

STERILE WATER- water injection

Henry Schein, Inc.

Sterile Water For Injection, USP Single Dose 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 H₂O. 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 concentrations 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 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 Category C. 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 for 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 patients, 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 appropriated 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 25C (68 to 77F). [See USP Controlled Room Temperature.]

Product repackaged by: Henry Schein, Inc., Bastian, VA 24314

From Original Manufacturer/Distributor's	To Henry Schein Repackaged Product NDC and Unit of Sale	Total Strength/Total Volume (Concentration)
---	--	--

NDC and Unit of Sale	Product NDC and Unit of Sale	per unit
NDC 0409-4887-10 Tray of 25 Single-Dose Plastic Fliptop Vials	NDC 0404-9959-10 1 10 mL Single-Dose Plastic Fliptop Vial in a bag (Vial bears NDC 0409- 4887-17)	10 mL
NDC 0409-4887-20 Tray of 25 Single-Dose Plastic Fliptop Vials	NDC 0404-9959-20 1 20 mL Single-Dose Plastic Fliptop Vial in a bag (Vial bears NDC 0409- 4887-23)	20 mL
NDC 0409-4887-50 Tray of 25 Single-Dose Plastic Fliptop Vials	NDC 0404-9959-50 1 50 mL Single-Dose Plastic Fliptop Vial in a bag (Vial bears NDC 0409- 4887-24)	50 mL

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

LAB-1292-2.0

Revised: 05/2021

SAMPLE PACKAGE LABEL

STERILE WATER

10 mL

INJECTION, USP
Single - Dose

FOR DRUG DILUENT USE.
USE ASEPTIC TECHNIQUE.
Contains no antimicrobial or other added substance.
Sterile, nonpyrogenic.
Use only if clear and seal is intact and undamaged. Do not give intravenously unless rendered nearly isotonic. Use promptly; discard unused portion.

Keep out of children's reach.
Store at 20 to 25C (68 to 77F). (See USP Controlled Room Temperature.)

NDC: 
0404-9959-10

ITEM# :2580432
LOT# XXXXXXXXX
EXP: mm - dd - yy

SEE MANUFACTURER'S INSERT
FOR COMPLETE PRODUCT AND
PRESCRIBING INFORMATION


Packaged By
Henry Schein, Inc.
80 Summit View Lane
Bastian, VA 24314


MANUFACTURER INFORMATION
Mfr: Hospira

ORIG MFG LOT: XX - XXX - XX
NDC: 0409 - 4887 - 10

LBL : XXXXXX

RX ONLY

Sterile Water		MANUFACTURER INFORMATION Mfr: Hospira, Inc. ORIG MFG LOT: XX-XXX-XX NDC: 0409-4887-20	RX ONLY
20 mL	Injection, USP Single - dose		
<p>FOR DRUG DILUENT USE. Contains no antimicrobial or other added substance. Sterile, nonpyrogenic. Use only if clear and seal is intact and undamaged. Do not give intravenously unless rendered nearly isotonic. Use promptly; discard unused portion. USE ASEPTIC TECHNIQUE. Remove cover from FlipTop vial and cleanse stopper with antiseptic. With Sterile Syringe and Needle: 1. Aspirate desired portion of vial contents and add to suitable container. 2. Discard any remaining fluid in FlipTop vial.</p> <p>Keep out of children's reach.</p> <p>Store at 20 to 25C (68 to 77F). (See USP Controlled Room Temperature.)</p>			
NDC:  0404-9959-20			
ITEM# :2580440 LOT# XXXXXXXXX EXP: mm-dd-yy		LBL : XXXXXX	
<p>SEE MANUFACTURER'S INSERT FOR COMPLETE PRODUCT AND PRESCRIBING INFORMATION</p> <p>Packaged By Henry Schein, Inc. 80 Summit View Lane Bastian, VA 24314</p>			

Sterile Water		MANUFACTURER INFORMATION Mfr: Hospira, Inc. ORIG MFG LOT: XX-XXX-XX NDC: 0409-4887-50	RX ONLY
50 mL	Injection, USP Single - dose		
<p>FOR DRUG DILUENT USE. Contains no antimicrobial or other added substance. Sterile, nonpyrogenic. Use only if clear and seal is intact and undamaged. Do not give intravenously unless rendered nearly isotonic. Use promptly; discard unused portion. USE ASEPTIC TECHNIQUE. Remove cover from FlipTop vial and cleanse stopper with antiseptic. With Sterile Syringe and Needle: 1. Aspirate desired portion of vial contents and add to suitable container. 2. Discard any remaining fluid in FlipTop vial.</p> <p>Keep out of children's reach.</p> <p>Store at 20 to 25C (68 to 77F). (See USP Controlled Room Temperature.)</p>			
NDC:  0404-9959-50			
ITEM# :2480809 LOT# XXXXXXXXX EXP: mm-dd-yy		LBL : XXXXXX	
<p>SEE MANUFACTURER'S INSERT FOR COMPLETE PRODUCT AND PRESCRIBING INFORMATION</p> <p>Packaged By Henry Schein, Inc. 80 Summit View Lane Bastian, VA 24314</p>			

STERILE WATER

water injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-9959(NDC:0409-4887)
Route of Administration	INTRAVENOUS, INTRAMUSCULAR, 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:0404-9959-10	1 in 1 BAG	01/12/2022	08/31/2027
1		10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:0404-9959-20	1 in 1 BAG	01/12/2022	
2		20 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
3	NDC:0404-9959-50	1 in 1 BAG	01/12/2022	
3		50 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	NDA018801	01/12/2022	

Labeler - Henry Schein, Inc. (012430880)