

STERILE WATER- water irrigant
ICU Medical Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sterile Water

Important Prescribing Information

September 3, 2024

Subject: Temporary distribution of Sterile water and 0.9% Sodium chloride Semi-Rigid Bottle (SRB) Irrigation with non-U.S. labeling to address drug shortages

Dear Healthcare Professional,

In order to address shortages of critical irrigation drug products, ICU Medical is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of products from our portfolio which are manufactured and intended for the Canadian market. Temporarily and effective immediately, ICU Medical will make available for sale in the US the products listed below. These products are manufactured in the same facility and to the same specifications as ICU Medical's FDA-approved drug products; however, they are not labeled with current FDA-approved labeling. The information contained in this letter pertains only to the products listed below, which are not approved by FDA.

Product Description	Size	Canadian DIN	NDC
Sterile Water for Irrigation, USP	1000 mL	DIN 00038229	0990-8139-10
0.9% Sodium Chloride Irrigation, USP	250 mL	DIN 00037834	0990-5138-25
0.9% Sodium Chloride Irrigation, USP	500 mL	DIN 00037834	0990-5138-50
0.9% Sodium Chloride Irrigation, USP	1000 mL	DIN 00037834	0990-8138-10

There are some key differences in the labeling between the U.S. FDA-approved products and the Canadian products. Please see the product comparison tables at the end of this letter for additional information.

The barcode may not register accurately on the U.S. scanning systems. Institutions should manually input the product into their systems to confirm that barcode systems provide correct information when the product is scanned. Alternative procedures should

be followed to assure that the correct drug product is being used and administered to individual patients.

The U.S. FDA-approved products are available by prescription only in the U.S. However, the Canadian products do not have the statement "Rx only" on their labeling.

Please refer to the FDA-approved package insert for the full prescribing information of each drug product.

If you have any questions about ordering SRB irrigation products, please contact ICU Medical Customer Care at (877) 946-7747 or email uscustomer@icumed.com. For medical questions, please call ICU Medical Information at (800) 241-4002 or email Med-info_US@icumed.com.


To report adverse events or quality problems experienced with the use of this product, please call ICU Medical Global Complaint Management at (844) 654-7780 or email ProductComplaintsPP@icumed.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call (800) 332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to (800) FDA-0178 (1-800-332-0178).

Our team is working with customers to mitigate the impact of this shortage and are committed to returning to full levels of production as soon as possible.

Sincerely,

 **Stuart Green**
Digitally signed by Stuart Green
Date: 2024.09.03 08:16:48 -05'00'

Stuart Green
Senior Director, Quality

Representative Product Labels Comparison Tables

Sterile Water for Irrigation, USP

	US FDA Approved Product	Canadian Approved Product
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1000 mL NDC 0990-7139-09

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



1000 mL Sterile Solution / Solution Stérile DIN 00038229 N° 07139019

Sterile Water for Irrigation, USP Eau stérile pour irrigation USP

**100%
 FOR INTRAPERITONEAL
 IRRIGATION AND TOPICAL USE
 ONLY • NOT FOR INJECTION**
 Nonpyrogenic • Single-Use
 Contains no antimicrobial or other added substance. **Dosage:** As directed. Do not heat container over 66°C. Discard unused portion. **Storage:** 20 to 25°C. **Protect from freezing.**

pH approx. 5.5

**POUR IRRIGATION, UTILISATION
 INTRAPERITONEALE ET TOPIQUE
 SUELEMENT • NE PAS INJECTER**

Apyrogène • Uniservice

Sans antimicrobien ni autre additif. **Posologie:** selon les instructions. Ne pas chauffer le contenant à plus de 66°C. Jeter tout reste. **Entreposage:** 20 à 25°C. **Craint le gel.**

*Questions or Concerns
 Des questions ou problèmes:*

ICU Medical Canada Inc.
 Saint-Laurent, QC H4S 0A9

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Product Name	Sterile Water for Irrigation, USP	Sterile Water for Irrigation, USP
Indications	For irrigation only	For intraperitoneal, irrigation and topical use only
Active Ingredients	Sterile Water	Sterile Water
Additional Information	pH 5.5 (5.0 – 7.0)	pH approx. 5.5
Storage Conditions	Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature]	20 to 25°C
Container Type	AQUALITE™ Semi-Rigid Bottle	AQUALITE™ Semi-Rigid Bottle
Language	English	English and French
Additional Product Identifier	NDC number	DIN and product catalog number
Barcode	GS1 Primary Data Structure Includes product NDC Number	GS1 Primary Data Structure Includes Canada Manufacturer Number and unique product code

0.9% Sodium Chloride Irrigation, USP

	US FDA Approved Product		Canadian Approved Product
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1000 mL NDC 0990-7138-09

0.9% SODIUM CHLORIDE Irrigation, USP

Each 100 mL contains sodium chloride, 900 mg. 308 mOsmol/liter (calc.). May contain NaOH and/or HCl for pH adjustment. pH 5.6 (4.5 – 7.0). Sterile, nonpyrogenic. **Indications:** Isotonic solution for irrigation. **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



(01)00309907138091

1000 mL AQUALITE™/MC DIN 00037834 N° 07138019

0.9% Sodium Chloride Irrigation USP Chlorure de sodium à irrigation USP

For Intraperitoneal, Irrigation and Topical Use

•NOT FOR INJECTION
 Sterile Solution • Nonpyrogenic • Single-Dose
 Use only if solution is clear and seal intact. Discard unused portion. **Each mL contains:** Sodium chloride 9 mg. May contain NaOH/HCl for pH adjustment. Contains no bacteriostat. **Usual Dose:** As directed. Do not heat container over 66°C. **Storage:** 20 to 25°C. **Protect from freezing.**

pH approx. 5.6

Pour irrigation, utilisation, intrapéritonéale et topique
•NE PAS INJECTER

Solution Stérile • Apyrogène • Uniservice
 N'utiliser que si la solution est limpide et le dispositif d'inviolabilité, intact. Jeter tout reste. **Chaque mL contient:** chlorure de sodium 9 mg. Peut contenir NaOH/HCl pour ajuster le pH. Sans agent bactériostatique. **Posologie usuelle:** selon les instructions. Ne pas chauffer le contenant à plus de 66°C. **Entreposage:** 20 à 25°C. **Craint le gel.**

Questions or Concerns
 Des questions ou problèmes:
ICU Medical Canada Inc.
 Saint-Laurent, QC H4S 0A9

icumedical



(01)00887709110632

Product Name	0.9% Sodium Chloride Irrigation, USP	0.9% Sodium Chloride Irrigation, USP
Indications	Isotonic solution for irrigation	For intraperitoneal, irrigation and topical use only
Active Ingredients	Each 100 mL contains sodium chloride, 900 mg	Each mL contains: Sodium chloride 9 mg
Additional Information	pH 5.6 (4.5 – 7.0)	pH approx. 5.6
Storage Conditions	Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature]	20 to 25°C
Container Type	AQUALITE™ Semi-Rigid Bottle	AQUALITE™ Semi-Rigid Bottle
Language	English	English and French
Additional Product Identifier	NDC number	DIN and product catalog number
Barcode	GS1 Primary Data Structure Includes product NDC Number	GS1 Primary Data Structure Includes Canada Manufacturer Number and unique product code

PRINCIPAL DISPLAY PANEL - 1000 mL Bottle Label

1000 mL

Sterile

Solution

DIN 00038229

N° 07139019

AQUALITE™

Sterile Water for Irrigation, USP

100%

FOR INTRAPERITONEAL,
IRRIGATION AND TOPICAL USE
ONLY • NOT FOR INJECTION

Nonpyrogenic • Single-Use

Contains no antimicrobial or other
added substance. Dosage: As
directed. Do not heat container over
66°C. Discard unused portion. Storage:
20 to 25°C. Protect from freezing.

pH approx. 5.5

Questions or Concerns

ICU Medical Canada Inc.

Saint-Laurent, QC H4S 0A9

RL-7288

LOT

EXP

1000 mL

Sterile
Solution
Stérile

DIN 00038229
N° 07139019

AQUALITE™/MC

Sterile Water for Irrigation, USP Eau stérile pour irrigation USP

100%
**FOR INTRAPERITONEAL
IRRIGATION AND TOPICAL USE
ONLY • NOT FOR INJECTION**

Nonpyrogenic • Single-Use

Contains no antimicrobial or other added substance. **Dosage:** As directed. Do not heat container over 66°C. Discard unused portion. **Storage:** 20 to 25°C. **Protect from freezing.**

pH approx. 5.5

**POUR IRRIGATION, UTILISATION
INTRAPERITONEALE ET TOPIQUE
SUELEMENT • NE PAS INJECTER**

Apyrogène • Uniservice

Sans antimicrobien ni autre additif. **Posologie:** selon les instructions. Ne pas chauffer le contenant à plus de 66°C. Jeter tout reste. **Entreposage:** 20 à 25°C. **Craint le gel.**

*Questions or Concerns
Des questions ou problèmes:*

ICU Medical Canada Inc.
Saint-Laurent, QC H4S 0A9

icumedical

RL-7288

LOT

EXP



STERILE WATER

water irrigant

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-8139
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:0990-8139-10	12 in 1 CASE	08/01/2024	
1		1000 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
UNAPPROVED DRUG FOR USE IN DRUG SHORTAGE		08/01/2024	

Labeler - ICU Medical Inc. (118380146)

Revised: 9/2024

ICU Medical Inc.