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.

Sodium chloride 0.9% for irrigation

Health Care Provider Letter

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.

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)

• 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 **productqualityissues** associated with this imported product, please contact Baxter Product Surveillance through Baxter Product Feedback Portal (https://productfeedback.baxter.com/)

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

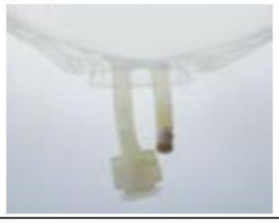
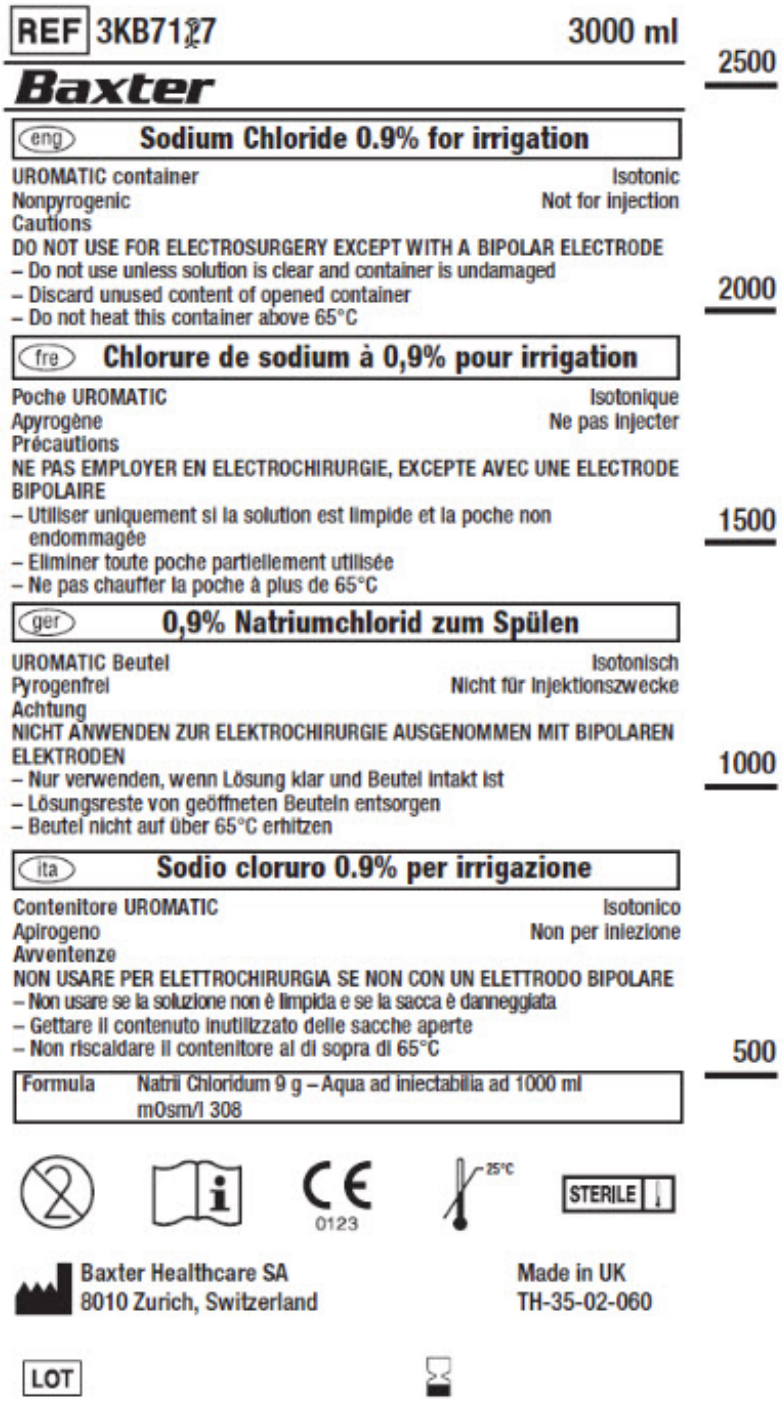
	FDA-approved product	Imported product from the UK
Product name	**0.9% Sodium Chloride Irrigation USP**	**Sodium Chloride 0.9% for Irrigation**
Label Volume	3000 mL	3000 mL
Language(s) of the labels	English	English, French, German and Italian
Indications	0.9% Sodium Chloride Irrigation, USP in UROMATIC 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	Contains medication port and administration port; Pull off port protector (blue color), right side 	Contains medication port and administration port; **twist off port protector (natural color), left side** 

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.

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL



Container Label

REF 3KB7127 3000 ml

Baxter Logo

eng **Sodium Chloride 0.9% for irrigation**
UROMATIC container
Isotonic
Nonpyrogenic
Not for injection
Cautions
DO NOT USE FOR ELECTROSURGERY EXCEPT WITH A BIPOLER ELECTRODE

- Do not use unless solution is clear and container is undamaged
- Discard unused content of opened container
- Do not heat this container above 65°C

fre **Chlorure de sodium à 0,9% pour irrigation**

ger **0,9% Natriumchlorid zum Spülen**

ita **Sodio cloruro 0.9% per irrigazione**

Formula
Natril Chloridum 9 g – Aqua ad injectabilia ad 1000 ml
mOsm/l 308

Do Not Re-Use Symbol
Consult Instructions for Use Symbol
European Conformity Symbol
Temperature Limit 25°C Symbol
Sterile Symbol

Manufacturer Symbol
Baxter Healthcare SA
8010 Zurich, Switzerland

Made in UK
TH-35-02-060

Lot Symbol
Use-by Date Symbol

2500

2000

1500

1000

500

SODIUM CHLORIDE
sodium chloride irrigant

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0110
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:0338-0110-04	4 in 1 CARTON	11/13/2024	
1	NDC:0338-0110-01	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		11/13/2024	

Labeler - Baxter Healthcare Company (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Ltd		221478644	ANALYSIS(0338-0110) , LABEL(0338-0110) , MANUFACTURE(0338-0110) , PACK(0338-0110) , STERILIZE(0338-0110)

Revised: 11/2024 Baxter Healthcare Company