

SODIUM CHLORIDE- sodium chloride irrigant
Baxter Healthcare Company

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.

0.9% Sodium chloride irrigation, usp

Health Care Professional Letter



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

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

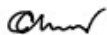
- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178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



*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

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

- 0.9% Sodium Chloride Irrigation, USP (click <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=886f889b-f3cf-4197-b307-6cfa88c89436>)

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**: <https://www.fda.gov/safety/medwatch->

fda-safety-information-and-adverse-event-reporting-program

- **Regular mail or Fax:** Download form <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program> 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/>).

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 ingredients	Each 100 mL contains 900 mg Sodium Chloride, USP Sodium 154 mEq/L Chloride 154 mEq/L	Each 100 mL contains 900 mg Sodium Chloride, USP Sodium 154 mEq/L Chloride 154 mEq/L
Additional information	pH 5.5 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)	pH approx 5.5 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 

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: Black. Lot number, and expiration date are not shown.

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

JB7127 3000 mL DIN 00786160 **2700**
0.9% Sodium Chloride
Irrigation USP

Chlorure de Sodium **2400**
à 0.9% pour Irrigation
USP

(01)00809080000395

NaCl 0.9%

Irrigation

NOT FOR INJECTION / IRRIGATION ONLY **1500**
NE PAS INJECTER / POUR L'IRRIGATION
APPROX mOsmol /L - 308
APPROX pH 5.5
PER 100 mL - SODIUM CHLORIDE USP - 900 mg **1200**
PAR 100 mL - CHLORURE DE SODIUM USP - 900 mg
CAUTIONS 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 / STORE AT **900**
15°C TO 25°C
ATTENTIONS USAGE UNIQUE / JETER PORTION INUTILISEE /
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 **600**
ENTRE 15°C ET 25°C
NONPYROGENIC / STERILE / APYROGENE

NaCl 0.9%

UROMATIC PVC CONTAINER/CONTENANT DE PVC **300**
BAXTER AND UROMATIC ARE TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER ET UROMATIC SONT DES MARQUES DE COMMERCE DE BAXTER
INTERNATIONAL INC
Baxter
Baxter Corporation
Mississauga ON L5N 0C2

07-25-77-352

JB7127
3000 mL
DIN 00786160
0.9% Sodium Chloride
Irrigation USP
Chlorure de Sodium
à 0.9% pour Irrigation
USP

2D Barcode
(01)00809080000395

NaCl 0.9%
Irrigation

NOT FOR INJECTION / IRRIGATION ONLY
NE PAS INJECTER / POUR L'IRRIGATION
APPROX mOsmol /L - 308
APPROX pH 5.5

PER **100** mL - SODIUM CHLORIDE USP - **900** mg

PER **100** mL - CHLORURE DE SODIUM USP - **900** mg

CAUTIONS 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 / STORE AT
15°C TO 25°C

ATTENTIONS USAGE UNIQUE / JETER PORTION INUTILISEE /
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
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ENTRE 15°C TO 25°C

NONPYROGENIC / STERILE / APYROGENE

NaCl 0.9%

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 Logo

Baxter Corporation

Mississauga ON L5N 0C2

No Latex Label

07-25-77-352

2700

2400

2100

1800

1500

1200

900

600

300

SODIUM CHLORIDE

sodium chloride irrigant

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-9834
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-9834-04	4 in 1 CARTON	12/03/2024	
1	NDC:0338-9834-01	3000 mL in 1 BAG; 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		12/03/2024	

Labeler - Baxter Healthcare Company (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Corporation		205087968	ANALYSIS(0338-9834) , LABEL(0338-9834) , MANUFACTURE(0338-9834) , STERILIZE(0338-9834) , PACK(0338-9834)

Establishment

Name	Address	ID/FEI	Business Operations
SGS Canada Inc		203668041	ANALYSIS(0338-9834)

Revised: 12/2024

Baxter Healthcare Company