



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.

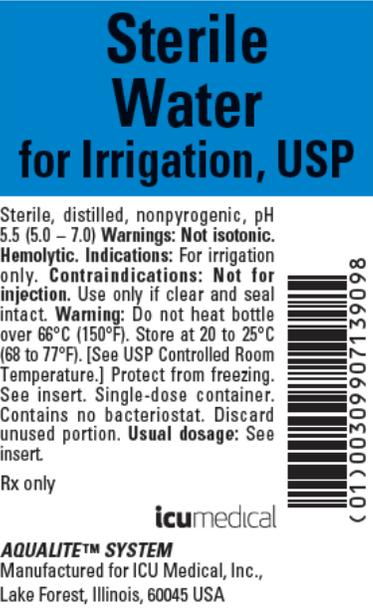
Sincerely,



Stuart Green
Senior Director, Quality

Representative Product Labels Comparison Tables

Sterile Water for Irrigation, USP

| | US FDA Approved Product | Canadian Approved Product |
|--------------------------------------|--|---|
| | <p>1000 mL NDC 0990-7139-09</p>  <p>AQUALITE™ SYSTEM Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045 USA</p> |  <p>AQUALITE™MNC 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. 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. <i>Questions or Concerns Des questions ou problèmes:</i> ICU Medical Canada Inc. Saint-Laurent, QC H4S 0A9 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 |

Representative Product Labels Comparison Tables

0.9% Sodium Chloride Irrigation, USP

| | US FDA Approved Product | Canadian Approved Product |
|--------------------------------------|--|---|
| | <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.  (01)00309907138091</p> <p>AQUALITE™ SYSTEM Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045 USA</p> | <p>1000 mL AQUALITE™MC DIN 00037834 N° 07138019</p> <p>0.9% Sodium Chloride Irrigation USP Chlorure de sodium à irrigation USP</p> <p>For Intrapertitoneal, 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.</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'intégrité 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  (01)00887709110632 icumedical</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 |