STERILE WATER- water injection, solution
Baxter Healthcare Company

Sterile Water for Injection, USP
in VIAFLEX Plastic Container
For Drug Diluent Use Only

DESCRIPTION

Sterile Water for Injection, USP, is sterile, nonpyrogenic, distilled water in a single dose container for intravenous administration after addition of a suitable solute. It may also be used as a dispensing container for diluent use. No antimicrobial or other substance has been added. The pH is 5.5 (5.0 to 7.0). The osmolarity is 0.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

CLINICAL PHARMACOLOGY

Sterile Water for Injection, USP is used for fluid replacement only after suitable additives are introduced to approximate isotonicity and to serve as a vehicle for suitable medications.

INDICATIONS AND USAGE

Sterile Water for Injection, USP is indicated in the aseptic preparation of parenteral solutions.

CONTRAINDICATIONS

Sterile Water for Injection, USP is a hemolytic agent due to its hypotonicity. Therefore, it is contraindicated for intravenous administration without additives.

WARNINGS

Do not use for intravenous injection unless adjusted to approximate isotonicity with a suitable solute.

Hemolysis may occur following infusion of Sterile Water for Injection, USP. Hemoglobin induced renal failure has been reported following hemolysis.

PRECAUTIONS

Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS

The administration of a suitable admixture of prescribed additives may be associated with adverse reactions because of the solution or the technique of administration including febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate

therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

Following suitable admixture of prescribed additives, the dosage is usually dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations. See directions accompanying additive drug.

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

Injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. **Do not store an unused portion of Sterile Water for Injection, USP**. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

Sterile Water for Injection, USP is supplied in VIAFLEX plastic containers as follows:

1000 mL	2B0304	NDC 0338-0013-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the port outlet protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. 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. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. See following directions.

Preparation for Administration After Rendering Isotonic

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

Warning: Additives may be incompatible.

To add medication before administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Printed in USA

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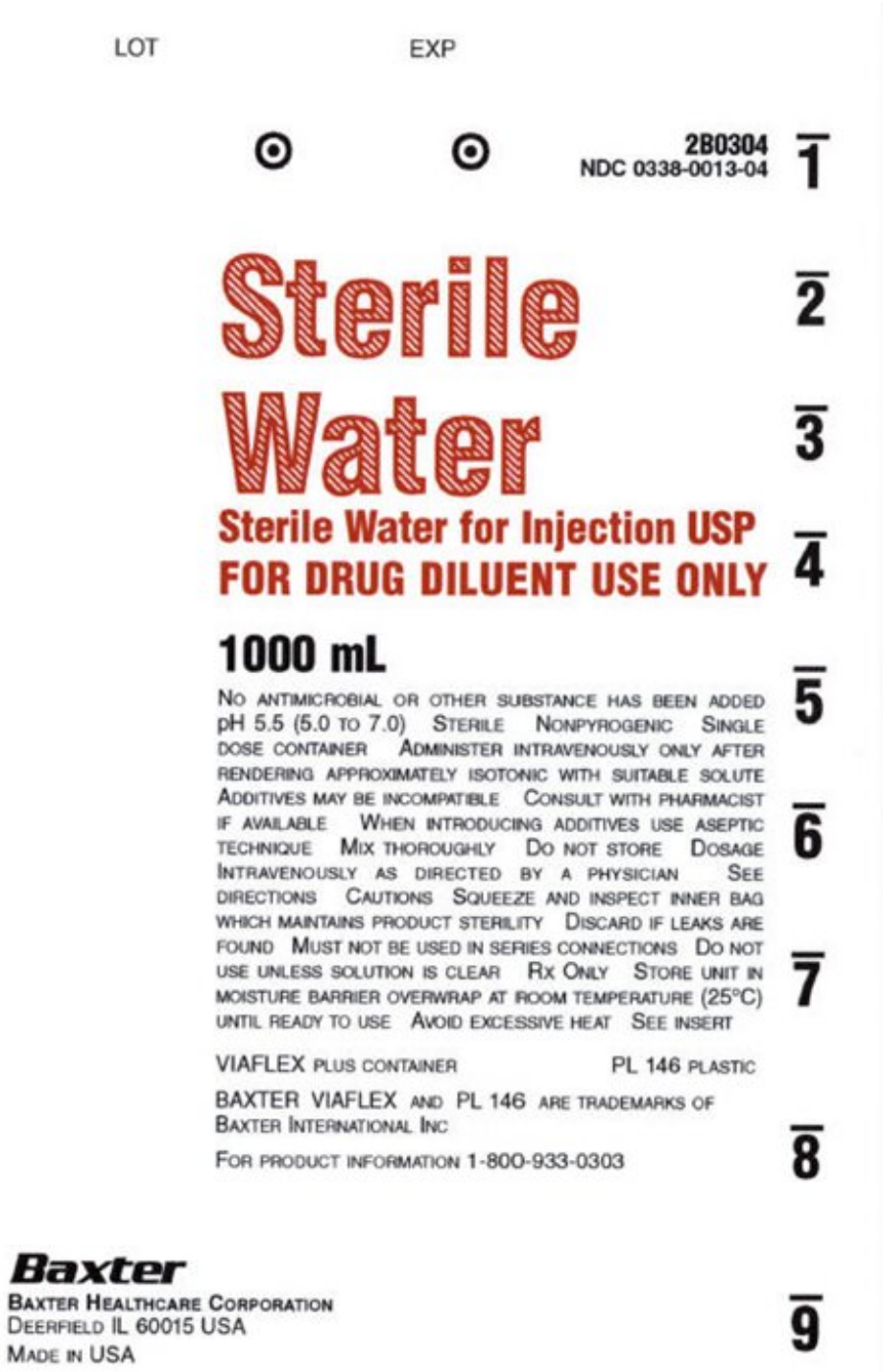
PACKAGE LABEL.PRINCIPLE DISPLAY PANEL



Sterile Water Container Label

Sterile Water Container Label

LOT EXP

2B0304

NDC 0338-0013-04

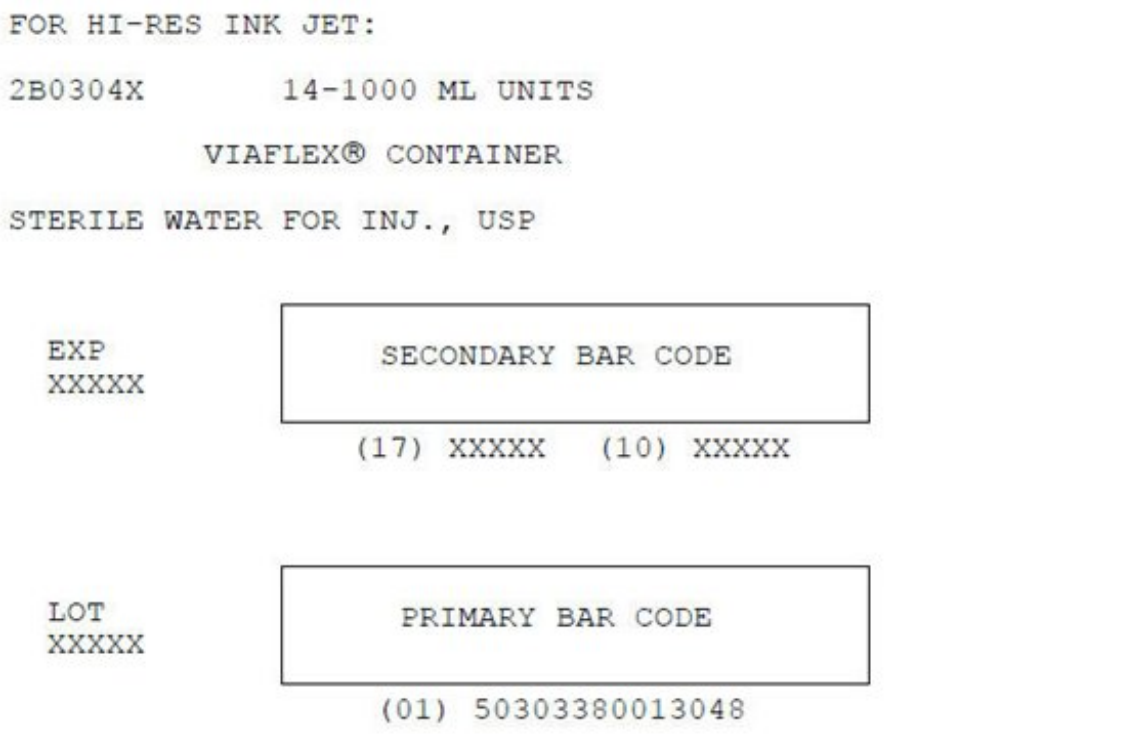
STERILE WATER

STERILE WATER FOR INJECTION USP

FOR DRUG DILUENT USE ONLY

1000mL

NO ANTIMICROBIAL OR OTHER SUBSTANCE HAS BEEN ADDED
pH 5.5 (5.0 TO 7.0) STERILE NONPYROGENIC SINGLE
DOSE CONTAINER ADMINISTER INTRAVENOUSLY ONLY AFTER
RENDERING APPROXIMATELY ISOTONIC WITH SUITABLE SOLUTE
ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST
IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC
TECHNIQUE MIX THOROUGHLY DO NO STORE DOSAGE
INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE
DIRECTIONS CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE
FOUND MUST NOT BE USED IN SERIES CONNECTIONS DO NOT
USE UNLESS SOLUTION IS CLEAR RX ONLY STORE UNIT IN
MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C)
UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT
VIAFLEX PLUS CONTAINER PL 146 PLASTIC
BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF
BAXTER INTERNATIONAL INC
FOR PRODUCT INFORMATION 1-800-933-0303
BAXTER
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN THE USA



Sterile Water Carton Label

Sterile Water Carton Label

2B0304X 14-1000 ML UNITS

VIAFLEX® CONTAINER

STERILE WATER FOR INJ., USP

EXP

XXXXX

SECONDARY BAR CODE

(17) XXXXX (10) XXXXX

LOT

XXXXX

PRIMARY BAR CODE

(01) 50303380013048

NOTE: Lot and Exp. Date added at time of printing.

Secondary bar code human readable is variable and will be

added at time of printing. The parenthesis are not

encoded in actual bar code.

STERILE WATER

water injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0013
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	100 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0338-0013-04	1000 mL in 1 BAG; Type 0: Not a Combination Product	06/30/1982	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018632	06/30/1982	

Labeler - Baxter Healthcare Company (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	API MANUFACTURE(0338-0013) , ANALYSIS(0338-0013) , LABEL(0338-0013) , MANUFACTURE(0338-0013) , PACK(0338-0013) , STERILIZE(0338-0013)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0013)

Revised: 12/2019 Baxter Healthcare Company