STERILE WATER- water injection
Hospira, Inc.

Sterile Water **Rx only**
for Injection, USP

Glass Vial
Plastic Vial

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.

Sterile Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection which contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. For I.V. injection, add sufficient solute to make an approximately isotonic solution.

Water for Injection, USP is chemically designated H_2O.

The glass vial is Type I or II 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 labeled volume.

CLINICAL PHARMACOLOGY

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 for distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by Sterile Water for Injection, USP when used only as a pharmaceutic aid for diluting or dissolving drugs for parenteral injection, is unlikely to exert a significant effect on fluid balance except possibly in neonates or very small infants.

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

Sterile Water for Injection, USP must be made approximately isotonic prior to use.

WARNINGS

Intravenous administration of Sterile Water for Injection without a solute may result in hemolysis.

PRECAUTIONS

Do not use for intravenous injection unless the osmolar concentration of additives results in an approximate isotonic admixture.

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 Sterile Water for Injection. It is also not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection with additives should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness have been established in pediatric patients. However, 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 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 **WARNINGS**, **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

Sterile Water for Injection, USP is supplied in the following:

Unit of Sale	Total Content
NDC 0409-4887-05 Tray of 25 Glass Fliptop Vials	1 mL
NDC 0409-4887-10 Tray of 25 Plastic Fliptop Vials	10 mL
NDC 0409-4887-34 Tray of 30 Plastic Fliptop Vials	10 mL
NDC 0409-4887-20 Tray of 25 Plastic Fliptop Vials	20 mL
NDC 0409-4887-50 Tray of 25 Plastic Fliptop Vials	50 mL
NDC 0409-4887-99 Case of 25 Glass Fliptop Vials	100 mL

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

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

Hospira

LAB-1292-1.0

Revised: 05/2018

RL-4469

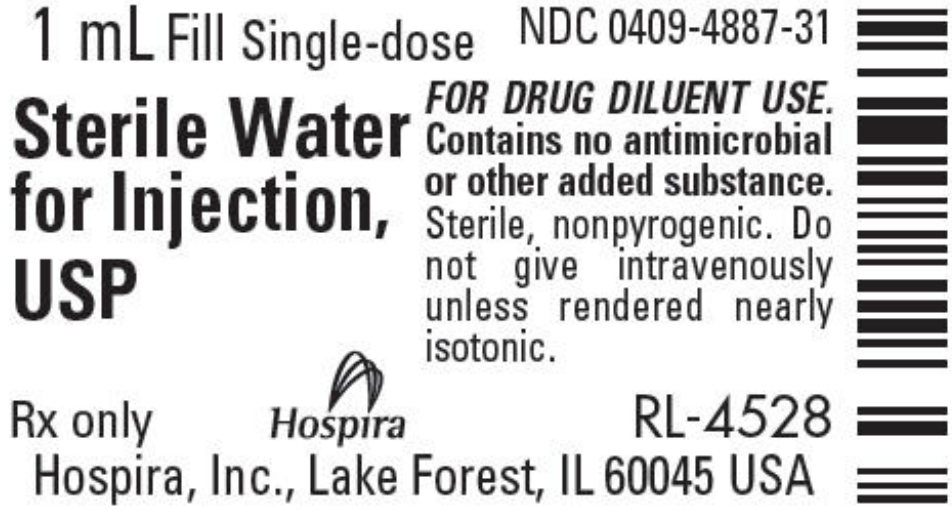
PRINCIPAL DISPLAY PANEL - 1 mL Vial Label

NDC 0409-4887-31
1 mL Fill Single-dose

Sterile Water
for Injection,
USP

FOR DRUG DILUENT USE.
Contains no antimicrobial
or other added substance.
Sterile, nonpyrogenic. Do
not give intravenously
unless rendered nearly
isotonic.

Rx only
Hospira
RL-4528
Hospira, Inc., Lake Forest, IL 60045 USA



PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

10 mL Single-dose

Sterile Water
for Injection, USP

FOR DRUG DILUENT USE

10 mL Single-dose

Sterile Water
for Injection, USP

FOR DRUG DILUENT USE

Rx only NDC 0409-4887-17

Contains no antimicrobial or other added substance. Sterile, nonpyrogenic. Do not give intravenously unless rendered nearly isotonic.

Hospira, Inc. RL-4428
Lake Forest, IL 60045 USA

Hospira

IM-2359

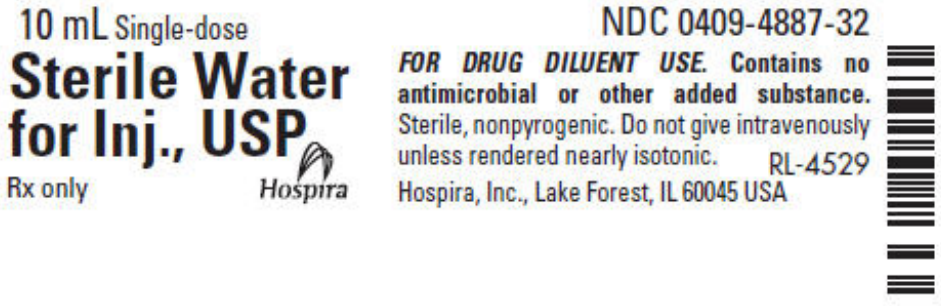
PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

10 mL Single-dose

Sterile Water
for Inj., USP

Rx only

Hospira



PRINCIPAL DISPLAY PANEL - 10 mL Vial Carton

10 mL Single-dose

Rx only

30 Units/NDC 0409-4887-34

Sterile Water for Injection, USP

FOR DRUG DILUENT USE

Hospira

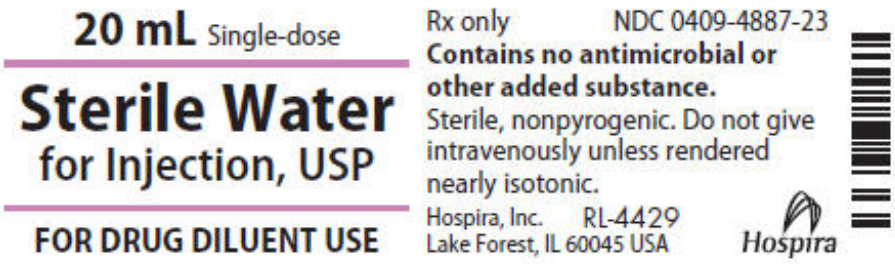
Hospira, Inc., Lake Forest, IL 60045 USA

PRINCIPAL DISPLAY PANEL - 20 mL Vial Label

20 mL Single-dose

Sterile Water
for Injection, USP

FOR DRUG DILUENT USE



PRINCIPAL DISPLAY PANEL 20 mL Vial Carton

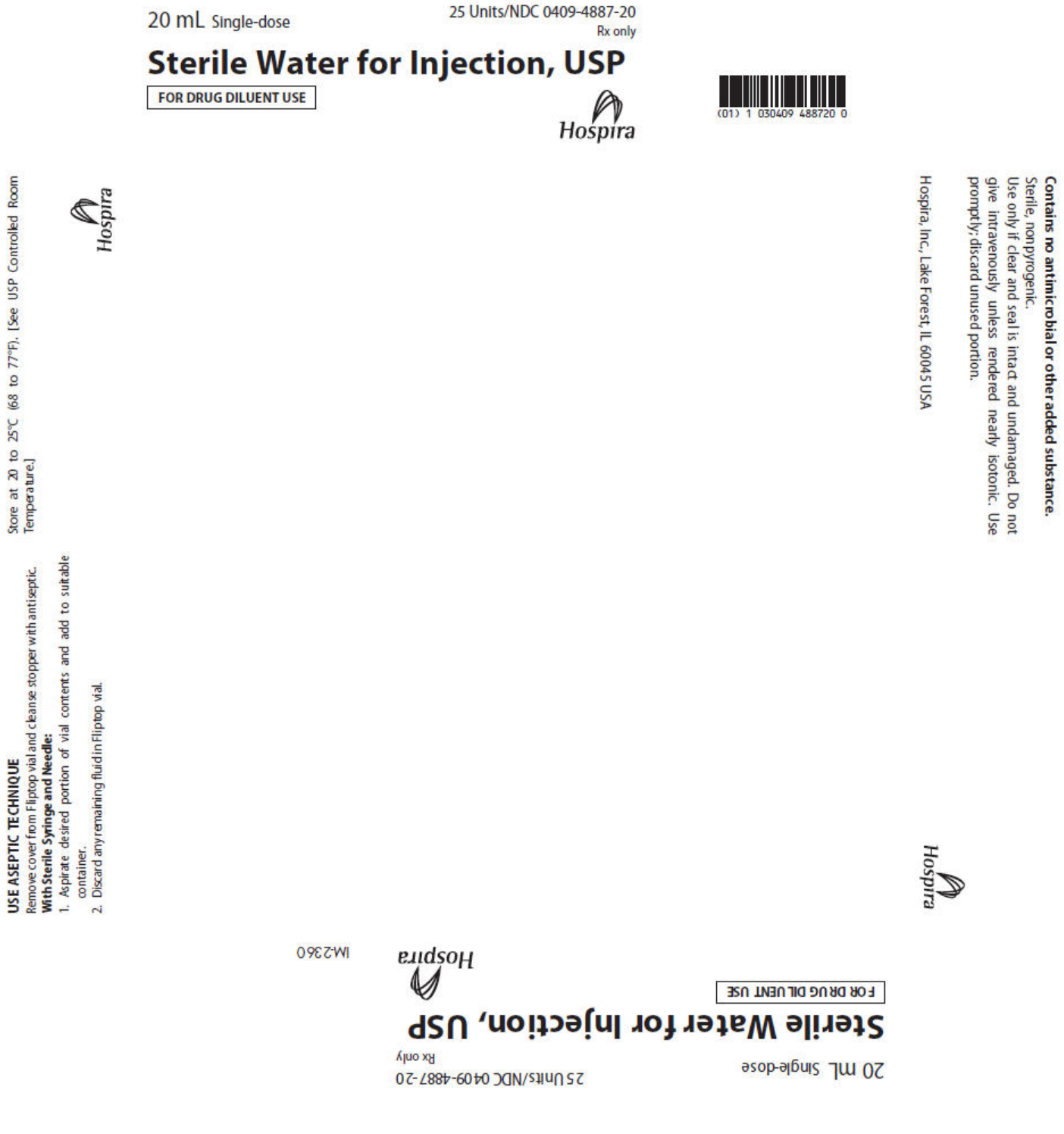
20 mL Single-dose

25 Units/NDC 0409-4887-20
Rx only

Sterile Water for Injection, USP

FOR DRUG DILUENT USE

Hospira

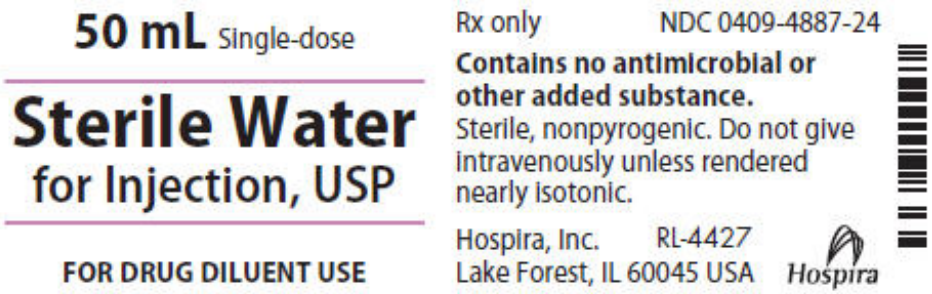


PRINCIPAL DISPLAY PANEL - 50 mL Vial Label

50 mL Single-dose

Sterile Water
for Injection, USP

FOR DRUG DILUENT USE



PRINCIPAL DISPLAY PANEL - 50 mL Vial Carton

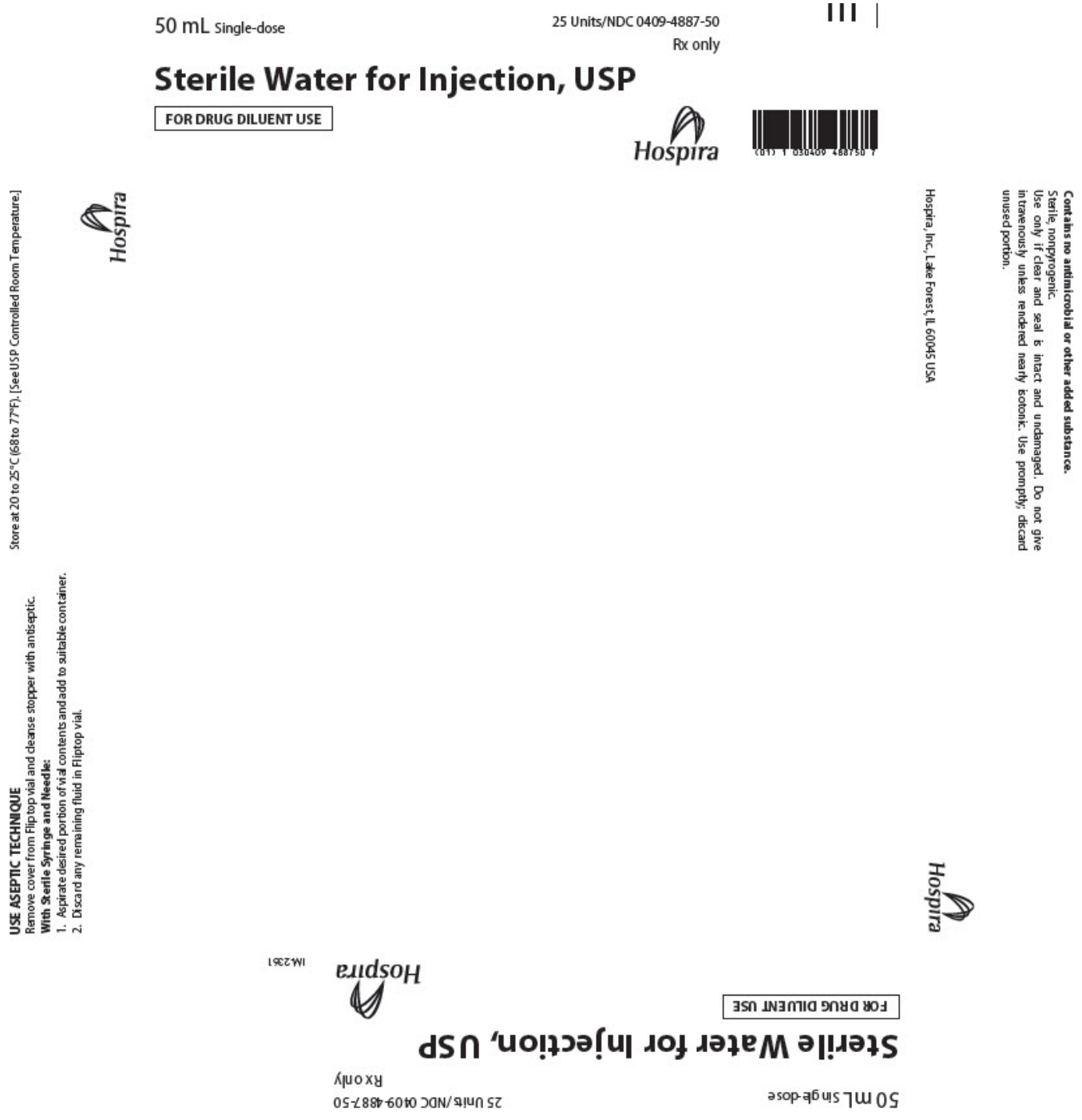
50 mL Single-dose

25 Units/NDC 0409-4887-50
Rx only

Sterile Water for Injection, USP

FOR DRUG DILUENT USE

Hospira



STERILE WATER

water injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-4887
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4887-99	25 in 1 CASE	08/03/2005	
1	NDC:0409-4887-25	100 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0409-4887-05	25 in 1 TRAY	01/31/2011	05/01/2013
2	NDC:0409-4887-31	1 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
3	NDC:0409-4887-10	25 in 1 TRAY	08/01/2005	
3	NDC:0409-4887-17	10 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
4	NDC:0409-4887-34	30 in 1 TRAY	07/30/2015	
4	NDC:0409-4887-32	10 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
5	NDC:0409-4887-20	25 in 1 TRAY	06/16/2005	
5	NDC:0409-4887-23	20 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
6	NDC:0409-4887-50	25 in 1 TRAY	08/04/2005	
6	NDC:0409-4887-24	50 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018801	06/16/2005	

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0409-4887) , LABEL(0409-4887) , MANUFACTURE(0409-4887) , PACK(0409-4887)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		827731089	ANALYSIS(0409-4887)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Healthcare India Private Limited		860037912	ANALYSIS(0409-4887) , LABEL(0409-4887) , MANUFACTURE(0409-4887) , PACK(0409-4887)