Important Prescribing Information

November 21, 2024

Subject: Temporary importation of 0.9% Sodium Chloride Injection from Shanghai, China, labeled in Chinese, to address drug shortages

Dear Healthcare Professional,

To prevent a drug shortage of large volume parenteral fluid drug products, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Injection (250 mL; 500 mL and 1,000 mL) from Baxter's manufacturing facility in Shanghai, China. FDA has not approved these products manufactured by Baxter's Shanghai 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 these imported products in the United States.

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

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Injection	250 mL	A6C1322	40	0338-9804-01
	500 mL	A6C1323	24	0338-9810-01
	1,000 mL	A6C1324	12	0338-9806-01

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 products listed in the table above. Parenteral drug products should be inspected visually for particulate matter and bag defects prior to administration, whenever solution or container permits.

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

- The imported products have primary container labels written in Chinese. The primary container labels contain the active pharmaceutical ingredient, concentration, volume, and product code in English.

- The imported products' administration port system is fully compatible with Baxter sets marketed in the United States.

- **CORRECTION: The 250 mL product is NOT compatible for admixing with Baxter's Vial Mate adapter because the Vial-Mate adapter can introduce particles into the admixture.**

- The imported products use a carton box that is taped closed. To avoid damage to the solution container, take care not to use sharp instruments to open the carton.

- **The imported products do not contain barcodes 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 Injection is available only by prescription in the United States. However, the imported products do not have the statement "Rx only" on the labeling.

Additional key differences in the labeling between the FDA-approved product and the imported products are stated in the product comparison table at the end of this letter as follows:

Table 1. Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP
Table 2. Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP

Please refer to the FDA approved package insert for the full prescribing information of the drug product as follows:

- 0.9% Sodium Chloride Injection, 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: Nov 21, 2024 14:32 EST

Cecilia Soriano
President, Infusion Therapies & Technologies
Baxter Healthcare Corporation

Product Comparison Tables

Table 1. Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP

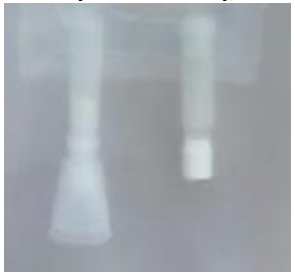
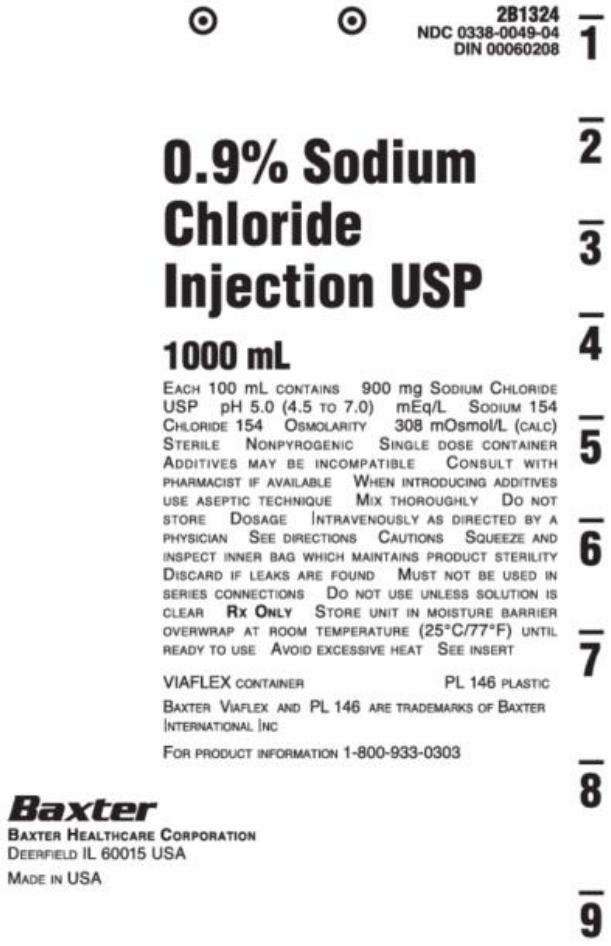
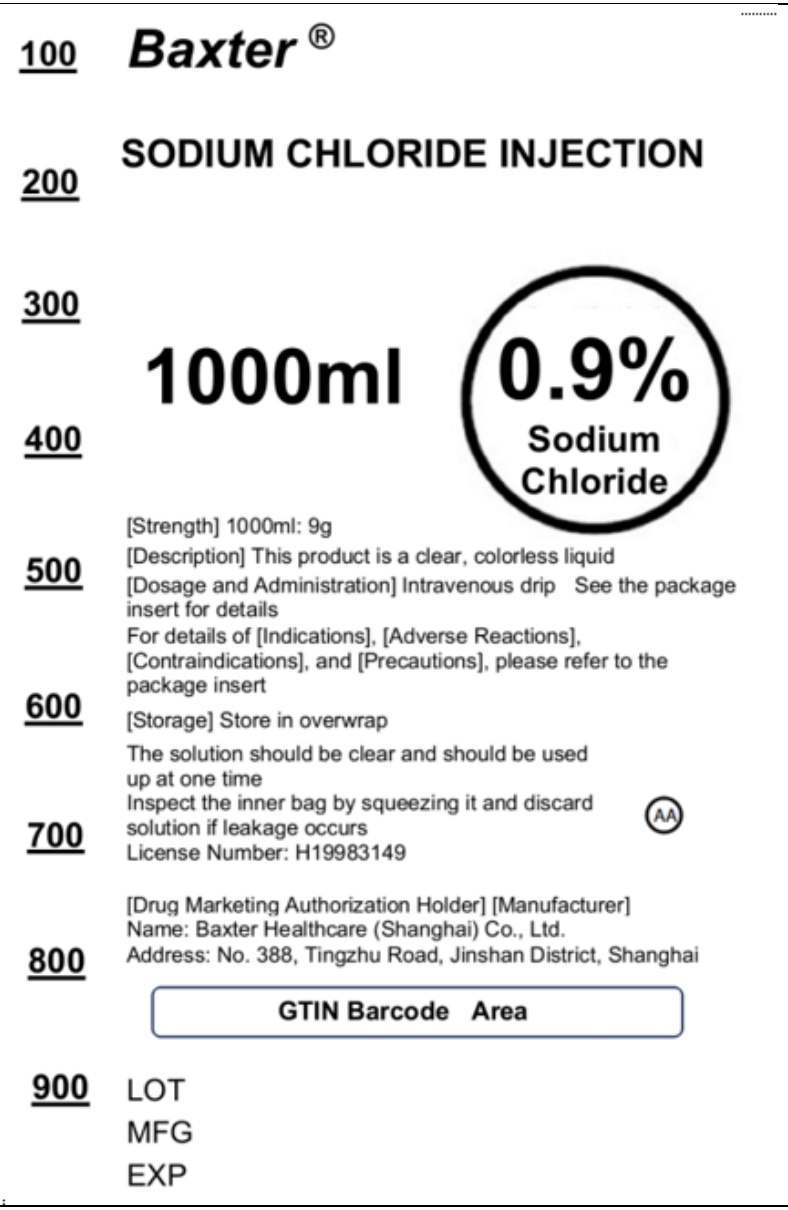
	FDA-approved product	Imported product from Shanghai, China
Product name	**0.9% Sodium Chloride Injection USP**	**0.9% Sodium Chloride Injection**
Label volume	**100 mL; 150 mL; 250 mL; 500 mL; 1000 mL**	**250 mL, 500 mL, 1000 mL**
Language of the Labels	English	**Chinese**
Indications	Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.	Sodium Chloride Injection is indicated as a source of water and electrolytes.
Active ingredients	Each 100 mL contains 900 mg Sodium Chloride, USP	Each 100 mL contains 900 mg Sodium Chloride
Additional information	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
Medication and Administration 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 (white color), left side** 

Table 2. Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP

FDA-approved product	Imported product from Shanghai, China
0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection
Label Color: Black. Barcode not shown. **1000 mL shown as representative label.**	Label Color: Black. **1000 mL shown as representative label.**
	

	0.9% Sodium Chloride Injection
	English translation **1000 mL shown as representative label.**
	 100 *Baxter* ® 200 **SODIUM CHLORIDE INJECTION** 300 **1000ml** **0.9% Sodium Chloride** 400 [Strength] 1000ml: 9g 500 [Description] This product is a clear, colorless liquid [Dosage and Administration] Intravenous drip See the package insert for details For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert 600 [Storage] Store in overwrap The solution should be clear and should be used up at one time Inspect the inner bag by squeezing it and discard solution if leakage occurs (AA) 700 License Number: H19983149 [Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. 800 Address: No. 388, Tingzhu Road, Jinshan District, Shanghai **GTIN Barcode Area** 900 LOT MFG EXP