STERILE WATER - water injection, solution
Becton Dickinson and Company

Sterile Water for Injection, USP

FOR DRUG DILUENT USE ONLY

freeflex®

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 pharmaceutic aid (vehicle) and parenteral fluid replenisher after addition of an appropriate solute.

Water for Injection, USP is chemically designated H_2O.

The flexible container is fabricated from a specially formulated non-plasticized, film

containing polypropylene and thermoplastic elastomers (free*flex*® 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^+) 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 - 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:

Product No.	**NDC**		

	No.	Bag Size	Bags Per Carton
1727175007	17271-750-07	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:

BD

Becton, Dickinson and Company
1 Becton Drive,

Franklin Lakes, NJ 07417 USA
For product inquiry: 1-800-523-0502
Distributed by BD. Manufactured by Fresenius Kabi.

Made in Germany.

451640

Issued: June 2019

PACKAGE LABEL - PRINCIPAL DISPLAY – Sterile Water for Injection Bag Label
NDC 17271-750-07
free*flex*® 1,000 mL

Sterile Water for Injection, USP

DO NOT GIVE INTRAVENOUSLY.

FOR DRUG DILUENT USE ONLY.

For intravenous use.

Rx only

NDC 17271-750-07

100

freeflex®

1,000 mL

Sterile Water for Injection, USP

200

DO NOT GIVE INTRAVENOUSLY.
FOR DRUG DILUENT USE ONLY.

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).

300

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.

(01)00317271750078

700

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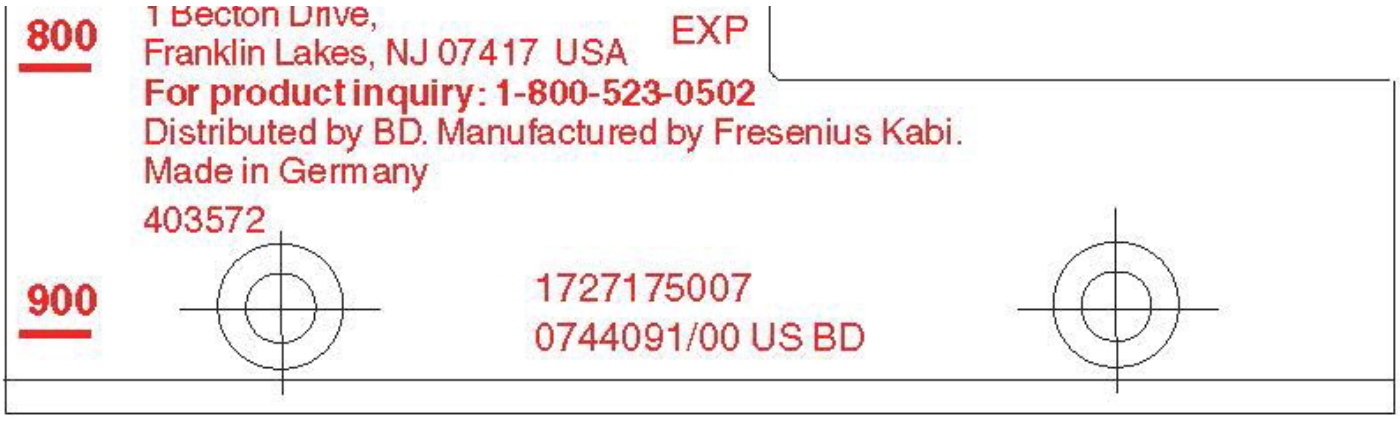
Becton, Dickinson and Company

LOT



PACKAGE LABEL - PRINCIPAL DISPLAY – Sterile Water for Injection Case Label
NDC 17271-750-07 REF 1727175007
Sterile Water for Injection, USP

1,000 mL x 10 Rx only

NDC 17271-750-07 REF 1727175007

QTY 10

Sterile Water for Injection, USP

1,000 mL x 10 Rx only

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

LOT

EXP

BD

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1 Becton Drive,
Franklin Lakes, NJ 07417 USA
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Manufactured by Fresenius Kabi.
Made in Germany.

63744
0755221/00 US BD

(01)50317271750073

STERILE WATER

water injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17271-750
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	1000 mL in 1000 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17271-750-07	10 in 1 CASE	02/28/2020	
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	02/28/2020	

Labeler - Becton Dickinson and Company (124987988)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Deutschland GmbH		506719546	manufacture(17271-750) , analysis(17271-750)

Revised: 2/2020 Becton Dickinson and Company