

**SODIUM CHLORIDE- sodium chloride 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.

Sodium Chloride

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



(01)00309907139098

1000 mL Sterile Solution Stérile DIN 00038229 N° 07139019

**AQUALITE™
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





(01)00887709110601

	<p>1000 mL NDC 0990-7139-09</p> <p>Sterile Water for Irrigation, USP</p> <p>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.</p> <p>Rx only</p> <p>icumedical</p> <p>AQUALITE™ SYSTEM Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045 USA</p>	<p>1000 mL Sterile Solution Stérile DIN 00038229 N° 07139019</p> <p>AQUALITE™ Sterile Water for Irrigation, USP Eau stérile pour irrigation USP</p> <p>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.</p> <p>pH approx. 5.5</p> <p>POUR IRRIGATION, UTILISATION INTRAPERITONEALE ET TOPIQUE SUELEMENT • NE PAS INJECTER</p> <p>Apyrogène • Uniservice</p> <p>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.</p> <p><i>Questions or Concerns Des questions ou problèmes:</i> ICU Medical Canada Inc. Saint-Laurent, QC H4S 0A9</p> <p>icumedical</p>
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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	<p>1000 mL NDC 0990-7138-09</p> <p>0.9% SODIUM CHLORIDE Irrigation, USP</p> <p>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</p>  <p>(01)00309907138091</p>	<p>1000 mL AQUALITE™MDC DIN 00037834 N° 07138010</p> <p>0.9% Sodium Chloride Irrigation USP Chlorure de sodium à irrigation USP</p> <p>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 9mg. 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.</p> <p>pH approx. 5.6</p> <p>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.</p> <p>Questions or Concerns Des questions ou problèmes: ICU Medical Canada Inc. Saint-Laurent, QC H4S 0A9 icumedical</p>  <p>(01)0088709110632</p>
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 - 250 mL Bottle Label

250 mL

Sterile Solution

DIN 00037834

N° 06138125

AQUALITE™

0.9%

Sodium Chloride
Irrigation USP

For Intraperitoneal, Irrigation and Topical
Use • NOT FOR INJECTION • Nonpyrogenic
• Single-Use

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. Dosage:
As directed. Do not heat over 66°C. Storage: 20 to
25°C. Protect from freezing.

pH approx. 5.6

Questions or Concerns

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

RL-7298

LOT
EXP

250 mL Sterile Solution/ DIN 00037834
Solution Stérile N° 06138125
AQUALITE™/MC

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

For Intraperitoneal, Irrigation and Topical Use • **NOT FOR INJECTION** • Nonpyrogenic • Single-Use

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. **Dosage:** As directed. **Do not heat over 66°C.** **Storage:** 20 to 25°C. **Protect from freezing.**

pH approx. 5.6

Pour irrigation, utilisation, intrapéritonéale et topique • **NE PAS INJECTER** • 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 l'ajustement du pH. Sans agent bactériostatique. **Posologie:** selon les instructions. **Ne pas chauffer à plus de 66°C.** **Entreposage:** 20 à 25°C. **Craint le gel.**

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



RL-7298

LOT



EXP

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

500 mL

Sterile Solution

DIN 00037834

N° 06138023

AQUALITE™

0.9%

Sodium Chloride Irrigation USP

For Intraperitoneal, Irrigation and Topical Use

• NOT FOR INJECTION • Nonpyrogenic • Single-Use

Use only if solution is clear and seal intact. Discard unused portion. Each mL contains: Sodium chloride 9 mg. May contain NaOH and/or HCl for pH adjustment. Contains no bacteriostat. Dosage: As directed. Do not heat over 66°C. Storage: 20 to 25°C. Protect from freezing.

pH approx. 5.6

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

icumedical

RL-7297

LOT

EXP

500 mL Sterile Solution/ Solution Stérile DIN 00037834
N° 06138023
AQUALITE™/MC

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

For Intraperitoneal, Irrigation and Topical Use
• NOT FOR INJECTION • Nonpyrogenic • Single-Use

Use only if solution is clear and seal intact. Discard unused portion. Each mL contains: Sodium chloride 9 mg. May contain NaOH and/or HCl for pH adjustment. Contains no bacteriostat. Dosage: As directed. Do not heat over 66°C. Storage: 20 to 25°C. Protect from freezing.

pH approx. 5.6

Pour irrigation, utilisation, intrapéritonéale et topique

• NE PAS INJECTER • 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 du NaOH et/ou du HCl pour l'ajustement du pH. Sans agent bactériostatique. Posologie: selon les instructions. Ne pas chauffer 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



RL-7297

LOT

EXP

PRINCIPAL DISPLAY PANEL - 1000 mL Bottle Label

1000 mL
AQUALITE™

DIN 00037834
N° 07138019

0.9%

Sodium Chloride
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

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

icumedical

RL-7286

LOT
EXP

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

RL-7286

LOT

EXP



SODIUM CHLORIDE

sodium chloride irrigant

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-5138
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)		SODIUM CHLORIDE	900 mg in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-5138-25	24 in 1 CASE	08/01/2024	
1		250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0990-5138-50	24 in 1 CASE	08/01/2024	
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
UNAPPROVED DRUG FOR USE IN DRUG SHORTAGE			08/01/2024	

SODIUM CHLORIDE			
sodium chloride irrigant			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-8138
Route of Administration	IRRIGATION		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)		SODIUM CHLORIDE	900 mg in 100 mL
Inactive Ingredients			
Ingredient Name		Strength	
WATER (UNII: 059QF0KO0R)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-8138-10	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.