

**STERILE WATER- water injection, solution**  
**Fresenius Kabi USA, LLC**

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**Sterile Water for Injection, USP**  
**FOR DRUG DILUENT USE ONLY**

**freeflex<sup>®</sup>**

Rx only

**DESCRIPTION:**

Sterile Water for Injection, USP is a sterile, nonpyrogenic, solute-free preparation of distilled water for injection. It is for use only as a sterile solvent or diluent vehicle for drugs or solutions suitable for parenteral administration. The pH is 5.5 (5.0 to 7.0).

Sterile Water for Injection contains no bacteriostat, antimicrobial agent or added buffer and is intended only for single dose injection after admixture with an appropriate solute or solution. When smaller amounts are required, the unused portion should be discarded.

Sterile Water for Injection is a pharmaceutical aid (vehicle) and parenteral fluid replenisher after addition of an appropriate solute.

Water for Injection, USP is chemically designated H<sub>2</sub>O.

The flexible container is fabricated from a specially formulated non-plasticized, film containing polypropylene and thermoplastic elastomers ( **freeflex<sup>®</sup>** bag). The amount of water that can permeate from the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the flexible container can leach out certain of the container's chemical components in very small amounts within the expiration period. The suitability of the container material has been confirmed by tests in animals according to USP biological tests for plastic containers.

**CLINICAL PHARMACOLOGY:**

When administered intravenously as a vehicle for drugs, sterile water for injection provides a source of water for parenteral fluid replenishment after sufficient solute is introduced to achieve an osmolarity of 112 mOsmol or more per liter.

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<sup>+</sup>) plays a major role in maintaining physiologic equilibrium.

**INDICATIONS AND USAGE:**

Sterile Water for Injection is indicated for use only as a solvent or diluent vehicle for parenterally administered drugs or solutions and as a source of water for parenteral fluid replenishment after suitable additives are introduced.

For intravenous administration, an osmolar concentration not less than two-fifths (0.4) of the normal osmolarity of the extracellular fluid (280 mOsmol/liter) is essential to avoid intravascular hemolysis.

## **CONTRAINDICATIONS:**

Do not administer without the addition of a solute.

## **WARNINGS:**

### **FOR DRUG DILUENT USE ONLY.**

Intravenous administration of Sterile Water for Injection without additives may result in hemolysis.

The intravenous administration of sterile water for injection 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 parenteral 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 for intravenous injection unless the osmolar concentration of additives totals at least 112 mOsmol/liter (two-fifths of the normal osmolarity of the extracellular fluid  $\approx$  280 mOsmol/liter).

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

### ***Pregnancy Category C***

Animal reproduction studies have not been conducted with sterile water for injection. It is also not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile water for injection with additives should be given to a pregnant woman only if clearly needed.

### ***Pediatric Use***

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

This product contains no more than 25 mcg/L of aluminum.

## **ADVERSE REACTIONS:**

Reactions which may occur because of the technique of administration include 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.

**OVERDOSAGE:**

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures (See WARNINGS).

**DOSAGE AND ADMINISTRATION:**

Following suitable admixture of prescribed additive, the dose is usually dependent upon the age, weight and clinical condition of the patient.

***Drug Interactions***

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, 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 and container permit (See PRECAUTIONS).

**HOW SUPPLIED:**

Sterile Water for Injection, USP is supplied in a single dose flexible plastic container as follows:

| <b>Product No.</b> | <b>NDC No.</b> | <b>Bag Size</b> | <b>Bags Per Carton</b> |
|--------------------|----------------|-----------------|------------------------|
| 917876             | 63323-178-76   | 1,000 mL Bag    | 10 Bags                |

The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

**INSTRUCTIONS FOR USE:**

Check flexible container solution composition, lot number, and expiry date.

Do not remove solution container from its overwrap until immediately before use.

Use sterile equipment and aseptic technique.

**To Open**

1. Turn solution container over so that the text is face down. Using the pre-cut corner tabs, peel open the overwrap and remove solution container.
2. Check the solution container for leaks by squeezing firmly. If leaks are found, or if the seal is not intact, discard the solution.
3. Do not use if the solution is cloudy or a precipitate is present.

**To Add Medication**

1. Identify WHITE Additive Port with arrow pointing toward container.
2. Immediately before injecting additives, break off WHITE Additive Port Cap with the arrow pointing toward container.
3. Hold base of WHITE Additive Port horizontally.
4. Insert needle horizontally through the center of WHITE Additive Port's septum and inject additives.
5. Mix container contents thoroughly.

**Preparation for Administration**

1. Immediately before inserting the infusion set, break off BLUE Infusion Port Cap with the arrow pointing away from container.

2. Use a non-vented infusion set or close the air-inlet on a vented set.
3. Close the roller clamp of the infusion set.
4. Hold the base of BLUE Infusion Port.
5. Insert spike through BLUE Infusion Port by rotating wrist slightly until the spike is inserted.  
**NOTE:** See full directions accompanying administration set.

**WARNING: DO NOT USE FLEXIBLE CONTAINER IN SERIES CONNECTIONS.**

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

Manufactured for:



Lake Zurich, IL 60047

Made in Germany

[www.fresenius-kabi.com/us](http://www.fresenius-kabi.com/us)

451727

Issued: December 2017

**PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - Sterile Water 1,000 mL Bag Label**  
**freeflex<sup>®</sup> 1,000 mL**

**Sterile Water for Injection, USP**

Do not give intravenously.

For drug diluent use only.

For intravenous use.

Rx only

100 NDC 63323-178-76 1,000 mL

**freeflex<sup>®</sup>**

**Sterile Water for Injection, USP**

200 **DO NOT GIVE INTRAVENOUSLY.  
FOR DRUG DILUENT USE ONLY.**


300 For intravenous use. Rx only  
Contains no antimicrobial or other substance. Admixtures should be used promptly with adequate precautions for maintaining sterility. pH 5.5 (5.0 to 7.0).


**WARNINGS: NOT ISOTONIC. HEMOLYTIC.**  
Do not give intravenously unless rendered nearly isotonic.  
Single-Dose Container. Discard Unused Portion.



400 Additives may be incompatible. Consultation with pharmacist is recommended. When introducing additives, use aseptic technique, mix thoroughly and do not store.  
**Usual dosage:** See package insert.  
The overwrap is a moisture barrier.

500 Use immediately once removed from overwrap.  
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from freezing. Sterile, nonpyrogenic. Use only if solution is clear and container is undamaged. Must not be used in series connections.

600 The container closure is not made with natural rubber latex.  
Non-PVC, Non-DEHP, Sterile.

700   
3 NDC 63323-178-76 5

800 Mid. for:  **FRESENIUS KABI** LOT  
Lake Zurich, IL 60047 EXP  
Made in Germany  
www.fresenius-kabi.com/us  
403283A

900  0743551/00 US 

## STERILE WATER

water injection, solution

### Product Information

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:63323-178 |
| <b>Route of Administration</b> | INTRAVENOUS             |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength           |
|---|-------------------|--------------------|
| <b>WATER</b> (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R) | WATER             | 1000 mL in 1000 mL |

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63323-178-76 | 10 in 1 CASE  | 11/24/2017           |                    |
| 1 |                  | 1000 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 |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA209689                               | 11/24/2017           |                    |

**Labeler** - Fresenius Kabi USA, LLC (608775388)

## Establishment

| Name                            | Address | ID/FEI    | Business Operations    |
|---------------------------------|---------|-----------|------------------------|
| Fresenius Kabi Deutschland GmbH |         | 506719546 | manufacture(63323-178) |

Revised: 6/2019

Fresenius Kabi USA, LLC