



Important Prescribing Information

December 18, 2024

Subject: Temporary importation of Sterile Water for Injection and 70% Dextrose Injection from Canada 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 Sterile Water for Injection USP 1,000 mL Pharmacy Bulk Package and 70% Dextrose Injection USP 3,000 mL Pharmacy Bulk Package from Baxter's manufacturing facility in Alliston, Canada. FDA has not approved these products manufactured by Baxter's Alliston 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.

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
Sterile Water for Injection USP	1,000 mL	JB0304	12	0338-9782-01
70% Dextrose Injection USP	3,000 mL	JB0297	4	0338-9789-01

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 are not intended for direct patient administration. When compounding with the imported products, check for compatibility of all additives and stability of the resulting preparation.

- The imported products’ port system is fully compatible with Baxter inlets and sets marketed in the United States. **Note that the imported product, Sterile Water for Injection USP, has an additive port as well as an outlet port, while the FDA-approved product only contains the outlet port. The imported product, 70% Dextrose Injection USP, has two outlet ports, one short and one long. We recommend connecting the inlet or set to the longer outlet port, although either ports can be used. The FDA-approved product only has one outlet port.**
- **The barcode on the imported product labels may not register accurately in U.S. scanning systems. The imported products do not have a linear barcode on the bag, rather they have a 2D barcode that contains the product Global Trade Identification Number (GTIN).** Institutions should manually input the products into their systems to ensure that barcode systems do not provide incorrect information when a 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.
- Sterile Water for Injection USP and 70% Dextrose 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 Sterile Water for Injection USP**
- Table 2 Label images of FDA-approved and imported Sterile Water for Injection USP**
- Table 3 Key differences between FDA-approved and imported 70% Dextrose Injection USP**
- Table 4 Label images of FDA-approved and imported 70% Dextrose Injection USP**

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>).

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

- Sterile Water for Injection USP (click [here](#))
- 70% Dextrose 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 by calling 1-888-229-0001.

Sincerely,

Lee Ann Schuette
Electronically signed by: Lee Ann Schuette
Reason: I approve this document
Date: Dec 18, 2024 15:42 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 Table

Table 1 Key differences between FDA-approved and imported Sterile Water for Injection USP



	FDA-approved product	Imported product from Canada
Product name	Sterile Water for Injection USP	Sterile Water for Injection USP
Label Volume	1,000 mL; 2,000 mL; 3,000 mL; 5,000 mL	1,000 mL
Language(s) of the labels	English	English and French
Indications	Sterile Water for Injection is indicated in the aseptic preparation of parenteral admixtures.	Sterile Water for Injection is indicated in the aseptic preparation of parenteral admixtures.
Active ingredients	Sterile Water Injection USP	Sterile Water Injection USP
Additional information	pH is 5.5 (5.0 to 7.0) Osmolarity 0 mOsmol/L (calc)	pH is 5.5 (5.0 to 7.0) Osmolarity 0 mOsmol/L (calc)
Storage conditions	Store at room temperature 25°C/77°F. Protect from freezing.	Store at 15°C/59°F to 25°C/77°F.
Container type	VIAFLEX (PVC)	VIAFLEX (PVC)
Port closures	Outlet port only with pull off port protector (blue color) 	Additive port and outlet port with pull off port protector (blue color) 

Table 3 Key differences between FDA-approved and imported 70% Dextrose Injection USP




	FDA-approved product	Imported product from Canada
Product name	70% Dextrose Injection USP	70% Dextrose Injection USP
Label Volume	2,000 mL	3,000 mL
Language(s) of the labels	English	English and French
Indications	Dextrose Injection is indicated as a source of calories when mixed with amino acids or other compatible intravenous fluids for patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.	Dextrose Injection is indicated as a fluid and nutrient replacement.
Active ingredients	Each 1,000 mL contains 700 g Dextrose Hydrous USP	Each 1,000 mL contains 700 g Dextrose Hydrous USP
Total content of active ingredient in product	1,400 g of dextrose per bag	2,100 g of dextrose per bag
Additional information	pH is 4.0 (3.2 to 6.5) Osmolarity 3,530 mOsmol/L (calc)	pH is 4.0 (3.2 to 6.5) Osmolarity 3,530 mOsmol/L (calc)
Storage conditions	Store at room temperature 25°C/77°F. Protect from freezing.	Store at 15°C/59°F to 25°C/77°F.
Container type	VIAFLEX (PVC)	VIAFLEX (PVC)
Port closures	1 outlet port only with pull off port protector (blue color) 	2 outlet ports with pull off port protectors (blue color) 

Table 4 Label images of FDA-approved and imported 70% Dextrose Injection USP

FDA-approved product	Imported product from Canada
70% Dextrose Injection USP	70% Dextrose Injection USP
Label Color: Blue (fully) . Barcode not shown.	Label Color: Black
<p>LOT EXP</p> <p>280296 2000 mL NDC 0338-0719-06 DIN 02014874</p> <p>DEXTROSE 1800</p> <p>Injection 1600</p> <p>USP 1400</p> <div style="border: 1px solid black; padding: 5px; display: inline-block; text-align: center;"> <p>70%</p> </div> <p>Pharmacy Bulk Package 1200 Not For Direct Infusion Must Be Diluted</p> <p>Rx Only</p> <p>EACH 100 mL CONTAINS 70 g DEXTROSE HYDROUS USP IN WATER FOR INJECTION USP pH 4.0 (3.2 to 6.5) SPECIFIC GRAVITY 1.24 (CALC) HYPERTONIC OSMOLARITY 3530 mOsmol/L (CALC) STERILE NONPYROGENIC CONTAINS NO MORE THAN 25 µg/L OF ALUMINUM COLOR VARIATION FROM LIGHT YELLOW TO AMBER IS NORMAL AND DOES NOT ALTER EFFICACY DOSAGE AND ADMINISTRATION SEE PACKAGE INSERT CAUTION DO NOT USE UNLESS SOLUTION IS CLEAR CLOSURE IS INTACT AND CONTAINER IS UNDamAGED CHECK FOR MINUTE LEAKS BY SQUEEZING FIRMLY IF LEAKS ARE FOUND DISCARD AS STERILITY MAY BE IMPAIRED AFFIX ACCOMPANYING LABEL FOR DATE AND TIME OF ENTRY WITHIN 4 HOURS AFTER INITIAL ENTRY DISCARD CONTAINER AND UNUSED CONTENTS 800 STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT PROTECT FROM FREEZING 600</p> <p>VIAFLEX CONTAINER PL 146 PLASTIC</p> <p>Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA BAXTER PL 146 AND VIAFLEX ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <div style="border: 1px solid black; padding: 5px; display: inline-block; text-align: center;"> <p>70%</p> </div> <p>DISTRIBUTED IN CANADA BY BAXTER CORPORATION MISSISSAUGA ON L5N 0C2 400</p> <p>200</p>	<p>JB0297 3000 mL DIN 02014874 2700</p> <p>70% Dextrose Injection USP Dextrose à 70% USP, Injectable</p> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> <p>DEXTROSE 70%</p> </div> <p>2400</p>  <p>Pharmacy Use Only / Dilute Before Infusing Pour Usage Par La Pharmacie Seulement / Diluer Avant La Perfusion 2100</p> <p><small>(01)00809080000654</small> Not for Direct Infusion / Ne pas utiliser pour perfuser directement 1800</p> <p>HYPERTONIC / HYPERTONIQUE CONTAINS NO MORE THAN 25 µg/L OF ALUMINUM / NE CONTIENT PAS PLUS DE 25 µg/L D'ALUMINIUM APPROX mOsmol/L - 3530 APPROX pH 4.0 1500 INTRAVENOUS FLUID AND NUTRIENT REPLENISHMENT / RECHARGE LIQUIDIENNE ET NUTRIMENT PAR INJECTION INTRAVEINEUSE PER 100 mL DEXTROSE HYDROUS USP - 70 g / WATER FOR INJECTION USP qs 1200 PAR 100 mL DEXTROSE HYDRATE USP - 70 g / EAU POUR INJECTION USP qs</p> <p>COLOUR VARIATION FROM LIGHT YELLOW TO AMBER IS NORMAL AND DOES NOT ALTER EFFICACY / IL EST NOR- MAL QUE LA COULEUR VARIE D'UN JAUNE PALE A UN JAUNE AMBRE ET CELA NAFFECTE PAS L'EFFICACITE AFFIX ACCOMPANYING LABEL FOR DATE AND TIME OF ENTRY / APPOSER UNE ETIQUETTE ET INSCRIRE LA DATE ET L'HEURE DU PRELEVEMENT INITIAL / DISCARD UNUSED CONTENTS WITHIN 4 HOURS OF INITIAL ENTRY / JETER LE CONTENANT 4 HEURES APRES LE PREMIER PRELEVEMENT 900</p> <p>CAUTIONS SQUEEZE AND INSPECT BAG / SEE DIREC- TIONS FOR USE / STORE AT 15°C TO 25°C 600 ATTENTIONS PRESSER ET INSPECTER LE SAC / VOIR MODE D'EMPLOI / GARDER ENTRE 15°C ET 25°C</p> <p>NONPYROGENIC / STERILE / APYROGENE / STÉRILE PRESCRIBING INFORMATION AVAILABLE ON REQUEST / INFORMA- TION POSOLOGIQUE DISPONIBLE SUR DEMANDE</p> <p>VIAFLEX PVC CONTAINER/CONTENANT DE PVC 300</p> <p><small>BAXTER AND VIAFLEX ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER ET VIAFLEX SONT DES MARQUES DE COMMERCE DE BAXTER INTERNATIONAL INC</small></p> <p>Baxter Baxter Corporation Mississauga ON L5N 0C2 88-70-20-462</p> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> <p>70%</p> </div> 