



Important Prescribing Information

November 13, 2024

Subject: Temporary importation of Sodium Chloride 0.9% for Irrigation from the United Kingdom 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 Sodium Chloride 0.9% for Irrigation (3000 mL) from Baxter's manufacturing facility in Thetford, United Kingdom. FDA has not approved this product manufactured by Baxter's Thetford 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 imported 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
Sodium Chloride 0.9% for Irrigation (UROMATIC)	3000 mL	3KB7127	4	0338-0110-01

It is important to note the following:

- After opening the carton or box, the bags should be inspected visually to confirm there is no visible particulate matter or bag defects, such as leaks. Container integrity is imperative to ensure sterility of the product listed in the table above. Irrigation drug products should be inspected visually for particulate matter and bag defects prior to application, whenever solution or container permits.
USE A NEW BAG IF PARTICULATES ARE VISIBLE OR IF THE BAG CONTAINS A LEAK.
- The imported product's port system is fully compatible with Baxter urology irrigation sets marketed in the United States.

- **The imported product does not contain barcode on the unit label.** Institutions should manually input the product into their systems to ensure that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to ensure that the correct drug product and concentration are being used in all systems and processes and administered to individual patients.
- 0.9% Sodium Chloride Irrigation USP is available only by prescription in the U.S. However, the imported Sodium Chloride 0.9% for Irrigation product does not have the statement “Rx only” on the labeling.

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 Sodium Chloride 0.9% for Irrigation

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

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 this imported product, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of this imported product 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 this imported product, 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 product, 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,

Lee Ann Schuette
Electronically signed by: Lee
Ann Schuette
Reason: I approve this
document
Date: Nov 13, 2024 12:12 CST

Lee Ann Schuette
VP Global and US Marketing IV solutions, Clinical Nutrition, Pharmacy Tools
Baxter Healthcare Corporation

Baxter, UROMATIC and Viaflex are trademarks of Baxter International Inc.

Product Comparison Tables

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



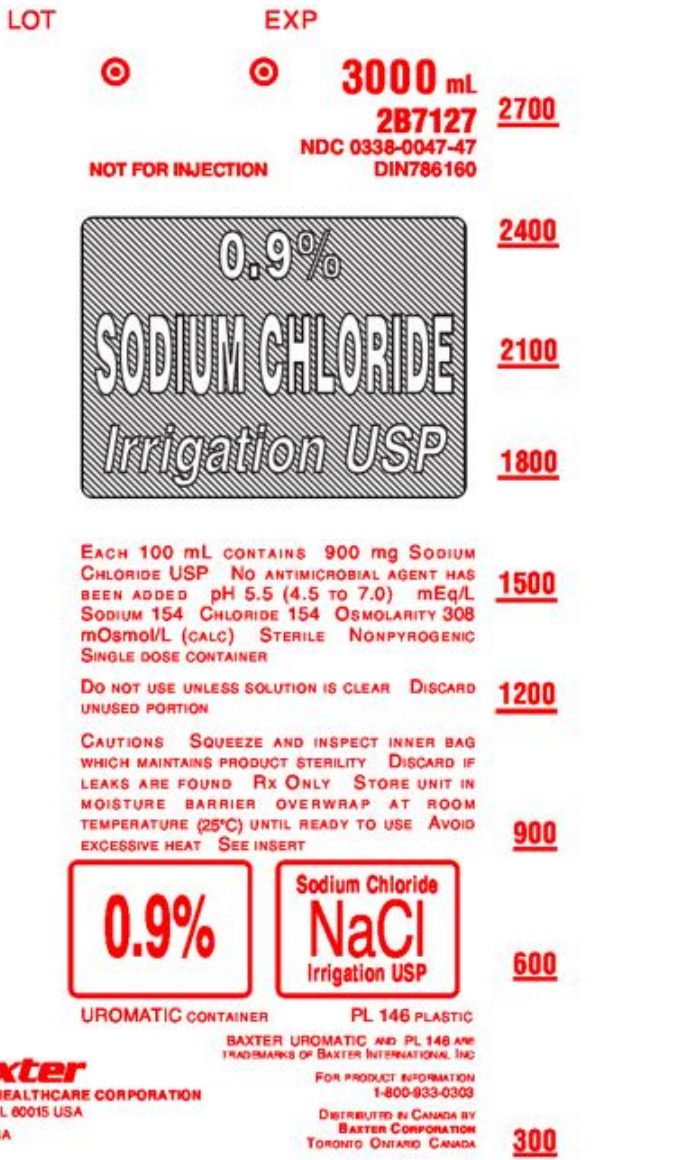
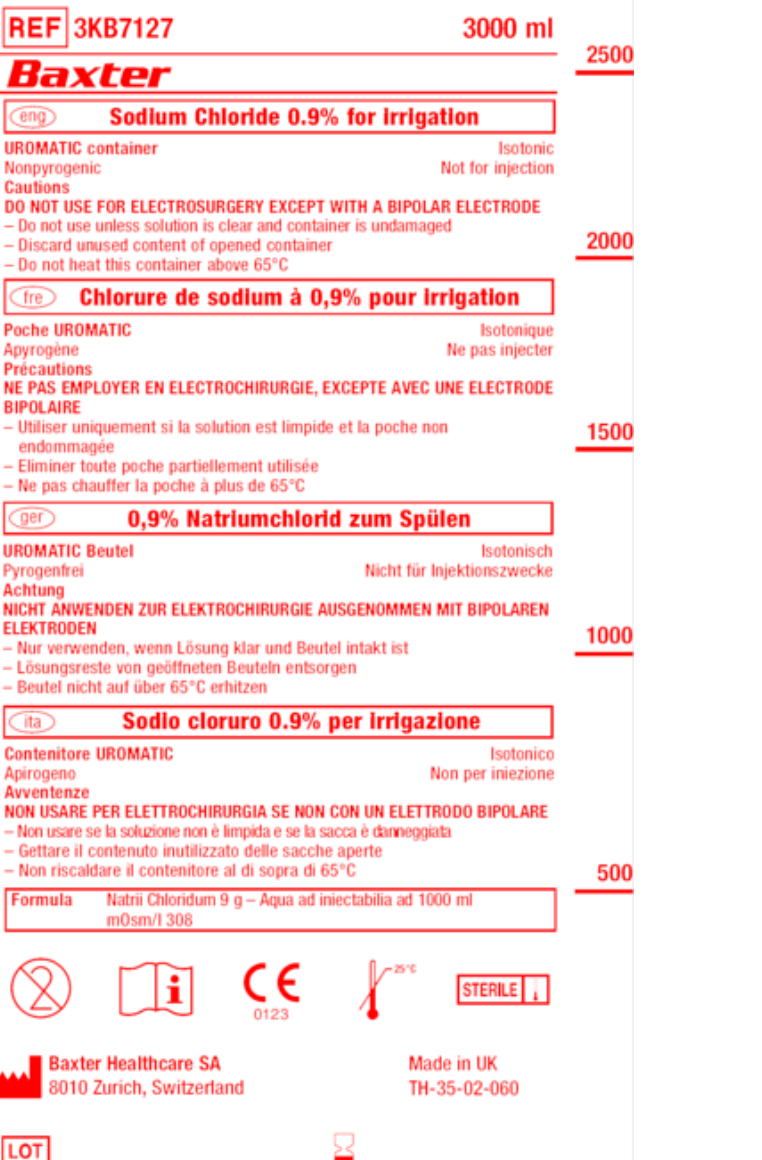
	FDA-approved product	Imported product from the UK
Product name	0.9% Sodium Chloride Irrigation USP	Sodium Chloride 0.9% for Irrigation
Label Volume	3000 mL	3000 mL
Language(s) of the labels	English	English, French, German and Italian
Indications	0.9% Sodium Chloride Irrigation, USP in UROMATIC container 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	This solution in UROMATIC container is intended for use as an irrigation solution in urological procedures and has good optical qualities to ensure a high degree of visibility during cystoscopic examinations.
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 Sodium 154 mEq/L Chloride 154 mEq/L
Additional information	pH 5.5 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)	pH 4.0 to 7.0 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 within their overpouch at a temperature below 25°C/77°F Do not heat above 65°C/149°F .
Container	UROMATIC Container - VIAFLEX (PVC)	UROMATIC Container - VIAFLEX (PVC)
Port closures	<p>Contains medication port and administration port; Pull off port protector (blue color), right side</p> 	<p>Contains medication port and administration port; twist off port protector (natural color), left side</p> 

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

FDA-approved product	Imported product from the UK
0.9% Sodium Chloride Irrigation USP	Sodium Chloride 0.9% for Irrigation
Label Color: Black and Red. Barcode, lot number, and expiry are not shown.	Label Color: Red (fully). Lot number, and expiration date are not shown.
 <p>LOT EXP</p> <p>3000 mL 2700</p> <p>287127 2700</p> <p>NDC 0338-0047-47</p> <p>DIN786160</p> <p>NOT FOR INJECTION</p> <p>0.9% SODIUM CHLORIDE Irrigation USP</p> <p>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 mOsm/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR. DISCARD UNUSED PORTION</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG 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</p> <p>0.9% Sodium Chloride NaCl Irrigation USP</p> <p>UROMATIC CONTAINER PL 146 PLASTIC</p> <p>BAXTER UROMATIC AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>FOR PRODUCT INFORMATION 1-800-933-0303</p> <p>DISTRIBUTED IN CANADA BY BAXTER CORPORATION TORONTO ONTARIO CANADA</p> <p>Baxter BAXTER HEALTHCARE CORPORATION Deerfield IL 60015 USA MADE IN USA</p>	 <p>REF 3KB7127 3000 ml 2500</p> <p>Baxter</p> <p>eng Sodium Chloride 0.9% for Irrigation</p> <p>UROMATIC container Isotonic</p> <p>Nonpyrogenic Not for injection</p> <p>Cautions</p> <p>DO NOT USE FOR ELECTROSURGERY EXCEPT WITH A BIPOLAR ELECTRODE</p> <p>- Do not use unless solution is clear and container is undamaged</p> <p>- Discard unused content of opened container</p> <p>- Do not heat this container above 65°C</p> <p>fre Chlorure de sodium à 0,9% pour irrigation</p> <p>Poche UROMATIC Isotonique</p> <p>Apyrogène Ne pas injecter</p> <p>Précautions</p> <p>NE PAS EMPLOYER EN ELECTROCHIRURGIE, EXCEPTE AVEC UNE ELECTRODE BIPOLAIRE</p> <p>- Utiliser uniquement si la solution est limpide et la poche non endommagée</p> <p>- Eliminer toute poche partiellement utilisée</p> <p>- Ne pas chauffer la poche à plus de 65°C</p> <p>ger 0,9% Natriumchlorid zum Spülen</p> <p>UROMATIC Beutel Isotonisch</p> <p>Pyrogenfrei Nicht für Injektionszwecke</p> <p>Achtung</p> <p>NICHT ANWENDEN ZUR ELEKTROCHIRURGIE AUSGENOMMEN MIT BIPOLAREN ELEKTRODEN</p> <p>- Nur verwenden, wenn Lösung klar und Beutel intakt ist</p> <p>- Lösungsreste von geöffneten Beuteln entsorgen</p> <p>- Beutel nicht auf über 65°C erhitzen</p> <p>ita Sodio cloruro 0.9% per irrigazione</p> <p>Contenitore UROMATIC Isotonico</p> <p>Apirogeno Non per iniezione</p> <p>Avvertenze</p> <p>NON USARE PER ELETTRICITÀ SE NON CON UN ELETTRODO BIPOLARE</p> <p>- Non usare se la soluzione non è limpida e se la sacca è danneggiata</p> <p>- Gettare il contenuto inutilizzato delle sacche aperte</p> <p>- Non riscaldare il contenitore al di sopra di 65°C</p> <p>Formula Natrii Chloridum 9 g – Aqua ad iniectionem ad 1000 ml mOsm/l 308</p> <p>LOT</p> <p>Baxter Healthcare SA 8010 Zurich, Switzerland</p> <p>Made in UK TH-35-02-060</p>