PRESCRIBING INFORMATION

Sterile Water For Injection, USP
In VIAFLEX Plastic Container

Parenteral Replenisher

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Date of Revision:
November 3, 2016

Submission Control No: 177550

Prescribing Information

Sterile Water For Injection, USP in VIAFLEX Plastic Container

Pharmacy Bulk Package
Not for Direct Infusion

SUMMARY PRODUCT INFORMATION

Sterile Water for Injection, USP, is a 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.: a single puncture, multiple dispensing package. 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 0 mOsmol/L (calc.). 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.

ACTION AND CLINICAL PHARMACOLOGY

Sterile Water for Injection, USP is used for fluid replacement only after suitable admixing to approximate isotonicity.

INDICATIONS AND CLINICAL USE

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 AND PRECAUTIONS

Hypotonic and hemolytic. Sterile Water for Injection, USP is hypotonic. Ensure that the product has appropriate tonicity before intended use. Do not administer Sterile Water for Injection, USP intravenously as it will cause hemolysis. Haemoglobin induced renal failure has been reported following haemolysis.

General

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentration, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

This solution is for compounding only, not for direct infusion. This product contains aluminum which 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 that 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 per kg per day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration on TPN products.

Do not use unless solution is clear and seal is intact. Drug product contains no more than 25 µg/L of aluminum.

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.

OVERDOSAGE

Overdose may occur in patients receiving large quantities of Sterile Water for Injection. Symptoms of overdose may include central nervous system changes (weakness, muscle twitching, headaches, nausea, vomiting, convulsions), behavioural changes (confusion, apathy, disorientation, and hyponatremia). Treatment may include withholding fluids until excessive water is excreted. In cases of severe hyponatremia, hypertonic saline can be administered to increase extracellular osmotic pressure and excretion of excess water by the kidneys.

DOSAGE FORMS, COMPOSITION AND PACKAGING

How Supplied

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

1000 mL	JB0304

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 15° C to 25° C and dispense within 4 hours.

Storage

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at 15° C to 25° C.

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Last revised: November 3, 2016