esi PHARMACEUTICALS

ELKINS-SINN, INC. 2 Esterbrook Lane, Cherry Hill, NJ 08003-4099
A subsidiary of A. H. Robins Company

NJ 609 424-370(
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June 18, 1992

Nashville Orthopaedic Associates, P.A.
Attn: Betty Wood, R.N.
Director, Patient Administration
301 21st Avenue, North
Nashville, TN 37203

RE: Dexamethasone, Gentamicin, & Bacteriostatic Sodium Chloride

Dear Betty :

Your request for material safety data sheets has been referred to me for reply.

Please be advised that we are a manufacturer of pharmaceuticals and drugs compounded for medicinal or nutritional use and where appropriate approved for such use by prescription by licensed physicians.

It would be our interpretation that those products which we supply to you as pharmaceuticals or nutrients would not fall within the category of chemical compounds or hazardous materials with which you are concerned. Under these circumstances we doubt that these are the type of products you would want to include in your inventory of material safety data sheets.

In any event, it is our belief that the current product information labels supplied with the products that we provide to you, which list ingredients, appropriate warnings and precautionary measures, are complete with more vital information for your use than any material safety data sheets.

Sincerely,

DIANE VONKAENEL
Director of Safety
and Industrial Hygiene

DVK: jmb

Bacteriostatic
0.9% Sodium Chloride
Injection, USP

Multiple-dose Plastic Vial

Multiple-dose LifeShield® Plastic Vial

NOT FOR INHALATION

Rx only

WARNING: NOT FOR USE IN NEONATES.

DESCRIPTION

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

Bacteriostatic 0.9% Sodium Chloride Injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride in water for injection. Each milliliter (mL) contains sodium chloride 9 mg and 0.9% (9 mg/mL) benzyl alcohol added as a bacteriostatic preservative. May contain hydrochloric acid for pH adjustment. It is supplied in a multiple-dose container from which repeated withdrawals may be made to dilute or dissolve drugs for medication. The pH is 5.0 (4.5 to 7.0).

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

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 Bacteriostatic 0.9% Sodium Chloride Injection, USP, when used only as a 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.

CONTRAINDICATIONS

Due to the potential toxicity of benzyl alcohol in neonates, solutions containing benzyl alcohol must not be used in this patient population.

Parenteral preparations with benzyl alcohol should not be used for fluid or sodium chloride replacement.

Parenteral preparations containing benzyl alcohol should not be used in epidural or spinal anesthetic procedures.

WARNINGS

Benzyl alcohol, a preservative in Bacteriostatic Sodium Chloride Injection, USP has been associated with toxicity in neonates. Data are unavailable on the toxicity of other preservatives in this age group. Preservative-free Sodium Chloride Injection should be used for flushing intravascular catheters. Where a sodium chloride solution is required for preparing or diluting medications for use in neonates, only preservative-free Sodium Chloride Injection should be used.

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 Bacteriostatic 0.9% Sodium Chloride Injection, USP. It is also not known whether Bacteriostatic 0.9% Sodium Chloride Injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Bacteriostatic 0.9% 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. However, due to potential toxicity of benzyl alcohol in neonates, solutions containing benzyl alcohol are contraindicated in this patient population.

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.

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.

Although adverse reactions to intravenous, intramuscular or subcutaneous injection of 0.9% benzyl alcohol are not known to occur in man, experimental studies of small volume parenteral preparations containing 0.9% benzyl alcohol in several species of animals have indicated that an estimated intravenous dose up to 30 mL may be safely given to an adult without toxic effects. Administration of an estimated 9 mL to a 6 kg neonate or infant is potentially capable of producing blood pressure changes.

OVERDOSAGE

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of sodium chloride or fluid overload except possibly in neonates and 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.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See **PRECAUTIONS**.

HOW SUPPLIED

Bacteriostatic 0.9% Sodium Chloride Injection, USP is supplied as:

Unit of Sale	Concentration
NDC 0409-1966-05 Tray of 25 Multiple-dose Plastic Fliptop Vials	0.9% (20 mL)
NDC 0409-1966-07 Tray of 25 Multiple-dose Plastic Fliptop Vials	0.9% (30 mL)
NDC 0409-1966-12 Tray of 25 Multiple-dose LifeShield® Plastic Fliptop Vials	0.9% (10 mL)

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

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

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

LAB-1096-3.0

Revised: 02/2019

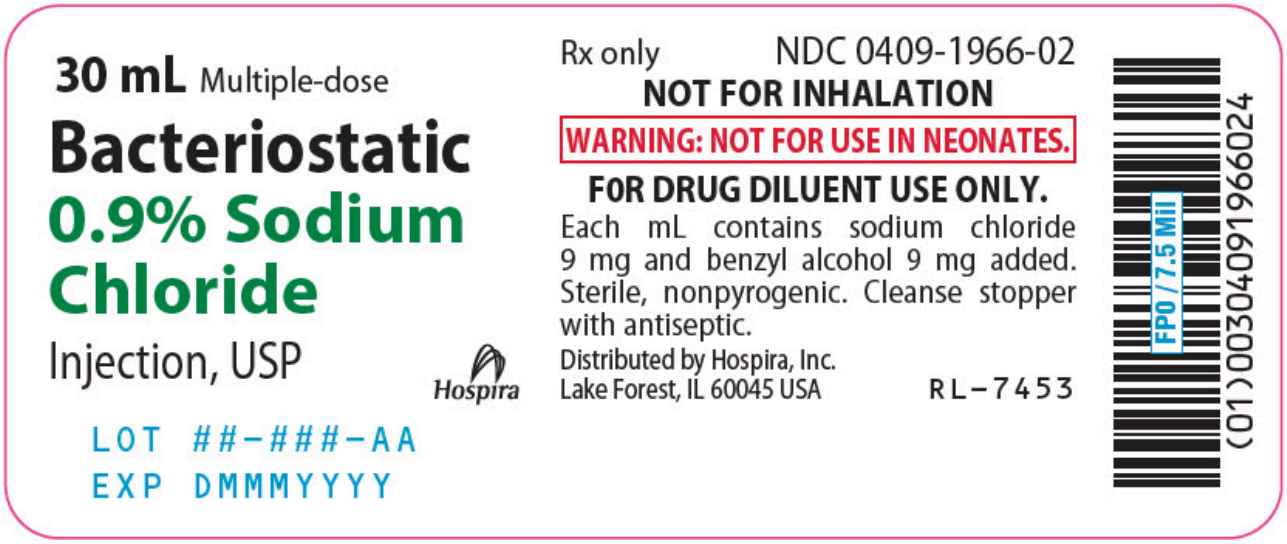
PRINCIPAL DISPLAY PANEL - 30 mL Vial Label

30 mL Multiple-dose
Bacteriostatic
0.9% Sodium
Chloride
Injection, USP

Hospira

LOT ##-###-AA

EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 30 mL Vial Tray

30 mL Multiple-dose Fliptop Vial

Bacteriostatic
0.9% Sodium
Chloride Injection, USP

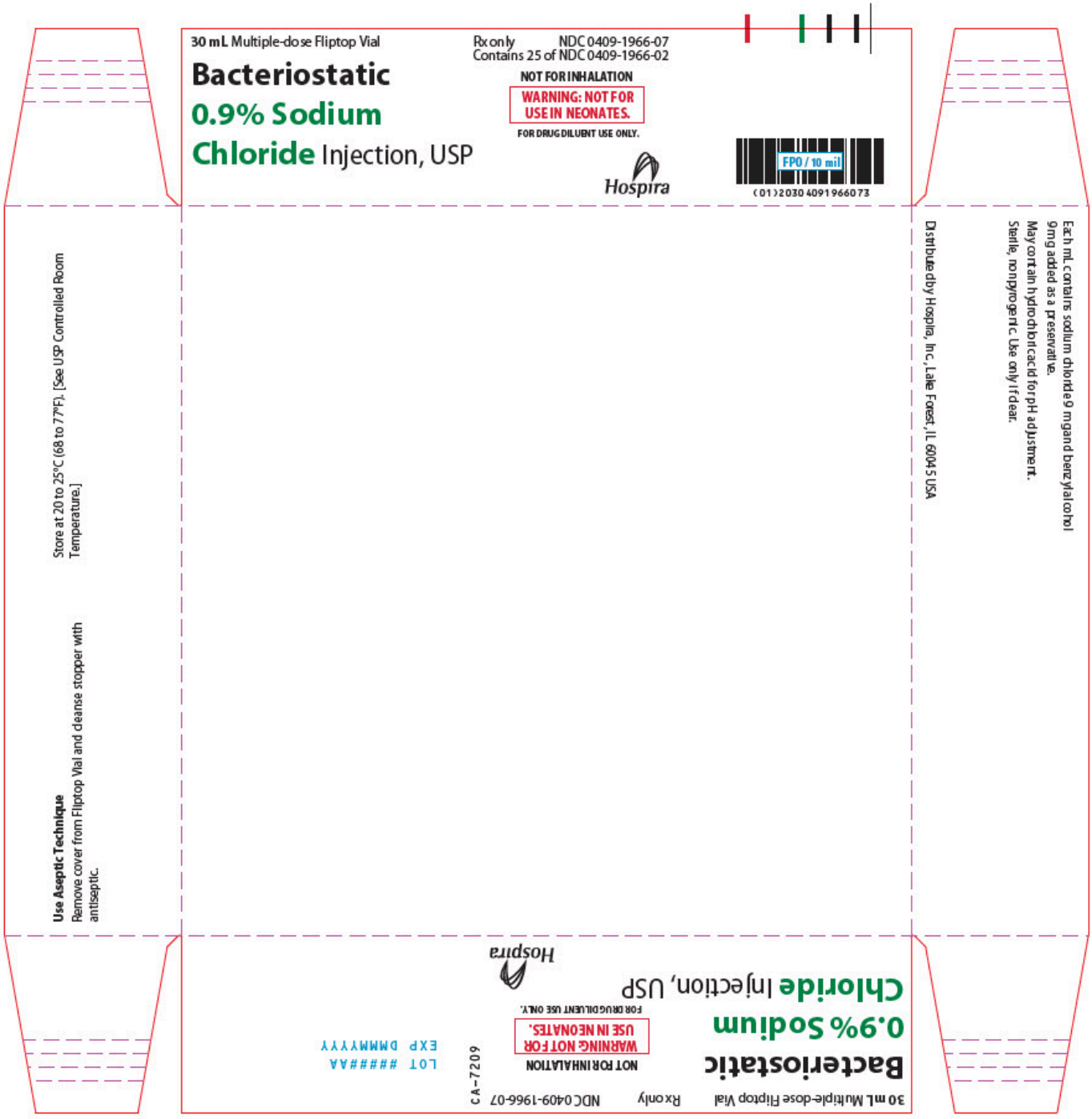
Rx only
NDC 0409-1966-07
Contains 25 of NDC 0409-1966-02

NOT FOR INHALATION

WARNING: NOT FOR
USE IN NEONATES.

FOR DRUG DILUENT USE ONLY.

Hospira

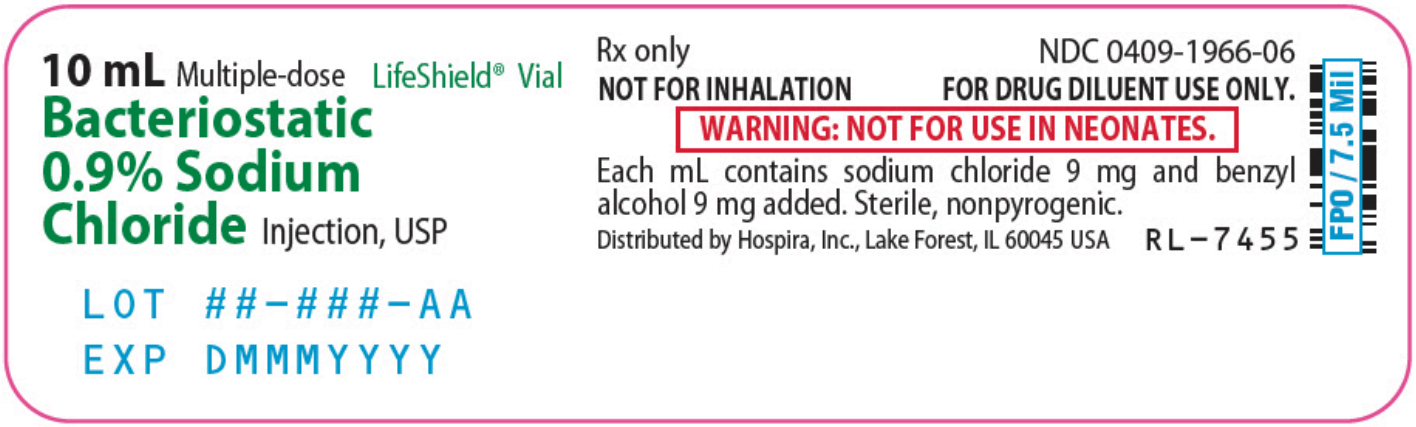


PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

10 mL Multiple-dose LifeShield® Vial
Bacteriostatic
0.9% Sodium
Chloride Injection, USP

LOT ##–###–AA

EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray

10 mL Multiple-dose LifeShield® Vial

Bacteriostatic
0.9% Sodium
Chloride Injection, USP

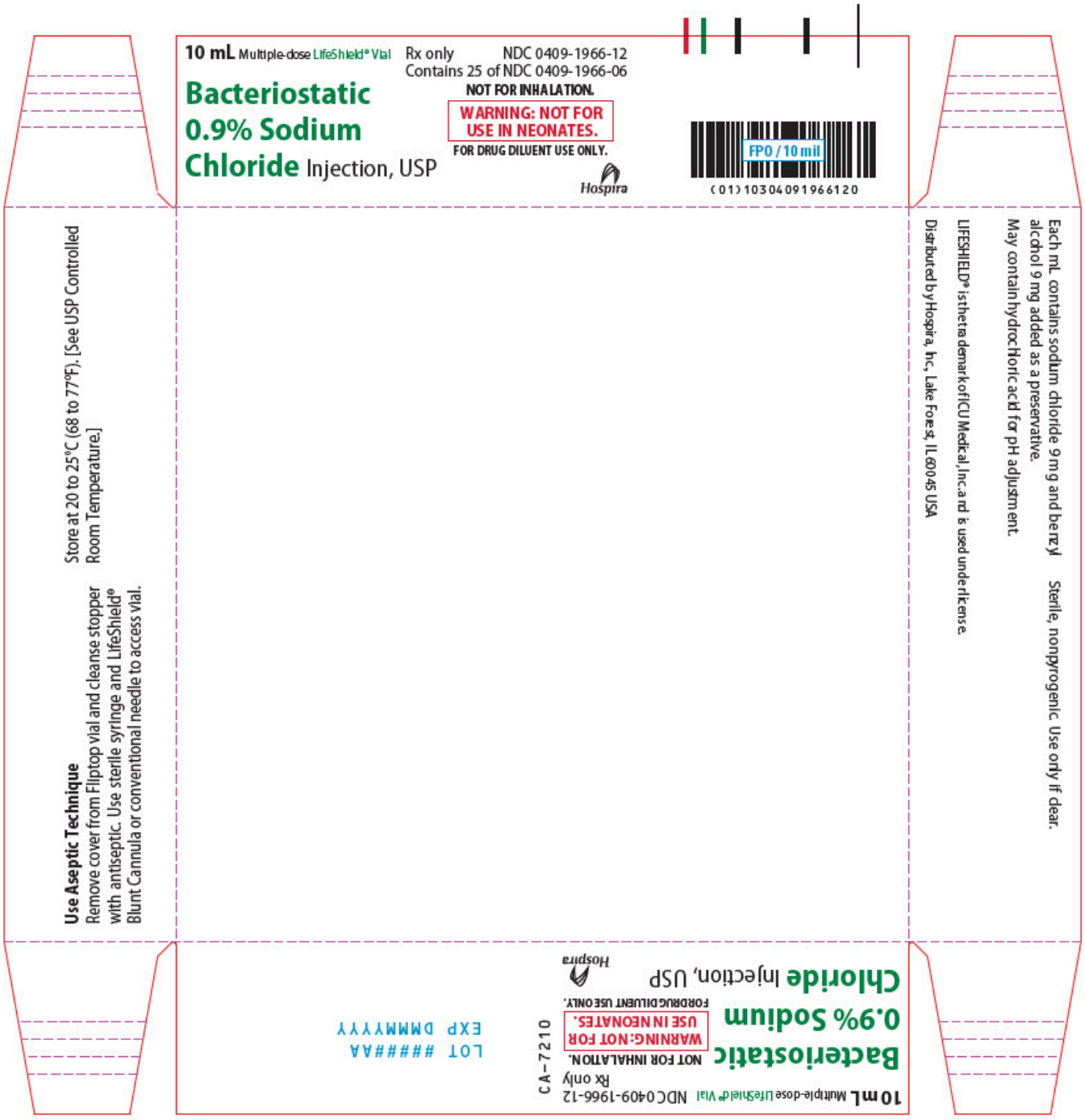
Rx only
NDC 0409-1966-12
Contains 25 of NDC 0409-1966-06

NOT FOR INHALATION.

WARNING: NOT FOR USE IN NEONATES.

FOR DRUG DILUENT USE ONLY.

Hospira



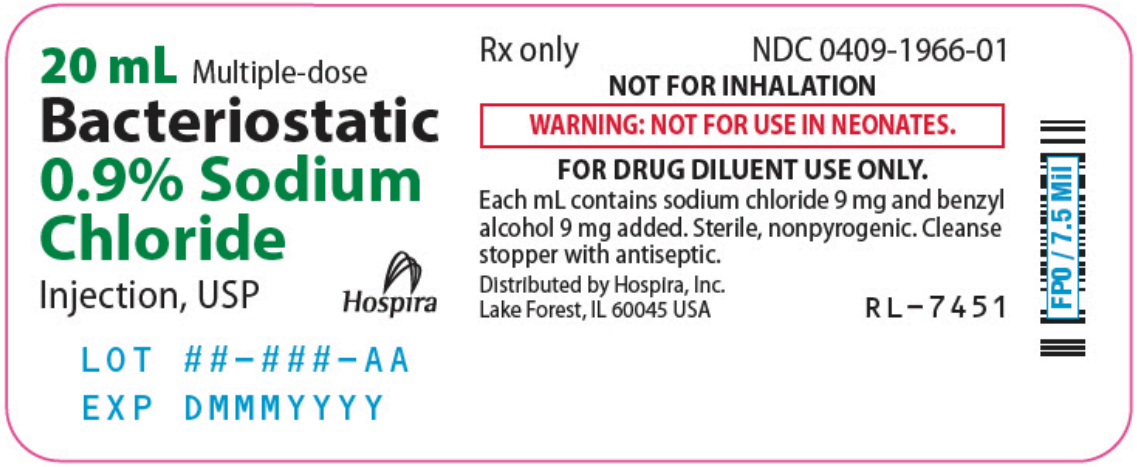
PRINCIPAL DISPLAY PANEL - 20 mL Vial Label

20 mL Multiple-dose
Bacteriostatic
0.9% Sodium
Chloride
Injection, USP

Hospira

LOT ##–###–AA

EXP DMMMYYYY



PRINCIPAL DISPLAY PANEL - 20 mL Vial Tray

20 mL Multiple-dose Fliptop Vial

Bacteriostatic
0.9% Sodium
Chloride Injection, USP

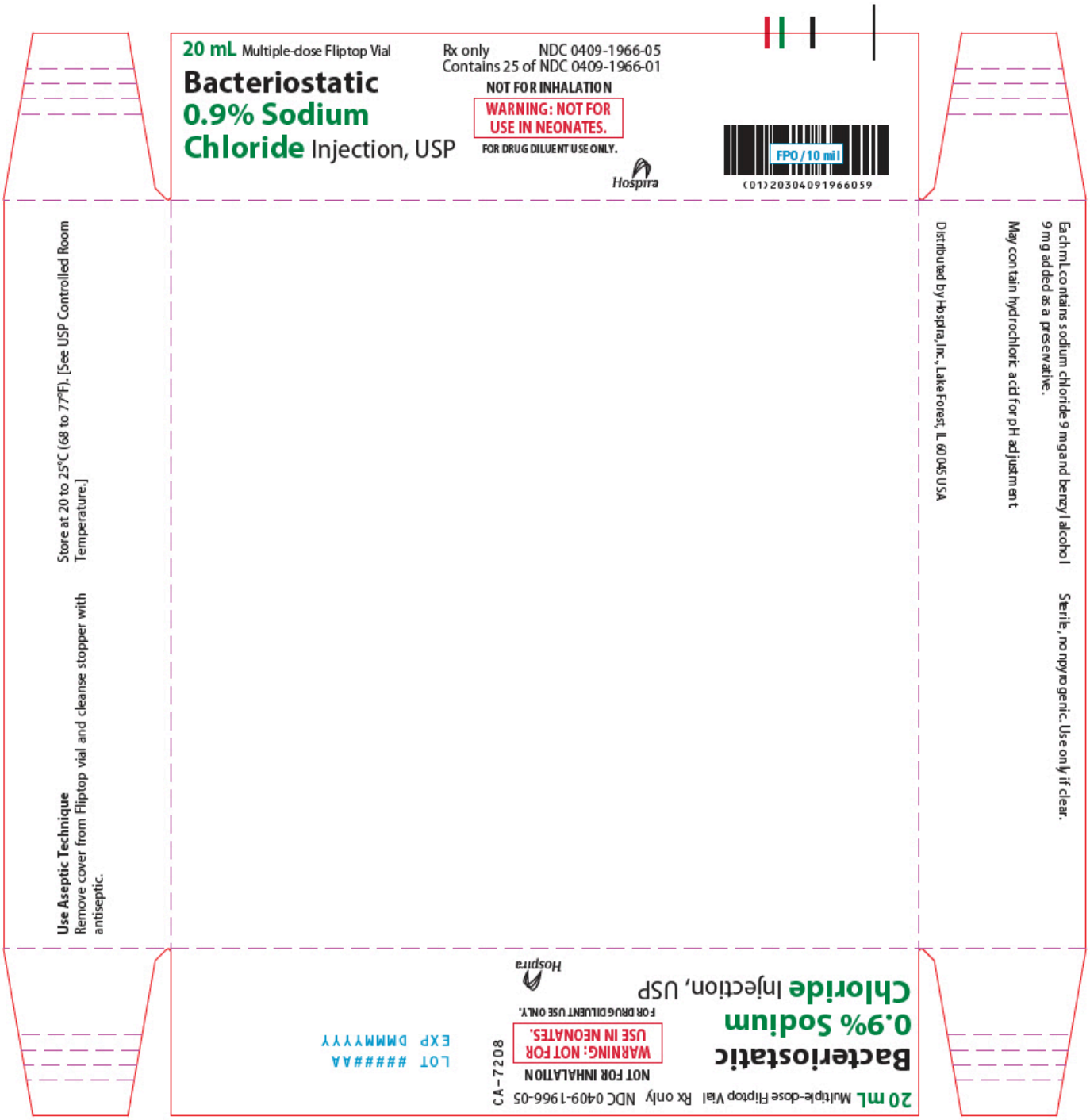
Rx only
NDC 0409-1966-05
Contains 25 of NDC 0409-1966-01

NOT FOR INHALATION

WARNING: NOT FOR USE IN NEONATES.

FOR DRUG DILUENT USE ONLY.

Hospira



BACTERIOSTATIC SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-1966
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	9 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-1966-07	25 in 1 TRAY	04/30/2005	
1	NDC:0409-1966-02	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:0409-1966-12	25 in 1 TRAY	10/07/2005	
2	NDC:0409-1966-06	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:0409-1966-05	25 in 1 TRAY	05/02/2005	
3	NDC:0409-1966-01	20 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018800	04/30/2005	

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0409-1966) , LABEL(0409-1966) , MANUFACTURE(0409-1966) , PACK(0409-1966)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		827731089	ANALYSIS(0409-1966)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Healthcare India Private Limited		860037912	ANALYSIS(0409-1966) , LABEL(0409-1966) , MANUFACTURE(0409-1966) , PACK(0409-1966)

Revised: 10/2020 Hospira, Inc.