STERILE WATER- water injection, solution
Baxter Healthcare Company

Sterile Water For Injection, USP
Pharmacy Bulk Package
Not for Direct Infusion
VIAFLEX Plastic Container

DESCRIPTION

Sterile Water for Injection, USP is sterile, nonpyrogenic, distilled water in a Pharmacy Bulk Package. A Pharmacy Bulk Package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion. No antimicrobial or other substance has been added. pH 5.5 (5.0 to 7.0). Osmolarity O mOsmol/L (calc.).

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. 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 admixing to approximate isotonicity.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

WARNINGS

This solution is for compounding only, not for direct infusion. Hemolysis may occur following infusion of Sterile Water for Injection, USP. Hemoglobin induced renal failure has been reported following hemolysis.

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 µg/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 solution is clear and seal is intact.

Drug product contains no more than 25 µg/L of aluminum.

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.

ADVERSE REACTIONS

The administration of a suitable admixture of prescribed drugs 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 drugs, the dosage is usually dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations. See directions accompanying drugs.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions where possible.

Sterile Water for Injection, USP in the Pharmacy Bulk Package is intended for use in the preparation of sterile, intravenous admixtures. Additives may be incompatible with the fluid withdrawn from this container. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. When compounding admixtures, use aseptic technique. Mix thoroughly. Do not store any unused portion of Sterile Water for Injection, USP.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC PHARMACY BULK PACKAGE CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port 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.

For compounding only, not for direct infusion.

Preparation for Admixing

1. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
2. Suspend container from eyelet support.
3. Remove plastic protector from outlet port at bottom of container.
4. Attach solution transfer set. Refer to complete directions accompanying set. Note: The closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set which allows measured dispensing of the contents.
5. VIAFLEX containers should not be written on directly since ink migration has not been investigated. Affix accompanying label for date and time of entry.
6. Once container closure has been penetrated, withdrawal of contents should be completed without delay. After initial entry, maintain contents at room temperature (25°C/77°F) and dispense within 4 hours.

HOW SUPPLIED

Sterile Water for Injection, USP is supplied in a VIAFLEX plastic Pharmacy Bulk Package container as follows:

2000 mL	2B0306	NDC 0338-0013-06
3000 mL	2B0307	NDC 0338-0013-08
5000 mL	2B0309	NDC 0338-0013-29

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F).

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

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Distributed in Canada by
Baxter Corporation
Mississauga, ON L5N 0C2

PACKAGE LABEL - PRINCIPLE DISPLAY PANEL

Container Label

Container Label

LOT EXP

2B0306 2000 mL
NDC 0338-0013-06 DIN 02014882

Sterile Water
For Injection USP

Pharmacy Bulk Package
Not For Direct Infusion

Rx Only

NO ANTIMICROBIAL OR OTHER SUBSTANCE HAS BEEN ADDED
pH 5.5 (5.0 TO 7.0) OSMOLARITY 0 mOsmol/L (CALC)
STERILE NONPYROGENIC

CONTAINS NO MORE THAN 25 µg/L OF ALUMINUM

ADDITIVES MAY BE INCOMPATIBLE WITH THE FLUID WITHDRAWN FROM THIS CONTAINER CONSULT WITH PHARMACIST IF AVAILABLE WHEN COMPOUNDING ADMIXTURES USE ASEPTIC TECHNIQUE
MIX THOROUGHLY DO NOT STORE

DOSAGE ADMIX FOR INTRAVENOUS ADMINISTRATION AS DIRECTED BY A PHYSICIAN SEE ACCOMPANYING DIRECTIONS FOR USE **ONCE CONTAINER CLOSURE HAS BEEN PENETRATED WITHDRAWAL OF CONTENTS SHOULD BE COMPLETED WITHOUT DELAY** AFFIX ACCOMPANYING LABEL FOR DATE AND TIME OF ENTRY DISPENSE CONTENTS WITHIN 4 HOURS AFTER INITIAL ENTRY

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR AND SEAL IS INTACT

STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT

VIAFLEX CONTAINER PL 146 PLASTIC

Baxter logo

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA

DISTRIBUTED IN CANADA BY
BAXTER CORPORATION
MISSISSAUGA ON L5N 0C2

1800

1600

1400

1200

1000

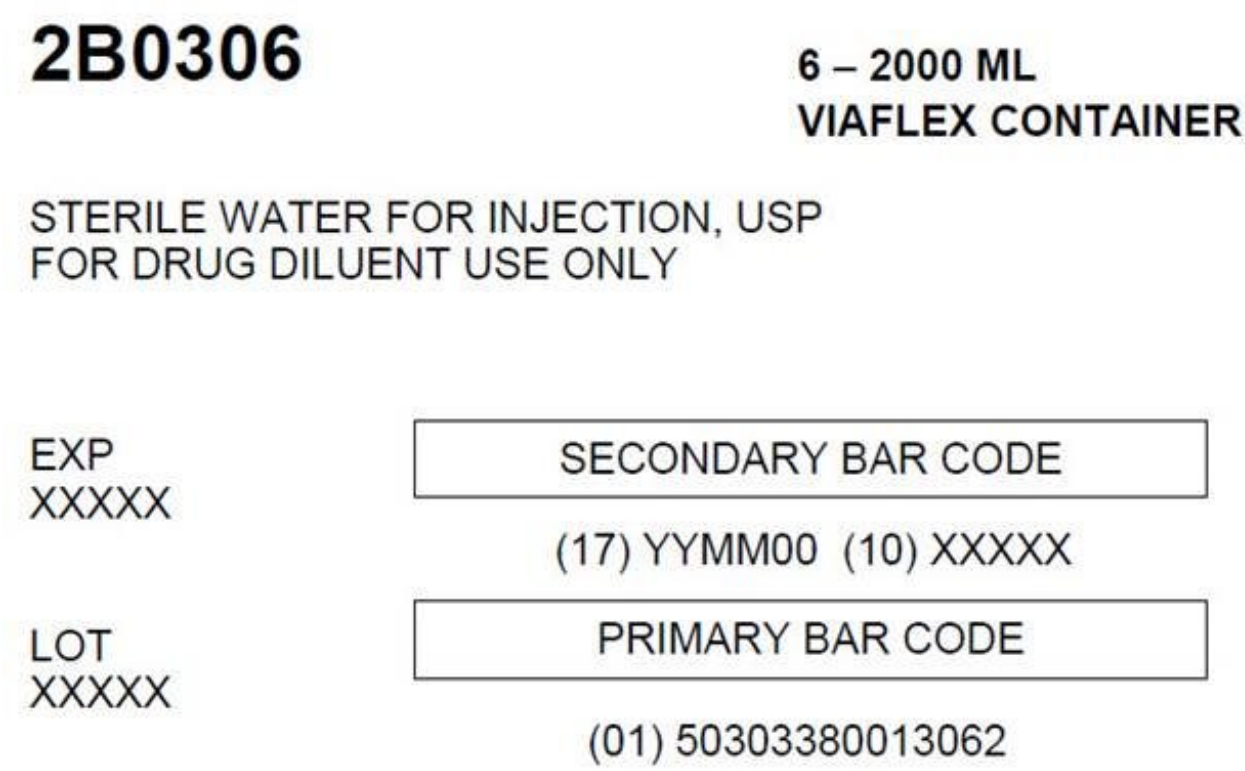
800

600

400

200

07-25-69-275/
07-25-34-056



Carton Label

Carton Label

2B0306 6 - 2000 ML
VIAFLEX CONTAINER

STERILE WATER FOR INJECTION, USP
FOR DRUG DILUENT USE ONLY

EXP
XXXXX

SECONDARY BAR CODE

(17) YYMM00 (10) XXXXX

LOT
XXXXX

PRIMARY BAR CODE

(01) 50303380013062

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:0338-0013-06	2000 mL in 1 BAG; Type 0: Not a Combination Product	06/30/1982	
2	NDC:0338-0013-08	3000 mL in 1 BAG; Type 0: Not a Combination Product	06/30/1982	
3	NDC:0338-0013-29	5000 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	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: 5/2016

Baxter Healthcare Company