# 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 uscustomercare@icumed.com. For medical questions, please call ICU Medical Information at (800) 241-4002 or email Medinfo 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 Kun Green

Digitally signed by Stuart Green

Date: 2024.09.03 08:16:48 -05'00'

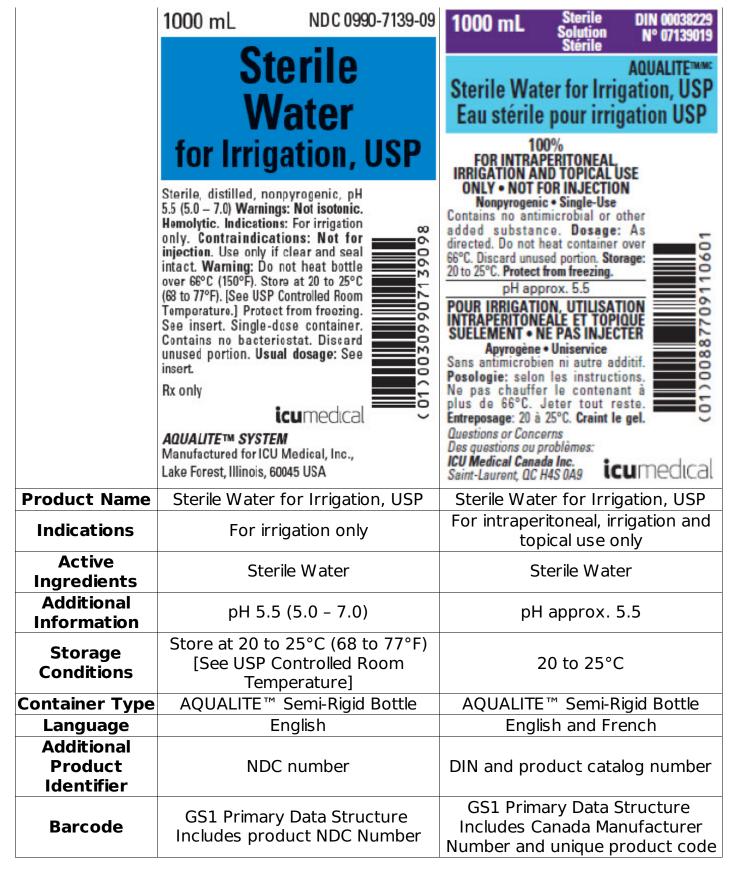
Stuart Green Senior Director, Quality

**Representative Product Labels Comparison Tables** 

Sterile Water for Irrigation, USP

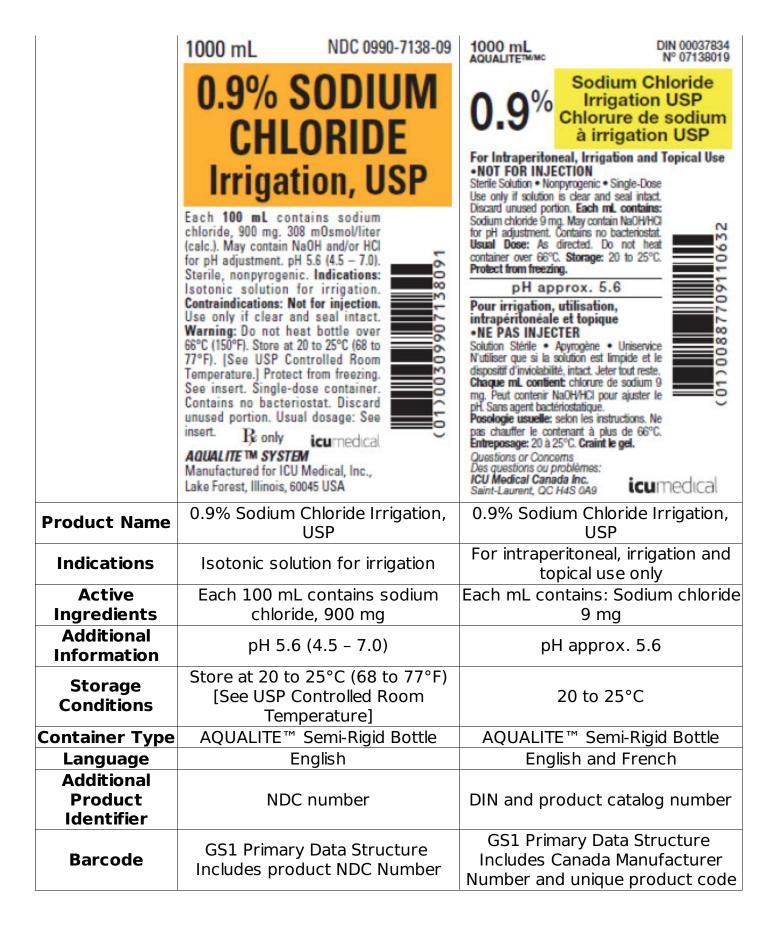
**US FDA Approved Product** 

**Canadian Approved Product** 



## 0.9% Sodium Chloride Irrigation, USP

US FDA Approved Product	Canadian Approved Product



#### PRINCIPAL DISPLAY PANEL - 1000 mL Bottle Label

1000 mL

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

**AQUALITETM/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

Apvrogène • 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

0

œ

08

0

RL-7288

EXP



### STERILE WATER

water irrigant

#### **Product Information**

**Product Type HUMAN PRESCRIPTION DRUG** Item Code (Source)

**IRRIGATION Route of Administration** 

## **Active Ingredient/Active Moiety**

**Basis of Strength Ingredient Name** Strength

NDC:0990-8139

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.