

STERILE WATER- water irrigant
ICU Medical Inc.

Sterile Water for Irrigation, USP

FOR ALL GENERAL IRRIGATION, WASHING, RINSING AND DILUTION PURPOSES

For Irrigation Only

Not For Injection By Usual Parenteral Routes

Flexible Irrigation Container

Semi-rigid Irrigation Container

Rx only

DESCRIPTION

Sterile Water for Irrigation, USP is a sterile, distilled, nonpyrogenic water for injection intended only for sterile irrigation, washing, rinsing and dilution purposes. pH 5.5 (5.0 to 7.0).

Sterile Water for Irrigation, USP contains no bacteriostat, antimicrobial agent or added buffer and is intended for use only as a single-dose or short procedure irrigation. When smaller volumes are required the unused portion should be discarded.

Sterile Water for Irrigation, USP may be classified as a sterile irrigant, wash, rinse, diluent and pharmaceutical vehicle.

Water for Irrigation, USP is chemically designated H₂O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly.

The semi-rigid container is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The container requires no vapor barrier to maintain the proper drug concentration.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient 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. 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.

CLINICAL PHARMACOLOGY

Sterile Water for Irrigation, USP exerts a mechanical cleansing action for sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters and surgical drainage tubes, and for washing, rinsing or soaking surgical dressings, instruments and laboratory specimens. It also serves as a diluent or vehicle for drugs used for irrigation or other pharmaceutical preparations.

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 Irrigation, USP is indicated for all general irrigation, washing, rinsing and dilution purposes which permit use of sterile, nonpyrogenic, solute-free water.

CONTRAINDICATIONS

NOT FOR INJECTION BY USUAL PARENTERAL ROUTES.

WARNINGS

FOR IRRIGATION ONLY.

This preparation is solute-free and its entry into the circulation will cause hemolysis.

Solutions for urologic irrigation must be used with caution in patients with severe cardiopulmonary or renal dysfunction.

Irrigating fluids used during transurethral prostatectomy have been demonstrated to enter the systemic circulation in relatively large volumes, thus, Sterile Water for Irrigation, USP must be regarded as a systemic drug. Absorption of large amounts of Sterile Water for Irrigation, USP with or without 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 solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

Do not heat container over 66°C (150°F).

PRECAUTIONS

Do not use for irrigation that may result in absorption into the blood.

Caution should be observed when solute-free water is used for continuous irrigation or allowed to "dwell" inside body cavities because of possible absorption into the blood

stream and the production of intravascular hemolysis and circulatory overload.

Aseptic technique is essential with the use of sterile preparations for irrigation of body cavities, wounds and urethral catheters or for wetting dressings that come in contact with body tissues.

When used as a "pour" irrigation, no part of the contents should be allowed to contact the surface below the outer protected thread area of the semi-rigid wide mouth container.

The flexible container is designed for use with nonvented irrigation sets. When used for irrigation via appropriate irrigation equipment, the administration set should be attached promptly. Unused portions should be discarded and a fresh container of appropriate size used for the start up of each cycle or repeat procedure. For repeated irrigations of urethral catheters, a separate container should be used for each patient.

Do not administer unless water is clear, seal is intact and container is undamaged. Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Studies with Sterile Water for Irrigation, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers:

Caution should be exercised when Sterile Water for Irrigation, USP is administered to a nursing woman.

Pregnancy: *Teratogenic Effects.*

Pregnancy Category C. Animal reproduction studies have not been conducted with Sterile Water for Irrigation, USP. It is also not known whether Sterile Water for Irrigation, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Irrigation, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Possible adverse effects arising from the irrigation of body cavities, tissues, or indwelling catheters and tubes are completely avoidable when proper procedures are followed. Displaced catheters or drainage tubes can lead to irrigation or infiltration of unintended structures or cavities. Excessive volume or pressure during irrigation of closed cavities may cause undue distention or disruption of tissues. Accidental contamination from careless technique may transmit infection.

Should any adverse reaction occur, discontinue the irrigant, 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 (if solutes have been added to the irrigation), re-evaluate the patient and institute appropriate corrective measures. (See **WARNINGS**, **PRECAUTIONS** and **ADVERSE REACTIONS**.)

DOSAGE AND ADMINISTRATION

The dose is dependent upon the capacity or surface area of the structure to be irrigated and the nature of the procedure. When used as a diluent or vehicle for drugs, the manufacturer's recommendations should be followed.

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 container permits. (See **PRECAUTIONS**.)

HOW SUPPLIED

NDC No.	Product	Container Size (mL)	Container Type
0409-6139-22* 0990-6139-22*	Sterile Water for Irrigation USP	250	Semi-Rigid Irrigation
0409-6139-03* 0990-6139-03*	Sterile Water for Irrigation USP	500	Semi-Rigid Irrigation
0409-7139-09* 0990-7139-09*	Sterile Water for Irrigation USP	1000	Semi-Rigid Irrigation
0409-7139-36* 0990-7139-36*	Sterile Water for Irrigation USP	1500	Semi-Rigid Irrigation
0409-7973-05† 0990-7973-05†	Sterile Water for Irrigation USP	1000	Flexible Irrigation
0409-7973-07† 0990-7973-07†	Sterile Water for Irrigation USP	2000	Flexible Irrigation
0409-7973-08† 0990-7973-08†	Sterile Water for Irrigation USP	3000	Flexible Irrigation

* Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

† Manufactured by ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

ICU Medical is transitioning NDC codes from the "0409" to a "0990" labeler code. Both NDC codes are expected to be in the market for a period of time.

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

Revised: July, 2018

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA
EN-4662

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

500 mL
NDC 0990-6139-03

**Sterile Water
for Irrigation, USP**

Sterile, distilled, nonpyrogenic,
pH 5.5 (5.0 to 7.0). **Warning:**
Not isotonic. Hemolytic.
Indications: For irrigation only.
**Contraindications: Not for
injection.** Use only if clear and
seal intact. **Warnings:** Do not
heat bottle over 66°C (150°F).
Store at 20 to 25°C (68 to 77°F).
[See USP Controlled Room
Temperature.] Protect from
freezing. See insert. Single-
dose container. Contains no
bacteriostat. Discard unused
portion. **Usual dosage:** See
insert.
Rx only

AQUALITE™ SYSTEM

Manufactured for ICU Medical, Inc.,
Lake Forest, Illinois, 60045 USA

RL-7290

LOT

EXP

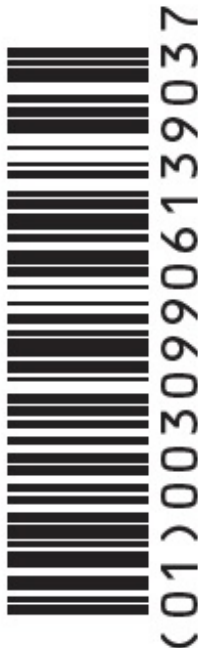
500 mL

NDC 0990-6139-03

Sterile Water

for Irrigation, USP

Sterile, distilled, nonpyrogenic, pH 5.5 (5.0 to 7.0). **Warning:** Not isotonic. Hemolytic. **Indications:** For irrigation only. **Contraindications:** Not for injection. Use only if clear and seal intact. **Warnings:** Do not heat bottle over 66°C (150°F). Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert. Single-dose container. Contains no bacteriostat. Discard unused portion. **Usual dosage:** See insert.
Rx only



AQUALITE™ SYSTEM

Manufactured for ICU Medical, Inc.,
Lake Forest, Illinois, 60045 USA

RL-7290

LOT

EXP

PRINCIPAL DISPLAY PANEL - 1500 mL Bottle Label

1500 mL

NDC 0990-7139-36

**Sterile
Water
for Irrigation, USP**

Sterile, distilled, nonpyrogenic, pH

5.5 (5.0 – 7.0) **Warnings: Not isotonic. Hemolytic. Indications:** For irrigation only. **Contraindications: Not for injection.** Use only if clear and seal intact. **Warning:** Do not heat bottle over 66°C (150°F). Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert. Single-dose container. Contains no bacteriostat. Discard unused portion. **Usual dosage:** See insert.

Rx only

icumedical

AQUALITE™ SYSTEM

Manufactured for ICU Medical, Inc.,
Lake Forest, Illinois, 60045 USA

RL-7294

LOT

EXP

1500 mL

NDC 0990-7139-36

Sterile Water for Irrigation, USP

Sterile, distilled, nonpyrogenic, pH 5.5 (5.0 – 7.0) **Warnings:** Not isotonic. Hemolytic. **Indications:** For irrigation only. **Contraindications:** Not for injection. Use only if clear and seal intact. **Warning:** Do not heat bottle over 66°C (150°F). Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert. Single-dose container. Contains no bacteriostat. Discard unused portion. **Usual dosage:** See insert.



Rx only

icumedical

AQUALITE™ SYSTEM

Manufactured for ICU Medical, Inc.,
Lake Forest, Illinois, 60045 USA

RL-7294

LOT

EXP

PRINCIPAL DISPLAY PANEL - 3000 mL Bag Label

3000 mL

NDC 0990-7973-08

**Sterile Water
for IRRIGATION,
USP**

STERILE, DISTILLED,
NONPYROGENIC.

INDICATIONS: FOR IRRIGATION.

CONTRAINDICATIONS:

NOT FOR INJECTION.

USE ONLY IF SOLUTION IS CLEAR
AND CONTAINER IS
UNDAMAGED.

WARNINGS: NOT ISOTONIC.

HEMOLYTIC.

DO NOT HEAT OVER 66°C (150°F).

OR STORE ABOVE 40°C (104°F).

SINGLE-DOSE CONTAINER.

CONTAINS NO BACTERIOSTAT.

DISCARD UNUSED PORTION.

USE ASEPTIC TECHNIQUE.

DOSAGE AND ADMINISTRATION:

AS DIRECTED BY PHYSICIAN.

pH 5.5 (5.0 TO 7.0)

RX ONLY

3

V

CONTAINS DEHP

IM-4379

ICU Medical, Inc.,
Lake Forest, Illinois, 60045, USA

icumedical

3000 mL

NDC 0990-7973-08

Sterile Water

for **IRRIGATION**,

USP

STERILE, DISTILLED,
NONPYROGENIC.

INDICATIONS: FOR IRRIGATION.

**CONTRAINDICATIONS:
NOT FOR INJECTION.**

USE ONLY IF SOLUTION IS CLEAR
AND CONTAINER IS
UNDAMAGED.

**WARNINGS: NOT ISOTONIC.
HEMOLYTIC.**

DO NOT HEAT OVER 66°C (150°F).
OR STORE ABOVE 40°C (104°F).

SINGLE-DOSE CONTAINER.
CONTAINS NO BACTERIOSTAT.

DISCARD UNUSED PORTION.
USE ASEPTIC TECHNIQUE.

DOSAGE AND ADMINISTRATION:
AS DIRECTED BY PHYSICIAN.

pH 5.5 (5.0 TO 7.0)

Rx ONLY



ICU Medical, Inc.,
Lake Forest, Illinois, 60045, USA

icumedical

PRINCIPAL DISPLAY PANEL - 3000 mL Bag Overwrap

2
HDPE

TO OPEN TEAR AT NOTCH

DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.
98-4321-R14-3/98

TO OPEN TEAR AT NOTCH



DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.

98-4321-R14-3/98

STERILE WATER

water irrigant

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-6139
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:0990-6139-22	24 in 1 CASE	10/01/2019	

1		250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0990-6139-03	24 in 1 CASE	09/01/2019	
2		500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017513	08/01/2019	

STERILE WATER				
water irrigant				

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-7139
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:0990-7139-09	12 in 1 CASE	12/01/2019	
1		1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0990-7139-36	9 in 1 CASE	10/01/2019	
2		1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017513	08/01/2019	

STERILE WATER				
water irrigant				

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-7973	
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:0990-7973-05	12 in 1 CASE	09/01/2019	
1		1 in 1 POUCH		
1		1000 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7973-07	6 in 1 CASE	10/01/2019	
2		1 in 1 POUCH		
2		2000 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0990-7973-08	4 in 1 CASE	08/01/2019	
3		1 in 1 POUCH		
3		3000 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
NDA		NDA018313	08/01/2019	

Labeler - ICU Medical Inc. (118380146)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0990-6139, 0990-7139, 0990-7973) , MANUFACTURE(0990-6139, 0990-7139, 0990-7973) , PACK(0990-6139, 0990-7139, 0990-7973) , LABEL(0990-6139, 0990-7139, 0990-7973)

Establishment

Name	Address	ID/FEI	Business Operations
ICU MEDICAL INC.		117395980	ANALYSIS(0990-6139, 0990-7139, 0990-7973) , MANUFACTURE(0990-7973) , PACK(0990-7973) , LABEL(0990-7973)

