

Important Prescribing Information

January 24, 2025

Subject: Temporary importation of 0.9% Sodium Chloride Injection, 5% and 10% Glucose Injection, and 5% Glucose/0.9% Sodium Chloride Injection from Shanghai, China, labeled in English 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 and 1,000 mL), 5% Glucose Injection (250 mL and 1,000 mL), 10% Glucose Injection (250 mL), and 5% Glucose/0.9% Sodium Chloride Injection (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 products in the United States.

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
	250 mL	A6C1322US	40	0338-9791-01
0.9% Sodium Chloride Injection	500 mL	A6C1323US	24	0338-9808-01
	1,000 mL	A6C1324US	12	0338-9793-01
Ell Churges Injection	250 mL	A6C0062US	40	0338-9795-01
5% Glucose Injection	1,000 mL	A6C0064US	12	0338-9801-01
10% Glucose Injection	250 mL	A6C0162US	40	0338-9797-01
5% Glucose/0.9% Sodium Chloride Injection	1,000 mL	A6C1064US	12	0338-9799-01

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

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' administration port system is fully compatible with Baxter sets marketed in the United States.
- The products listed in the table above contain black barcodes (versus the white barcode on the approved product) and the barcode has been placed in a different position. The barcode on the imported product is encoded with the National Drug Code (NDC) that is specific to the imported product. However, the barcodes may not register accurately in the U.S. scanning systems. 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 is being used in all systems and processes and administered to individual patients.
- 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 product uses 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.
- Dextrose, USP is a hydrated form of glucose. The imported glucose product is an anhydrous form of glucose. Therefore on an energy content per mL basis,
 - 5% Glucose/0.9% Sodium Chloride Injection (0.20 kcal/mL) is <u>NOT</u> equivalent to 5% Dextrose/0.9% Sodium Chloride Injection USP (0.17 kcal/mL),
 - 5% Glucose Injection (0.20 kcal/mL) is <u>NOT</u> equivalent to 5% Dextrose Injection USP (0.17 kcal/mL),
 - 10% Glucose Injection (0.40 kcal/mL) is <u>NOT</u> equivalent to 10% Dextrose Injection USP (0.34 kcal/mL).
- The imported glucose containing products are <u>NOT</u> directly interchangeable with dextrose containing injections USP. Protocols, order entry, and compounding systems will need to be adjusted.
- 0.9% Sodium Chloride Injection USP, 5% Dextrose Injection USP, 10% Dextrose Injection USP, and 5% Dextrose/0.9% Sodium Chloride Injection USP are available only by prescription in the U.S. However, the imported products do not have the statement "Rx only" on the labeling.

Additional key differences in the labeling between the FDA-approved products and the imported products are stated in the product comparison tables 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
- Table 3 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection
- Table 4
 Label images of FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection
- Table 5
 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection

Table 6 Label images of FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection

Table 7Key differences between FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported5% Glucose/0.9% Sodium Chloride Injection

Table 8Label images of FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5%Glucose/0.9% Sodium Chloride Injection

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.

To report product quality issues associated with these imported products, please contact Baxter Product Surveillance through Baxter - Product Feedback Portal (https://productfeedback.baxter.com/).

Please also refer to the local prescribing information of the imported product, translated into English, available for:

- 0.9% Sodium Chloride Injection (click here) •
- 5% Glucose Injection (click here)
- 10% Glucose Injection (click here)
- 5% Glucose/0.9% Sodium Chloride Injection (click here)

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

- 0.9% Sodium Chloride Injection USP (click here)
- 5% Dextrose Injection USP (click here)
- 10% Dextrose Injection USP (click here)
- 5% Dextrose/0.9% Sodium Chloride Injection USP (click here)

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 at 1-888-229-0001.

Sincerely,

Lee Ann Schuette Reason: I approve this document Date: Jan 24, 2025 13:29 CST

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

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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	English
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 2Label 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. Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.
• • • • • • • • • • • • • • • • • • •	100 Baxter [®] A6C1324US
0.9% Sodium ²	SODIUM CHLORIDE INJECTION
Chloride 3	³⁰⁰ 1000ml 0.9%
Injection USP 1000 mL EACH 100 mL CONTAINS 900 mg Sodium Chloride	400 Sodium Chloride
USP pH 5.0 (4.5 to 7.0) mEq/L Sodium 154 Chloride 154 Osmolarity 308 mOsmol/L (calc) Sterile Nonpyrogenic Single dose container Additives May be incompatible Consult with Pharmacist if available When introducing additives	[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],
USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS	600 [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
CLEAR RX ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT VIAFLEX CONTAINER PL 146 PLASTIC	TOOSolution if leakage occurs License Number: H19983149A)
BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC	[Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai
FOR PRODUCT INFORMATION 1-800-933-0303	GTIN Barcode Area
BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA	<u>900</u> LOT
	MFG EXP
9	

Table 3 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection

	FDA-approved product	Imported product from Shanghai, China
Product name	5% Dextrose Injection USP	5% Glucose Injection
Label volume	250 mL, 1000 mL	250 mL, 1000 mL
Language of the Labels	English	English
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	Glucose Injection is indicated as a source of water and calories.
Active ingredients	Each 100 mL contains 5 g Dextrose Hydrous USP	Each 100 mL contains 5 g Anhydrous Glucose
Additional	pH 4.0 (3.2 to 6.5)	4.0 (3.2 to 6.5)
information	Osmolarity 252 mOsmol/L (calc)	Osmolarity 278 mOsmol/L (calc)
Caloric content	170 kcal/L	200 kcal/L
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 4 Label images of FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection

5% Glucose Injection Label Color: Black. 1000 mL shown as representative label. Imported product co NDC number, which is not yet shown below. Barcode locatio and will contain a linear barcode with human readable info <u>100</u> Baxter ® A6C0064US GLUCOSE INJECTION
1000 mL shown as representative label. Imported product constrained with the shown below. Barcode location and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear barcode with human readable information and will contain a linear
GLUCOSE INJECTION
200 GEBCOSE INSECTION
³⁰⁰ 5%
400 1000ml
500 [Strength] 1000ml: 50g [Description] This product is a clear, colorless or almost 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
700 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 License Number: H19983151 AA
800 [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

Table 5	Key differences between FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection

	FDA-approved product	Imported product from Shanghai, China
Product name	10% Dextrose Injection USP	10% Glucose Injection
Label volume	250 mL	250 mL
Language of the Labels	English	English
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	Glucose Injection is indicated as a source of water and calories.
Active ingredients	Each 100 mL contains 10 g Dextrose Hydrous USP	Each 100 mL contains 10 g Anhydrous Glucose
Additional information	pH 4.0 (3.2 to 6.5) Osmolarity 505 mOsmol/L (calc)	pH 4.0 (3.2 to 6.5) Osmolarity 555 mOsmol/L (calc)
Caloric content	340 kcal/L	400 kcal/L
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 6
 Label images of FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection

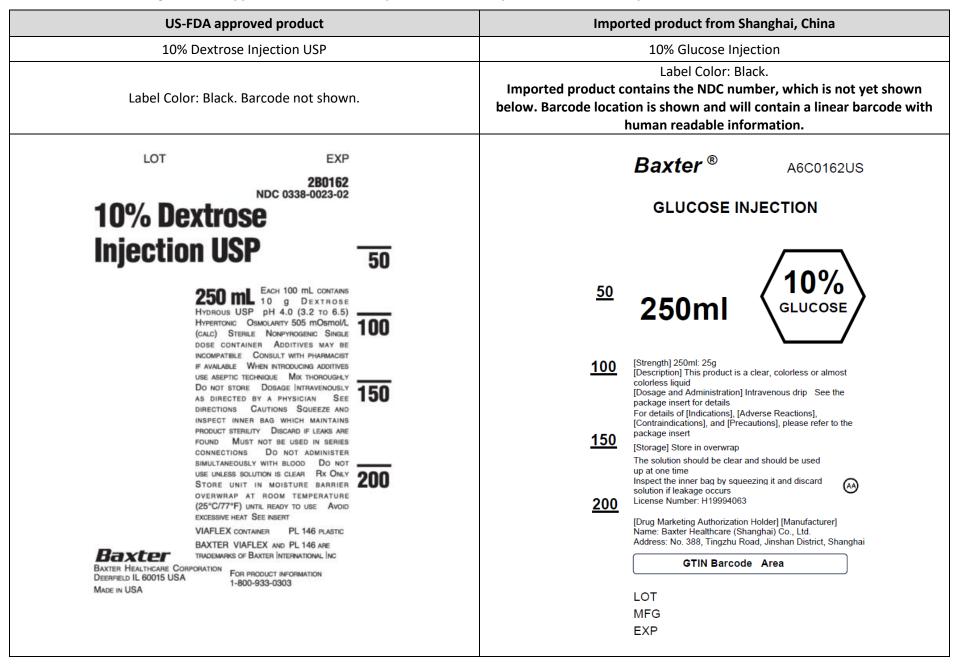


Table 7Key differences between FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% SodiumChloride Injection

	FDA-approved product	Imported product from Shanghai, China
Product name	5% Dextrose and 0.9% Sodium Chloride Injection USP	5% Glucose and 0.9% Sodium Chloride Injection
Label volume	1000 mL	1000 mL
Language of the Labels	English	English
Indications	Dextrose and Sodium Chloride Injection, USP is indicated as a source of fluid and electrolyte replenishment and caloric supply.	Glucose and Sodium Chloride Injection is indicated as a source of fluid and electrolyte replenishment and caloric supply.
Active ingredients	Each 100 mL contains 5 g Dextrose Hydrous USP and 900 mg Sodium Chloride USP	Each 100 mL contains 5 g Anhydrous Glucose and 900 mg Sodium Chloride
Additional information	pH 4.0 (3.2 to 6.5) Osmolarity 560 mOsmol/L (calc)	pH 4.0 (3.2 to 6.5) Osmolarity 585 mOsm/L (calc)
Caloric content	170 kcal/L	200 kcal/L
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)
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 8Label images of FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium ChlorideInjection

