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.

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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).

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