SODIUM CHLORIDE- sodium chloride injection, solution
Baxter Healthcare Corporation

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 Injection

HEALTH CARE PROVIDER LETTER

Baxter

Important Prescribing Information

[October 18, 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.

- The 250 mL product is compatible for admixing with Baxter's Vial-mate product.

- 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,

Lee Ann Schuette

Lee Ann Schuette (Oct 18, 2024 15:00 CDT)

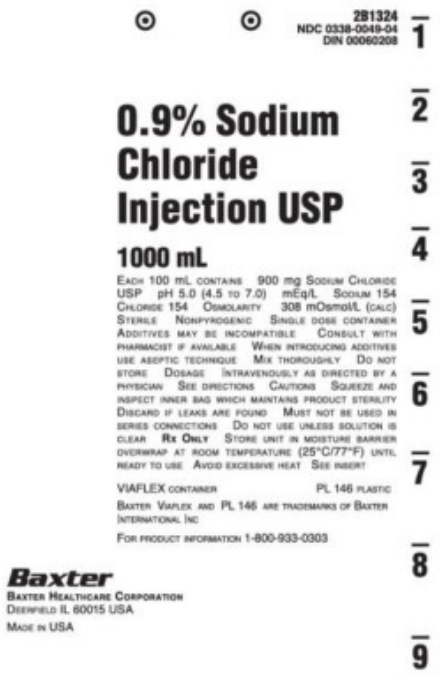
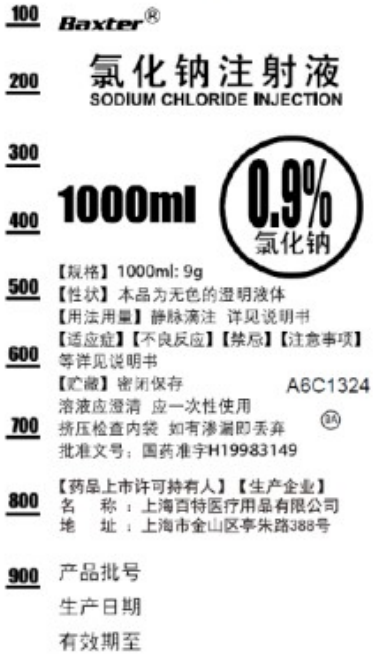
Lee Ann Schuette
VP Global and US Marketing IV solutions, Clinical Nutrition, Pharmacy Tools
Baxter Healthcare Corporation

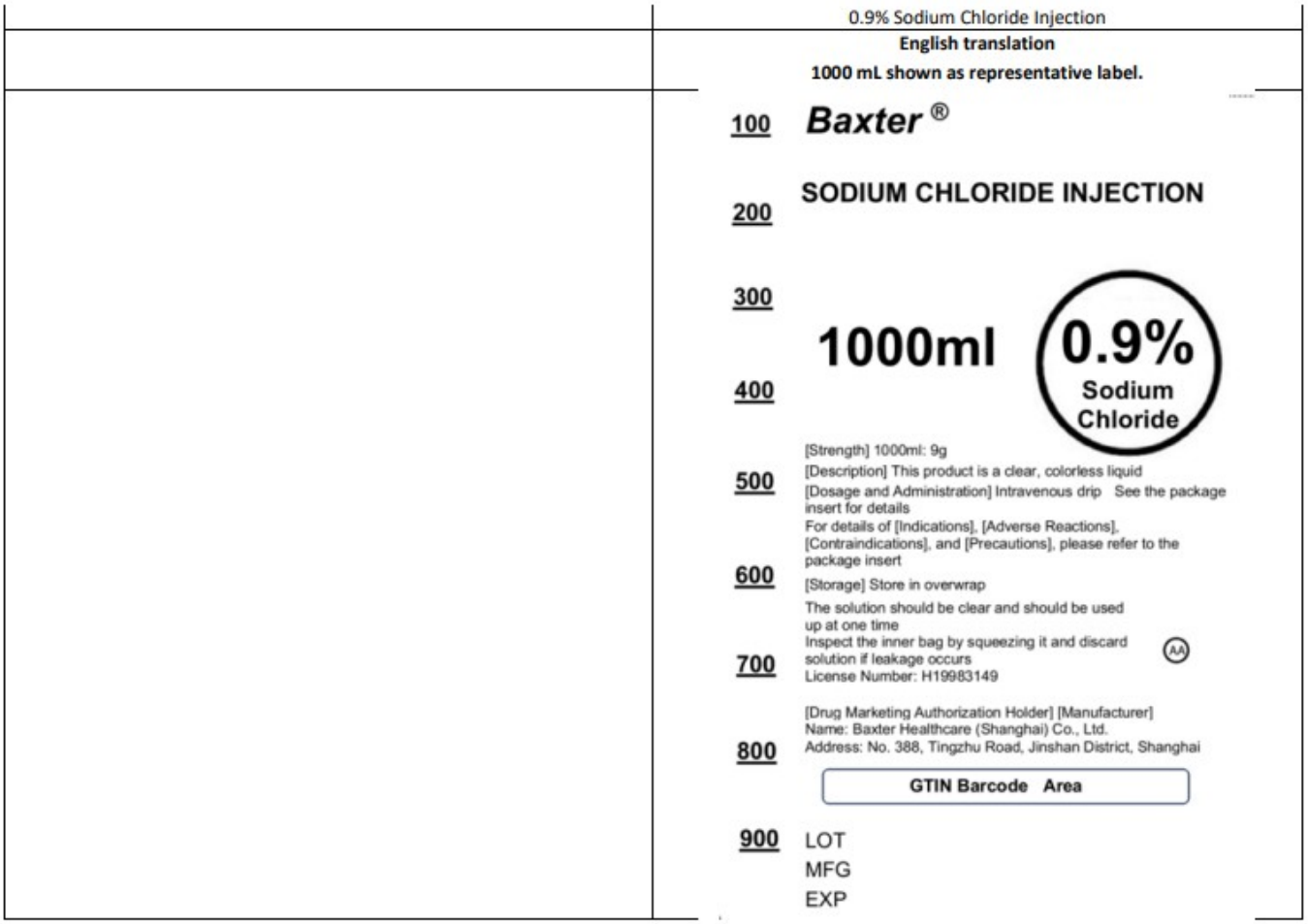
Product Comparison Table

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.**
	



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PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Container Label

Baxter Logo Trademark

A6C1322

SODIUM CHLORIDE INJECTION

50

100

150

200

250ml
0.9% Sodium Chloride

[Strength] 250ml: 2.25g
[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

[Storage] Store in overwrap

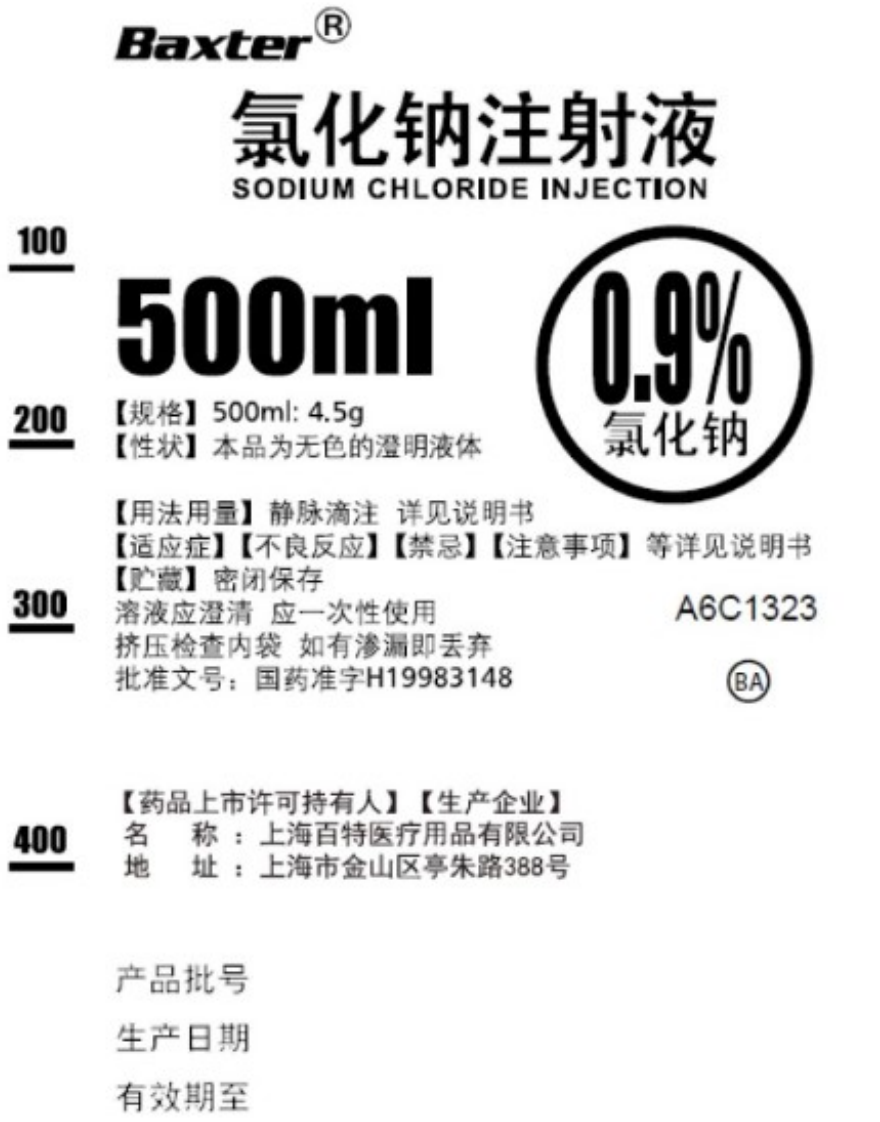
The solution should be clear and should be used up at one time
Inspect the inner bag by squeezing it and discard solution if leakage occurs
License Number: H19994066

AA

[Drug Marketing Authorization Holder] [Manufacturer]
Name: Baxter Healthcare (Shanghai) Co., Ltd.
Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

GTIN Barcode Area

LOT
MFG
EXP



Container Label

Baxter Logo Trademark

A6C1323

SODIUM CHLORIDE INJECTION

100

200

300

400

500ml
0.9% Sodium Chloride

[Strength] 500ml: 4.5g
[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

[Storage] Store in overwrap

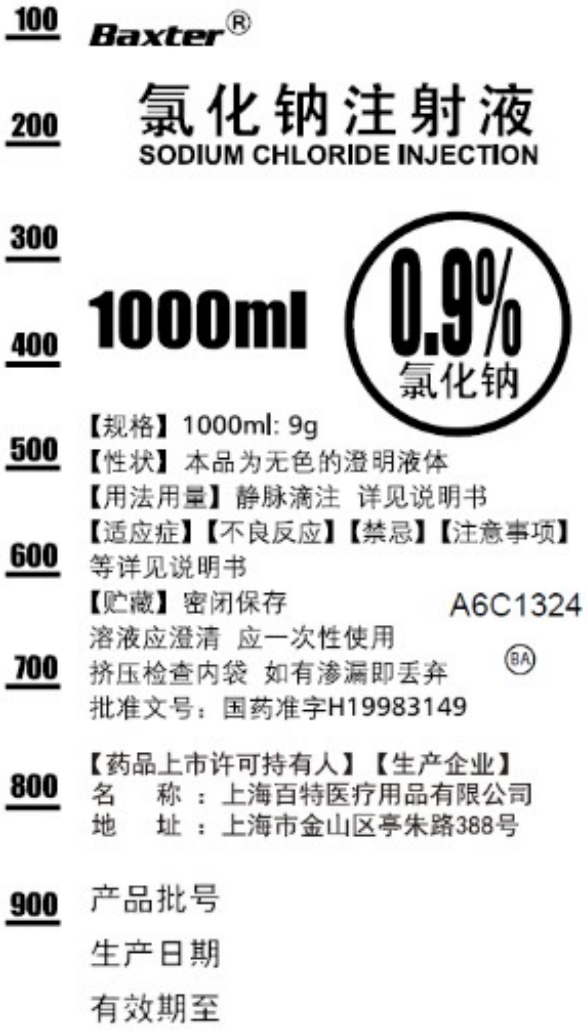
The solution should be clear and should be used up at one time
Inspect the inner bag by squeezing it and discard solution if leakage occurs
License Number: H19983148

AA

[Drug Marketing Authorization Holder] [Manufacturer]
Name: Baxter Healthcare (Shanghai) Co., Ltd.
Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

GTIN Barcode Area

LOT
MFG
EXP



Container Label

Baxter Logo Trademark

A6C1324

SODIUM CHLORIDE INJECTION

100

200

300

400

500

600

700

800

900

1000ml
0.9% Sodium Chloride

[Strength] 1000ml: 9g
[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

[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
License Number: H19983149

AA

[Drug Marketing Authorization Holder] [Manufacturer]
Name: Baxter Healthcare (Shanghai) Co., Ltd.
Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

GTIN Barcode Area

LOT
MFG
EXP

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9804
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 g in 1000 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-9804-40	40 in 1 CARTON	10/18/2024	
1	NDC:0338-9804-01	250 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		10/18/2024	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9806
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-9806-12	12 in 1 CARTON	10/18/2024	
1	NDC:0338-9806-01	1000 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			

Unapproved drug for use in drug shortage		10/18/2024	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9810
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 g in 1000 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0338-9810-24	24 in 1 CARTON	10/18/2024	
1	NDC:0338-9810-01	500 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		10/18/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare (Shanghai) Co. Ltd.		527191860	MANUFACTURE(0338-9804, 0338-9806, 0338-9810)