STERILE WATER- water injection
Fresenius Kabi USA, LLC

Sterile Water for Irrigation, USP

Rx only

DESCRIPTION

Sterile Water for Irrigation, USP is a sterile, hypotonic, nonpyrogenic irrigating fluid or pharmaceutic aid (solvent) entirely composed of Sterile Water for Injection, USP. It is prepared by distillation and contains no antimicrobial or bacteriostatic agents or added buffers.

The pH is 5.7 (5.0-7.0)

The flexible plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers. The solution contact layer is a copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during administration.

Not made with natural rubber latex, PVC or DEHP.

CLINICAL PHARMACOLOGY

Sterile Water for Irrigation is utilized for a variety of clinical indications. Because of its low refractive index (1.3325), water provides excellent visibility during endoscopic urological procedures. It is also utilized as a pharmaceutic aid, as well as in the preparation of enteral nutrient products.

Water is hypotonic and will cause hemolysis and will be readily absorbed by the tissues during surgical procedures; therefore, its use under such conditions is not recommended.

INDICATIONS AND USAGE

Sterile Water for Irrigation is indicated for use as an irrigating fluid or pharmaceutic aid. Sterile Water may also be used as an adjunct in the preparation of non-intravenously administered nutrient mixtures (see **DOSAGE AND ADMINISTRATION**).

CONTRAINDICATIONS

Not for injection.

WARNINGS

Sterile Water for Irrigation is hypotonic and will cause hemolysis, and is not recommended for use during surgical procedures.

After opening container, its contents should be used promptly to minimize the possibility of bacterial growth or pyrogen formation.

Discard unused portion of irrigating solution since it contains no preservative.

PRECAUTIONS

Use only if solution is clear and container and seal are intact.

ADVERSE REACTIONS

None known.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

None known.

DOSAGE AND ADMINISTRATION

Irrigation

Use as directed by physician.

This drug product should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Nutrient Mixtures

Sterile Water for Irrigation, USP may be used to prepare non-intravenously administered nutrient mixtures. It contains no electrolytes or other added substances. Refer to preparation instructions of particular mixture to be used. The plastic container may be used for administration of non-intravenous nutrient mixture to the patient as appropriate.

HOW SUPPLIED

Sterile Water for Irrigation, USP is supplied sterile and nonpyrogenic in single dose flexible plastic containers.

Product Code	Unit of Sale	Each
495010	NDC 65219-495-10 Package of 6 bags	NDC 65219-495-01 1000 mL fill in a 1500 mL bag
497020	NDC 65219-497-20	NDC 65219-497-02

	Package of 5 bags	2000 mL fill in a 2000 mL bag
499030	NDC 65219-499-30 Package of 4 bags	NDC 65219-499-03 3000 mL fill in a 3000 mL bag

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20 to 25°C (68 to 77°F). [see USP Controlled Room Temperature]; however, brief exposure up to 40°C (104°F) does not adversely affect the product.

INSTRUCTIONS FOR USE:

Not for Injection. Not for use with pressurized irrigation systems.

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

Irrigation solutions should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Do not use if the solution is cloudy or precipitate is present.

Check the solution container for leaks by squeezing firmly. If leaks are found, discard.

The intact port cap provides visual tamper evidence. Do not use if port cap is prematurely removed. Maintain strict aseptic technique during handling.

To Add Medication:

1. Identify WHITE Additive Port with arrow pointing toward solution container.
2. Immediately before injecting additives, break off WHITE Additive Port Cap with the arrow pointing toward solution container.
3. Hold base of WHITE Additive Port.
4. Insert needle (18 – 23 gauge) through the center of the WHITE Additive Port's resealable septum and inject additives.
5. Mix solution container contents thoroughly.
6. WHITE Additive port must be swabbed with disinfection agent before re-puncturing.
7. Check admixture visually for particulate matter.

Preparation for Administration

1. Immediately before inserting the irrigation set, break off BLUE Administration Port Cap with the arrow pointing away from the solution container.
2. Use non-vented irrigation set or close the air-inlet on a vented set. Refer to directions for use accompanying the irrigation set.
3. Hold the base of the BLUE Administration Port, twist and push spike until fully inserted.
4. The BLUE Administration Port contains a self-sealing septum that helps prevent leakage after removing the spike. The Administration Port is not intended to be spiked more than once.
5. Suspend solution container from hanger hole.
6. For Single Use Only. Discard unused portion.

Manufactured for:

FRESENIUS KABI

Lake Zurich, IL 60047

Made in Germany
www.fresenius-kabi.com/us

451819
Issued: September 2024

PACKAGE LABEL - PRINCIPAL DISPLAY – Sterile Water for Irrigation, USP 3000 mL Bag Label

solu*flex*® NDC 65219-**499**-03 **3000 mL**

STERILE WATER FOR IRRIGATION, USP

INDICATIONS: FOR IRRIGATION

CONTRAINDICATIONS: NOT FOR INJECTION

soluflex®

NDC 65219-499-03

3000 mL

STERILE WATER FOR IRRIGATION, USP

INDICATIONS: FOR IRRIGATION

CONTRAINDICATIONS: NOT FOR INJECTION

No antimicrobial agent or other substance has been added.
pH: 5.7 (5.0-7.0)

WARNINGS: HYPOTONIC AND HEMOLYTIC

See Package Insert.

Use only if solution is clear and container and seal are intact.

Sterile, nonpyrogenic. Single-Dose container. Discard unused portion.

Dosage: Irrigation. Use as directed by physician.

STORE at **20°** to **25°**C (**68°** to **77°**F) [see USP Controlled Room Temperature]. Avoid excessive heat. Protect from freezing.

Not made with natural rubber latex, PVC or DEHP.

Rx only

(01)00365219499039

Mfd. for:

FRESENIUS KABI

Lake Zurich, IL 60047
Made in Germany
www.fresenius-kabi.com/us

LOT

EXP

404061
0719441/00 US

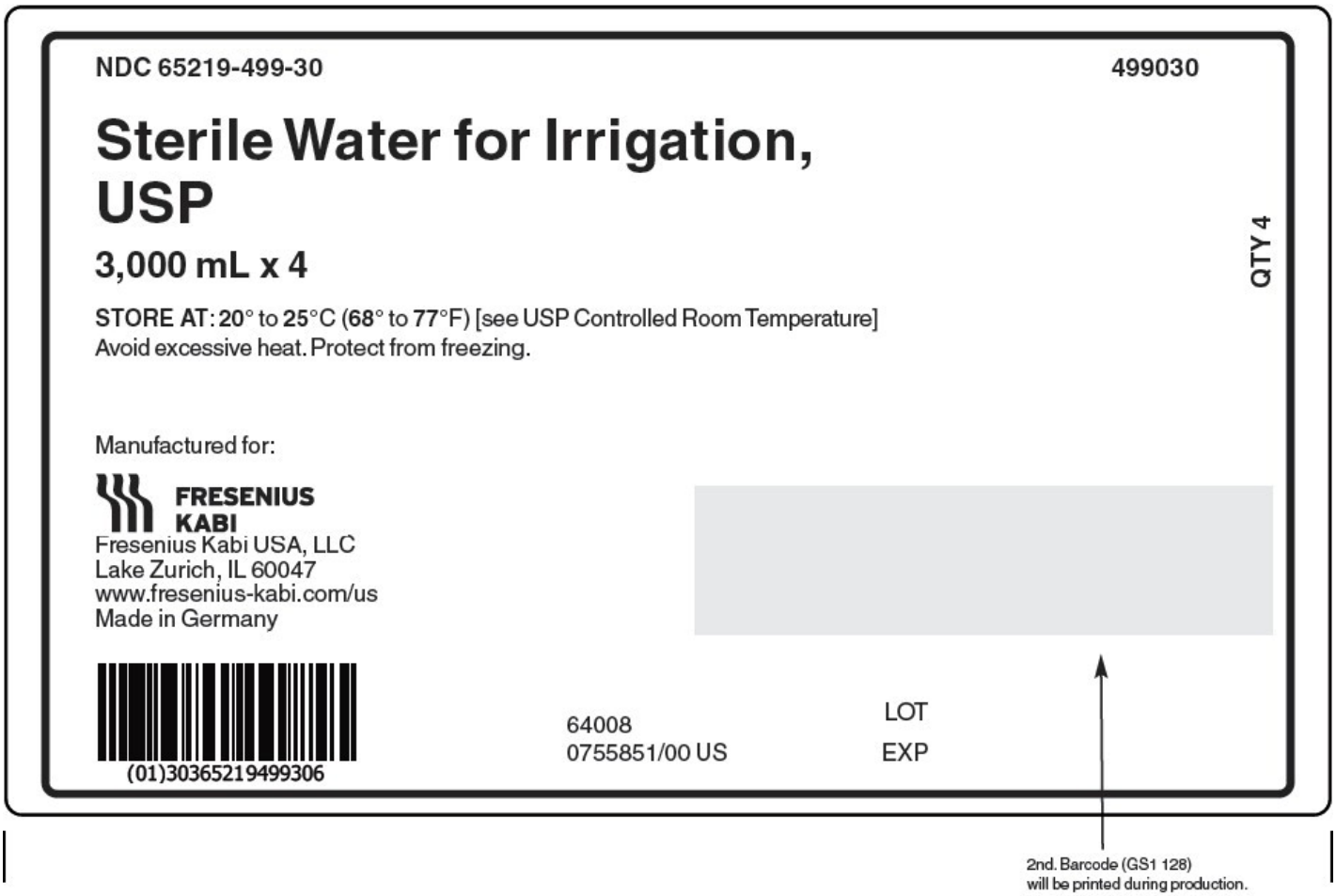
2500
2000
1500
1000

PACKAGE LABEL - PRINCIPAL DISPLAY - Sterile Water for Irrigation, USP 3000 mL Case Label

NDC 65219-499-30 499030

Sterile Water for Irrigation, USP

3,000 mL x 4



STERILE WATER

water injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-499
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65219-499-30	4 in 1 CASE	08/12/2024	
1	NDC:65219-499-03	3000 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216123	08/12/2024	

Labeler - Fresenius Kabi USA, LLC (013547657)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Deutschland GmbH		506719546	MANUFACTURE(65219-499) , ANALYSIS(65219-499) , API MANUFACTURE(65219-499)

Revised: 12/2024 Fresenius Kabi USA, LLC