

**STERILE WATER- water injection**  
**Hospira, Inc.**

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**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<sub>2</sub>O.

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<sup>+</sup>) 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 pharmaceutical 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:

<b>Unit of Sale</b>	<b>Total Content</b>
<b>NDC 0409-4887-05</b> Tray of 25 Single-dose Glass Fliptop Vials	1 mL
<b>NDC 0409-4887-10</b> Tray of 25 Single-dose Plastic Fliptop Vials	10 mL
<b>NDC 0409-4887-34</b> Tray of 30 Single-dose Plastic Fliptop Vials	10 mL
<b>NDC 0409-4887-20</b> Tray of 25 Single-dose Plastic Fliptop Vials	20 mL
<b>NDC 0409-4887-50</b> Tray of 25 Single-dose Plastic Fliptop Vials	50 mL
<b>NDC 0409-4887-99</b> Case of 25 Single-dose 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



LAB-1292-2.0

Revised: 05/2021

**PRINCIPAL DISPLAY PANEL - 100 mL Vial Label**

100 mL  
Single-dose

WARNINGS: NOT ISOTONIC. HEMOLYTIC.

Sterile Water  
For Inj., USP

FOR DRUG DILUENT USE ONLY

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

LOT ##-###-AA  
EXP DMMMYYYY

100 mL  
Single-dose

**WARNINGS: NOT ISOTONIC. HEMOLYTIC.**

NDC 0409-4887-25  
Rx only

# Sterile Water For Inj., USP

Contains no antimicrobial or other added substance. Single dose container. **DO NOT GIVE INTRAVENOUSLY UNLESS RENDERED NEARLY ISOTONIC.** Sterile, nonpyrogenic. Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.

**FOR DRUG DILUENT USE ONLY**

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

RL-7601



LOT ##-###-AA  
EXP DMMMYYYY

## PRINCIPAL DISPLAY PANEL - 1 mL Vial Label

1 mL Fill Single-dose

Sterile Water  
for Injection,  
USP

Rx only

Hospira

Hospira, Inc., Lake Forest, IL 60045 USA

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



RL-4528

Hospira, Inc., Lake Forest, IL 60045 USA

## PRINCIPAL DISPLAY PANEL - 10 mL Vial Label - NDC 0409-4887-17

10 mL Single-dose

Sterile Water  
for Injection, USP

FOR DRUG DILUENT USE

LOT ##-###-AA  
EXP DMMMYYYY

10 mL Single-dose

Rx only

NDC 0409-4887-17

**Sterile Water  
for Injection, USP**

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

FOR DRUG DILUENT USE

Distributed by **RL-7603**  
Hospira, Inc., Lake Forest, IL 60045 USA  *Hospira*

LOT ##-###-AA

EXP DMMYYYYY



**PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray - NDC 0409-4887-10**

10 mL Single-dose

Rx only

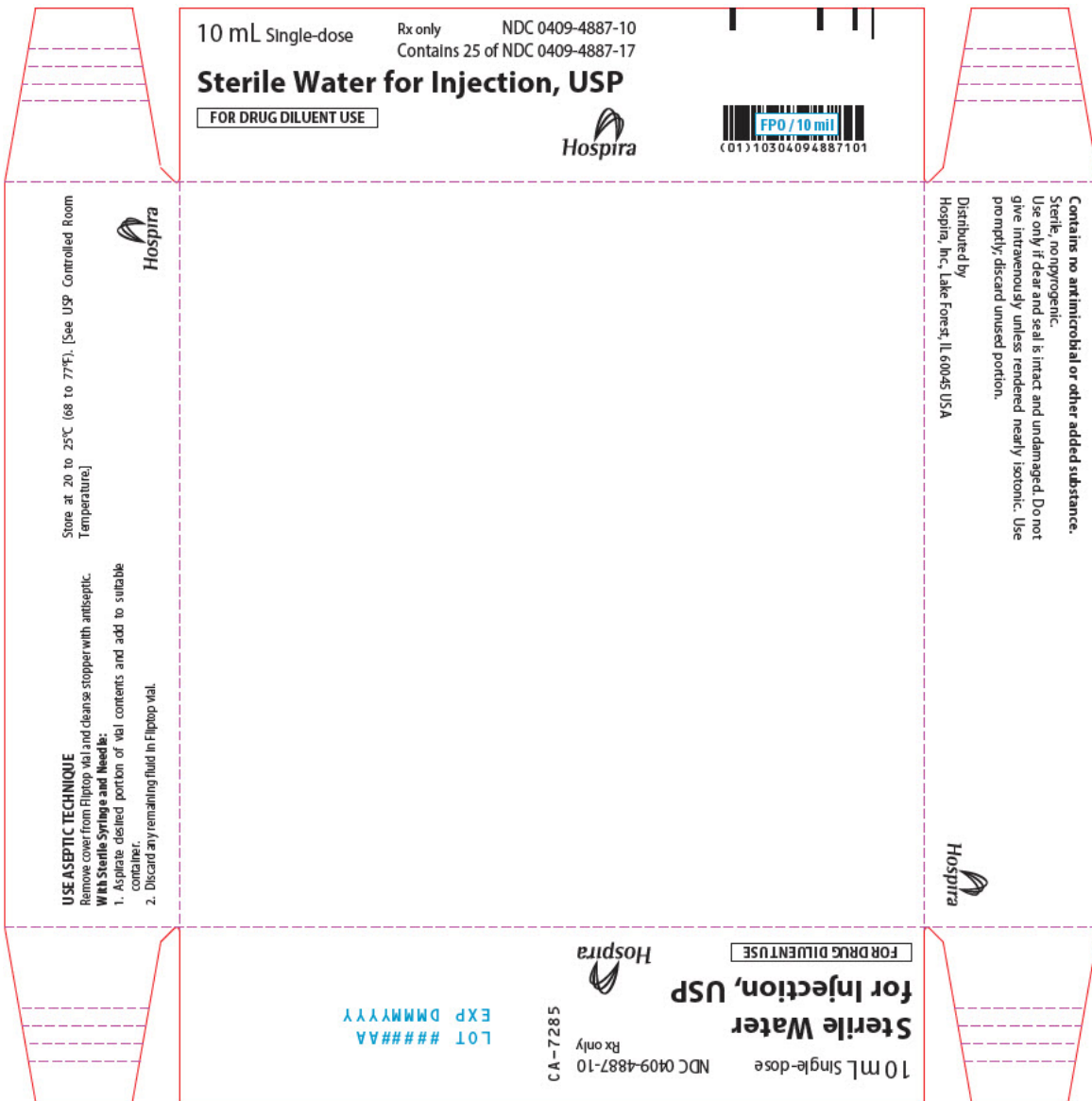
NDC 0409-4887-10

Contains 25 of NDC 0409-4887-17

Sterile Water for Injection, USP

FOR DRUG DILUENT USE

Hospira



**PRINCIPAL DISPLAY PANEL - 10 mL Vial Label - NDC 0409-4887-32**

10 mL Single-dose

Sterile Water  
 for Inj., USP

Rx only

Hospira

LOT ##-##-AA  
 EXP DMMYYYYY

10 mL Single-dose

# Sterile Water for Inj., USP

Rx only



**NDC 0409-4887-32**  
*FOR DRUG DILUENT USE.* Contains no antimicrobial or other added substance. Sterile, nonpyrogenic. Do not give intravenously unless rendered nearly isotonic. R L - 7 5 9 8  
Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LOT ##-###-AA

EXP DMMYYYYY



## PRINCIPAL DISPLAY PANEL - 10 mL Vial Tray - NDC 0409-4887-34

10 mL Single-dose

Rx only

NDC 0409-4887-34

Contains 30 of NDC 0409-4887-32

Sterile Water for Injection, USP

FOR DRUG DILUENT USE

Hospira



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

20 mL Single-dose

Sterile Water  
for Injection, USP

FOR DRUG DILUENT USE

LOT ##-##-##-AA  
EXP DMMYYYYY



**20 mL** Single-dose

**Sterile Water  
for Injection, USP**

**FOR DRUG DILUENT USE**

LOT ##-###-AA

EXP DMMYYYY

Rx only

NDC 0409-4887-23

**Contains no antimicrobial or  
other added substance.**

Sterile, nonpyrogenic. Do not give  
intravenously unless rendered  
nearly isotonic. RL-7599

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Lake Forest, IL 60045 USA



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

20 mL Single-dose

Rx only

NDC 0409-4887-20

Contains 25 of NDC 0409-4887-23

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

LOT ##-##-AA  
 EXP DMMYYYY

50 mL Single-dose

Rx only

NDC 0409-4887-24

# Sterile Water for Injection, USP

**Contains no antimicrobial or  
other added substance.**

Sterile, nonpyrogenic. Do not give  
intravenously unless rendered  
nearly isotonic. RL-7600

Distributed by Hospira, Inc.

Lake Forest, IL 60045 USA



**FOR DRUG DILUENT USE**

LOT ##-###-AA

EXP DMMMYYYY

## PRINCIPAL DISPLAY PANEL - 50 mL Vial Tray

50 mL Single-dose

Rx only

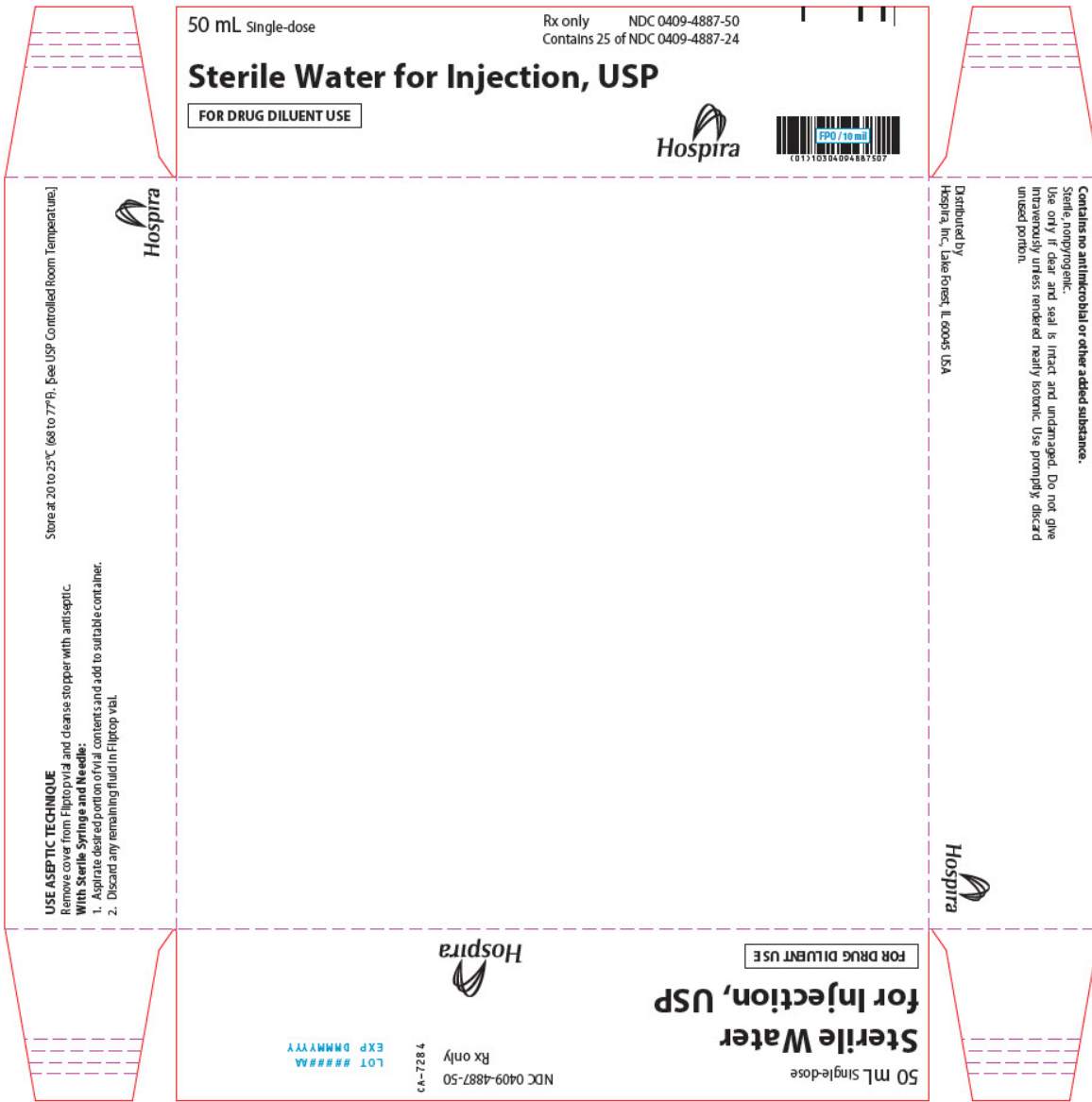
NDC 0409-4887-50

Contains 25 of NDC 0409-4887-24

Sterile Water for Injection, USP

FOR DRUG DILUENT USE

Hospira



STERILE WATER				
water injection				
Product Information				
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0409-4887	
<b>Route of Administration</b>	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS			
Active Ingredient/Active Moiety				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	WATER (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	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) , MANUFACTURE(0409-4887) , PACK(0409-4887) , LABEL(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) , MANUFACTURE(0409-4887) , PACK(0409-4887) , LABEL(0409-4887)

Revised: 1/2024

Hospira, Inc.