

## **Important Prescribing Information**

December 3, 2024

## Subject: Temporary importation of 0.9% Sodium Chloride Irrigation, USP from Alliston, Canada to address drug shortages

Dear Healthcare Professional,

To prevent a drug shortage of irrigation drug products, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Irrigation, USP (3,000 mL) from Baxter's manufacturing facility in Alliston, Canada. FDA has not approved this product manufactured by Baxter's Alliston facility.

You may be provided with additional letters for other imported products you receive. Please read each letter in its entirety because each letter may contain different, product-specific information.

At this time, no other entity except Baxter is authorized by the FDA to import or distribute this product in the United States.

Effective immediately, and during this temporary period, Baxter will offer the following imported product:

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Irrigation, USP (UROMATIC)	3,000 mL	JB7127	4	0338-9834-01

## It is important to note the following:

- The imported products' port system is fully compatible with Baxter urology irrigation sets marketed in the United States.
- The imported products do not have a linear barcode on the bag, rather they have a 2D barcode that contains the product Global Trade Identification Number (GTIN). The barcode on the imported product labels may not register accurately in U.S. scanning systems. Alternative procedures should be followed to ensure that the correct drug product is being used in all systems and processes and administered to individual patients. For example, institutions should consider manually inputting the product into their systems and ensure that barcode systems provide correct information when the product is scanned. Barcodes containing the NDC number for each imported product will additionally be made available digitally.

0.9% Sodium Chloride Irrigation, USP is available only by prescription in the U.S. However, the imported

product does not have the statement "Rx only" on the labeling.

USE A NEW BAG IF PARTICULATES ARE VISIBLE OR IF THE BAG CONTAINS A LEAK.

Additional key differences in the labeling between the FDA-approved product and the imported product

are stated in the product comparison tables at the end of this letter as follows:

Table 1. Key differences in FDA-approved 0.9% Sodium Chloride Irrigation, USP and Imported 0.9% Sodium

Chloride for Irrigation, USP

Label Images for FDA-approved 0.9% Sodium Chloride Irrigation USP and Imported 0.9% Sodium Table 2.

Chloride for Irrigation, USP

Please refer to the FDA-approved prescribing information for the drug product listed below:

0.9% Sodium Chloride Irrigation, USP (click here)

**Reporting Adverse Events or Product Quality Issues** 

To report adverse events associated with these imported products, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of these imported products may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by 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 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or

submit by fax to 1-800-FDA-0178 (1-800-332-0178).

To report product quality issues associated with these imported products, please contact Baxter Product

Surveillance through Baxter Product Feedback Portal (https://productfeedback.baxter.com/).

If you have any questions about the information contained in this letter or the use of the imported products,

please contact Baxter's Medical Information Service at 1-800-933-0303.

To place an order, please contact Baxter's Center for Service by calling 1-888-229-0001.

Sincerely,

Ohm

Electronically signed by: Maria Soriano Reason: I approve this document Date: Dec 3, 2024 09:39 EST

Cecilia Soriano

President, Infusion Therapies & Technologies

**Baxter Healthcare Corporation** 

Baxter, UROMATIC and Viaflex are trademarks of Baxter International Inc.
Attachments:
Product Comparison Tables 1 and 2

## **Product Comparison Tables**

Table 1. Key differences in FDA-approved 0.9% Sodium Chloride Irrigation, USP and Imported 0.9% Sodium Chloride for Irrigation, USP

	FDA-approved product 2B7127	Imported product from Alliston, Canada JB7127		
Product name	0.9% Sodium Chloride Irrigation, USP	0.9% Sodium Chloride Irrigation, USP		
Label Volume	3,000 mL	3,000 mL		
Language(s) of the labels	English	English and French		
Indications	0.9% Sodium Chloride Irrigation, USP in UROMATIC container is indicated for use as a urologic irrigating fluid with endoscopic instruments during transurethral procedures requiring distension, irrigation, and lavage of the urinary bladder. It may be used for lavage of an indwelling catheter to maintain patency	Not for Injection / Irrigation only.  Single use / Discard unused portion. Squeeze and inspect bag do not use if the outlet port protector is damaged detached or not present as solution path sterility may be impaired.		
Active	Each 100 mL contains 900 mg Sodium Chloride, USP	Each 100 mL contains 900 mg Sodium Chloride, USP		
ingredients	Sodium 154 mEq/L Chloride 154 mEq/L	Sodium 154 mEq/L Chloride 154 mEq/L		
Additional	pH 5.5 (4.5 to 7.0)	pH approx 5.5		
information	Osmolarity 308 mOsmol/L (calc)	Osmolarity 308 mOsm/L		
Storage conditions	Room temperature (25°C/77°F)  Warm in overwrap to near body temperature in a water bath or oven heated to not more than 45°C.	VIAFLEX containers should be stored at 15°C/59°F to 25°C/77°F.		
Container	UROMATIC Container - VIAFLEX (PVC)	UROMATIC Container - VIAFLEX (PVC)		
Port closures	Contains medication port and administration port; Pull off port protector (blue color), right side	Contains medication port and administration port; Pull off port protector (blue color), right side		

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Table 2. Label Images for FDA-approved 0.9% Sodium Chloride Irrigation USP and Imported 0.9% Sodium Chloride for Irrigation, USP

FDA-approved product 2B7127	Imported product from Alliston, Canada JB7127		
0.9% Sodium Chloride Irrigation, USP	0.9% Sodium Chloride Irrigation USP		
Label Color: Black and Red. Barcode, lot number, and expiry are not shown.	Label Color: <b>Black</b> . Lot number, and expiration date are not shown.		
LOT EXP	JB7127 3000 mL DIN 00786160 2700 0.9% Sodium Chloride Irrigation USP Chlorure de Sodium 2400		
0.900	à 0.9% pour Irrigation  (01)00809080000395 USP  2100		
2100 <u>2100</u>	NaCl 0.9% Irrigation		
Interior USP 1800	NOT FOR INJECTION / IRRIGATION ONLY NE PAS INJECTER / POUR L'IRRIGATION APPROX mOsmol /L - 308		
EACH 100 mL CONTAINS 900 mg SODIUM CHLORIDE USP NO ANTIMICROBIAL AGENT HAS BEEN ADDED pH 5.5 (4.5 to 7.0) mEq/L SODIUM 154 CHLORIDE 154 OSMOLARITY 308 mOsmol/L (calc) Sterile Nonpyrogenic Single dose container	APPROX pH 5.5 PER 100 mL - SODIUM CHLORIDE USP - 900 mg PAR 100 mL - CHLORURE DE SODIUM USP - 900 mg CAUTIONS SINGLE USE / DISCARD UNUSED PORTION /		
DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION  CAUTIONS SQUEEZE AND INSPECT INNER BAG	SQUEEZE AND INSPECT BAG / DO NOT USE IF THE OUTLET PORT PROTECTOR IS DAMAGED DETACHED OR NOT PRESENT AS SOLUTION PATH STERILITY MAY BE IMPAIRED / STORE AT 15°C TO 25°C		
WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND RX ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT  Sodium Chloride	ATTENTIONS USAGE UNIQUE / JETER PORTION INUTLISEE / PRESSER ET INSPECTER LE SAC / NE PAS UTILISER SI L'EMBOUT DE PROTECTION DE L' ORIFICE DE SORTIE EST ENDOMMAGÉ DÉTACHÉ OU ABSENT CAR LA STÉRILITÉ DE LA CANALISATION POURRAIT ÊTRE COMPROMISE / GARDER ENTRE 15°C ET 25°C NONPYROGENIC / STERILE / APYROGENE		
UROMATIC CONTAINER  PL 146 PLASTIC  BAXTER UROMATIC AND PL 146 AME INADIMANS OF BAXTER INTERNATIONAL, INC  FOR PRODUCT INDIMATION  BAXTER HEALTHCARE CORPORATION  DETRIBUTED IN CAMADA BY BAXTER COMPONATION  TORONDO OWNERS OF CAMADA  MADE IN USA  100 100 100 100 100 100 100 100 100 10	Nacio.9%  UROMATIC PVC CONTAINER/CONTENANT DE PVC BAXTER AND UROMATIC ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER ET UROMATIC SONT DES MARQUES DE COMMERCE DE BAXTER INTERNATIONAL INC Baxter Corporation Mississauqa ON L5N 0C2  107-25-77-352		

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