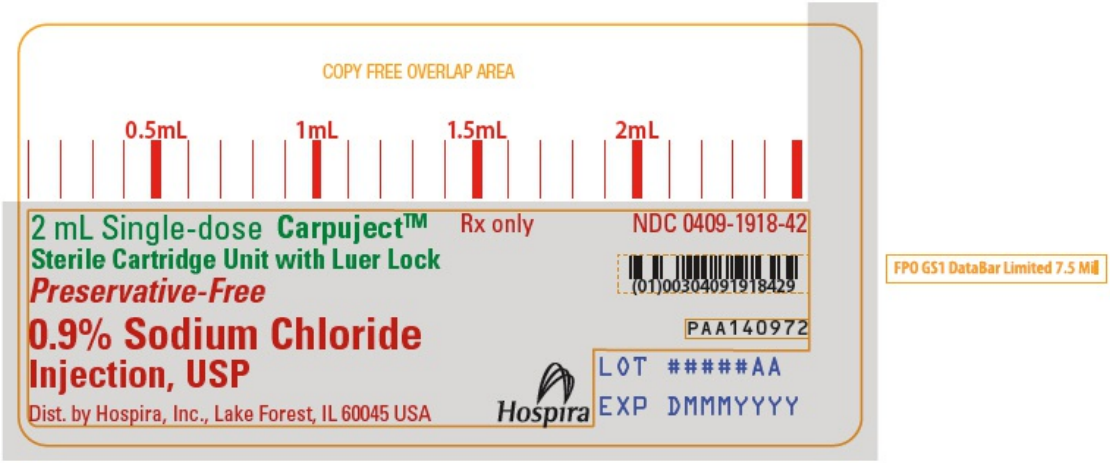
Rx only

NDC 0409-1918-42

PAA140972

Hospira

LOT #####AA
EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 2 mL Cartridge Container Label

2 mL Single-dose
Preservative-Free
50 Carpuject™ Sterile Cartridge Units
with Luer Lock
Needle not included

NDC 0409-1918-32
Rx only

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.
PAA116988

LOT #####AA
EXP DMMMYYYY

2 mL Single-dose
Preservative-Free
50 Carpuject™ Sterile Cartridge Units
with Luer Lock
Needle not included

NDC 0409-1918-32
Rx only

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.

PAA116988

LOT #####AA
EXP DMMMYYYY

FPO / 10 Mil
(01)10304091918327

BREAK SEAL TO OPEN

BREAK SEAL TO OPEN

2 mL Single-dose
Preservative-Free
50 Carpuject™ Sterile Cartridge Units
with Luer Lock
Needle not included

NDC 0409-1918-32
Rx only

0.9% Sodium Chloride Injection, USP

Carpuject Cartridges are to be used ONLY with Carpuject Holders.

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

Hospira

PRINCIPAL DISPLAY PANEL - 3 mL Cartridge Label

3 mL Single-dose Carpuject™
Sterile Cartridge Unit with Luer Lock

Preservative-Free
0.9% Sodium
Chloride
Injection, USP

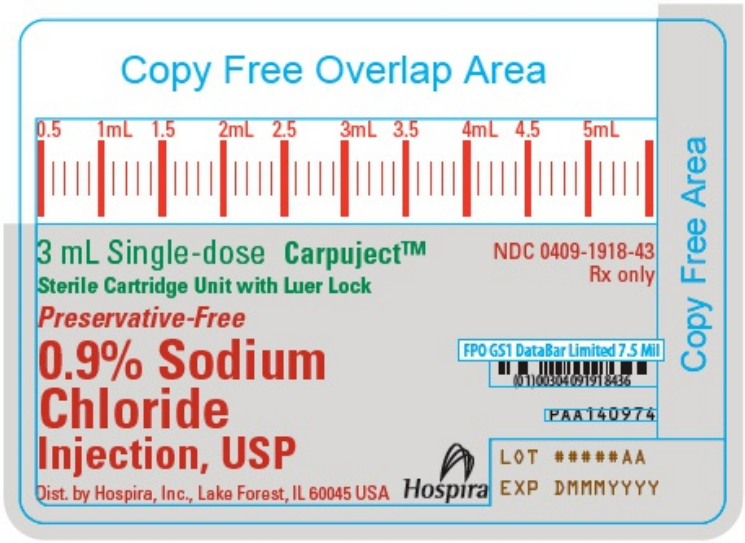
Dist. by Hospira, Inc., Lake Forest, IL 60045 USA

NDC 0409-1918-43
Rx only

PAA140974

Hospira

LOT #####AA
EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 3 mL Cartridge Container Label

3 mL Single-dose
Preservative-Free
NDC 0409-1918-33

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 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.
PAA116990

LOT #####AA
EXP DMMMYYYY

3 mL Single-dose **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

Carpuject 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. PAA116990

LOT #####AA
EXP DMMMYYYY

FPO / 10 Mil
(01)10304091918334

BREAK SEAL TO OPEN

BREAK SEAL TO OPEN

3 mL Single-dose **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

Carpuject Cartridges are to be used ONLY with Carpuject Holders.

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

Hospira

PRINCIPAL DISPLAY PANEL - 5 mL Cartridge Label

5 mL Single-dose Carpuject™
Sterile Cartridge Unit with Luer Lock

Preservative-Free
0.9% Sodium
Chloride
Injection, USP

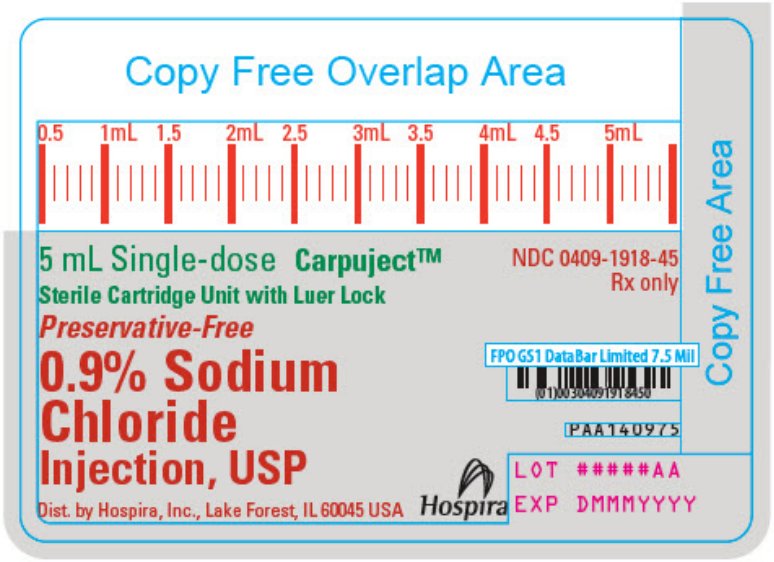
Dist. by Hospira, Inc., Lake Forest, IL 60045 USA

NDC 0409-1918-45
Rx only

PAA140975

Hospira

LOT #####AA
EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 5 mL Cartridge Container Label

5 mL Single-dose
Preservative-Free

25 Carpuject™ Sterile Cartridge Units
with Luer Lock

Needle not included

NDC 0409-1918-35
Rx only

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.
PAA116992

LOT #####AA
EXP DMMMYYYY

5 mL Single-dose
Preservative-Free
25 Carpuject™ Sterile Cartridge Units
with Luer Lock
Needle not included

NDC 0409-1918-35
Rx only

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.

PAA116992

LOT #####AA
EXP DMMMYYYY

FPO / 10 Mil
(01)10304091918358

BREAK SEAL TO OPEN

BREAK SEAL TO OPEN

5 mL Single-dose
Preservative-Free
25 Carpuject™ Sterile Cartridge Units
with Luer Lock
Needle not included

NDC 0409-1918-35
Rx only

0.9% Sodium Chloride Injection, USP

Carpuject Cartridges are to be used ONLY with Carpuject Holders.

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

Hospira

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-4888
Route of Administration	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (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		
5	NDC:0409-4888-90	10 in 1 TRAY	10/20/2021	
5	NDC:0409-4888-02	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			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-1918
Route of Administration	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (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	05/01/2018
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	02/01/2018
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	04/01/2018
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	05/01/2018

Labeler - Hospira, Inc. (141588017)

Establishment

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

Establishment

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

Establishment

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

Revised: 11/2024 Hospira, Inc.