STERILE WATER- water injection, solution
Hospira, Inc.

Sterile Water for Injection, USP

Pharmacy Bulk Package — Not for Direct Infusion.
FOR USE ONLY WITH AUTOMATED COMPOUNDING DEVICES.

Flexible Container R_x only

DESCRIPTION

Sterile Water for Injection, USP is a sterile, nonpyrogenic water for injection intended only for dilution purposes. The pH is 5.4 (5.0 to 7.0). The Pharmacy Bulk Package is a sterile dosage form which contains multiple single doses for use only in a pharmacy bulk admixture program.

Sterile Water for Injection, USP contains no bacteriostat, antimicrobial agent or added buffer.

Sterile Water for Injection, USP may be classified as a sterile diluent and pharmaceutical vehicle.

Sterile Water for Injection, USP is chemically designated H_2O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions inside the plastic container also can leach out certain of its chemical components in very small amounts before the expiration period is attained. However, the safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers.

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 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

Sterile Water for Injection, USP in the Pharmacy Bulk Package is indicated for use with automated compounding devices for preparing intravenous admixtures in the pharmacy.

CONTRAINDICATIONS

NOT FOR DIRECT INFUSION. DO NOT USE FOR NON-AUTOMATED ADMIXTURE PREPARATIONS.

WARNINGS

FOR DILUTION ONLY.

Do not heat over 66°C (150°F).

This preparation is **solute-free** and its entry into the circulation undiluted will cause **hemolysis**.

Absorption of large amounts of Sterile Water for Injection, USP with additives can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

Do not use unless water is clear, seal is intact and container is undamaged.

Aseptic technique is essential with the use of sterile preparations for compounding admixtures.

Discard container within 4 hours of entering closure.

ADVERSE REACTIONS

Accidental contamination from careless technique may transmit infection.

Should any adverse reaction occur, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination, if deemed necessary.

DOSAGE AND ADMINISTRATION

Sterile Water for Injection, USP in the 2000 mL flexible Pharmacy Bulk Package is designed for use with automated compounding devices for preparing intravenous admixtures. Dosages will be in accordance with the recommendation of the prescribing physician.

Sterile Water for Injection, USP is not intended for direct infusion. Admixtures should be made by or under the direction of a pharmacist using strict aseptic technique under a laminar flow hood. Compounded admixtures may be stored under refrigeration for up to 24 hours. Administration of admixtures should be completed within 24 hours after removal from refrigeration.

Drug Interactions

The Pharmacy Bulk Package is intended only for use in the preparation of sterile, intravenous admixtures using automated compounding devices.

Additives may be incompatible with the fluid withdrawn from this container. Consult with pharmacist, if available. When compounding admixtures, use aseptic technique, mix thoroughly and do not store.

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

Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish

gradually.

Recommended Directions for Use of the Pharmacy Bulk Package

Use Aseptic Technique

1. During use, container must be stored, and all manipulations performed, in an appropriate laminar flow hood.

2. Remove cover from outlet port at bottom of container.

3. Insert piercing pin of transfer set and suspend unit in a laminar flow hood. Insertion of a piercing pin into the outlet port should be performed only once in a Pharmacy Bulk Package solution. Once the outlet site has been entered, the withdrawal of container contents should be completed promptly in one continuous operation. Should this not be possible, a maximum time of 4 hours from transfer set pin or implement insertion is permitted to complete fluid transfer operations; i.e., discard container no later than 4 hours after initial closure puncture.

4. Sequentially dispense aliquots of Sterile Water for Injection, USP into I.V. containers using appropriate transfer set. During fluid transfer operations, the Pharmacy Bulk Package should be maintained under the storage conditions recommended in the labeling.

HOW SUPPLIED

Sterile Water for Injection, USP is supplied in 2000 mL flexible Pharmacy Bulk Packages (List No. 7118).

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

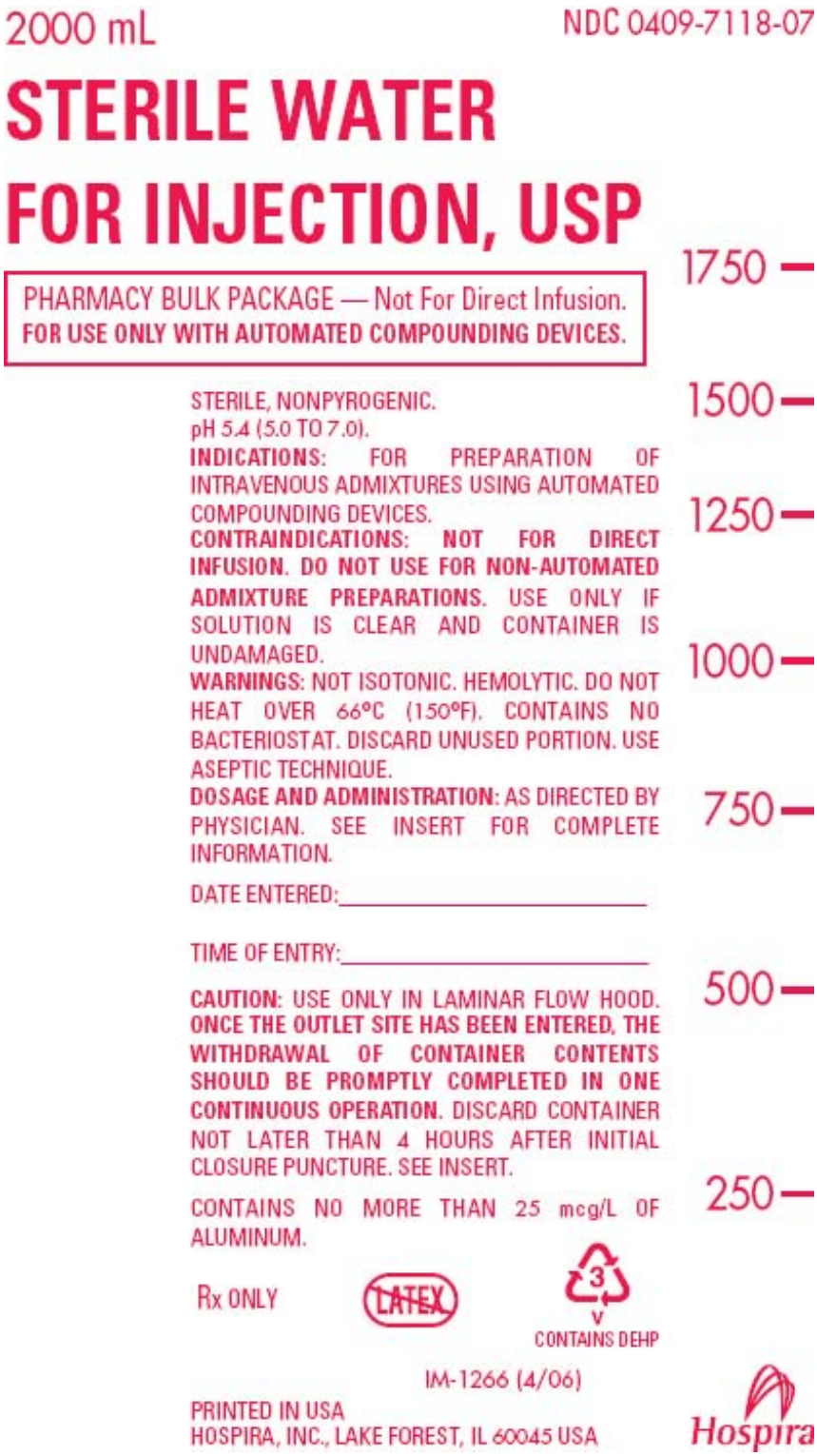
Patent 4,368,765

Revised: May, 2006

Printed in USA EN-1194

Hospira, Inc., Lake Forest, IL 60045 USA

IM-1266



PRINCIPAL DISPLAY PANEL - 2000 mL Bag Overwrap

TO OPEN TEAR AT NOTCH

2
HDPE

DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.

98-4321-R14-3/98

STERILE WATER

water injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-7118
Route of Administration	INTRAVENOUS		

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:0409-7118-07	6 in 1 CASE	08/03/2005	09/01/2020
1		2000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019869	08/03/2005	09/01/2020

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		827731089	ANALYSIS(0409-7118)

Revised: 9/2019 Hospira, Inc.