

Important Prescribing Information

October 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' administration port system is fully compatible with Baxter sets marketed in the
 United States. Note that the imported products have a medication port as well as an administration port,
 while the FDA-approved products only contain the administration 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 for 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 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
Lee Ann Schuette (Oct 18, 2024 08:59 CDT)

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)	
	Administration port only; Pull off port protector (blue color)	Contains medication port and administration port; Pull off port protector (blue color)	
Administration port closures		THE PARTY OF THE P	

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Table 2 Label images of FDA-approved and imported Sterile Water for Injection USP

FDA approved product	Imported product from Canada
Sterile Water for Injection USP	Sterile Water for Injection USP
Label Color: Red and Black. Barcode not shown.	Label Color: Red (fully). White 2D Barcode not shown.
Label Color: Red and Black. Barcode not shown. LOT EXP 280309 5000 mt NDC 0339-0013-29 5000 mt NDC 0339-0013-29 4500 Sterile Water For Injection USP Pharmacy Bulk Package Not For Direct Infusion Rx Only NO ANTIMICROBIAL OR OTHER SUBSTANCE HAS BEEN ADDED PH 5.5 (5.0 TO 7.0) OSMOLARITY 0 mOsmol/L (CALC) STERILE NONPYROGENIC CONTAINS NO MORE THAN 25 µg/L OF ALUMINUM ADDITIVES MAY BE INCOMPATIBLE WITH THE FLUID WITHDRAWN FROM THIS CONTAINER CONSULT WITH PHARMACIST IF AVAILABLE WHEN COMPOUNDING ADMIXTURES USE A SEPIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSAGE ADMIX FOR INTRAVENOUS ADMINISTRATION AS DIRECTED BY A PHYSICIAN SEE ACCOMPANYING DIRECTIONS FOR USE ONCE CONTAINER CLOSURE HAS BEEN PENETRATED WITHORAWAL OF CONTENTS SHOULD BE COMPLETED WITHOUT DELAY A FICK ACCOMPANYING LABEL FOR DATE AND TIME OF ENTRY DISPENSE CONTENTS WITHIN 4 HOURS AFTER INITIAL ENTRY CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR AND SEAL IS INTACT STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/T7°F) UNITL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT	Sterile WATER for Injection USP EAU stérile pour injection USP EAU stérile pour injection USP Sterile WATER / EAU stérile Not for Direct Infusion Ne pas utiliser pour perfuser directement PHARMACY BULK PACK AGE / CONDITIONNEMENT EN VRAC POUR LA PHARMACIE SINGLE PUNCTURE, MULTIPLE DISPENSING / PERFORATION UNIQUE, DISPENSATION MULTIPLE DISCARD UNUSED PORTION / JETEN TOUTE PARTIE INUTILISÉE APPROX momovil. 0 APPROX sels a sels access / Aucun Agent Antimicrobial cacent on on the substance has del accounte Cautions: Squeeze and no report had a fet a locuté Cautions: Squeeze and no report had a fet a locuté Cautions: Squeeze and no report had sels and complete / Must not be USED in Seriles connections / Store at 18°C to 28°C Misse sen dargoe: Presses et at inspecter la poche / consulter le mode Demploi / Ine pas utiliser pour les raccords en sèrie / conserver entre 15°C et 28°C Contains no more than 25 µgl. of Alluminum / Ne contient pas plus de 25 µgl. Cauluminum NOMPYROGENIC / STERILE / APYPROGENE / STÉRILE HYPOTONO / ADMIX CONTIENT / HYPOTONIQUE / POUR MÉLANGE SEULEM ENT DOSAGE / PRESCRIBING IN FORMATION AVAIL ABLE ON REQUEST / POSOLOGIE : RENSEIGNEMENTS POSOLOGIQUES DISPONIBLES SUR DEMANDE VIAFLEX PVC CONTAINER / CONTENANT EN PVC VIAFLEX BACTER MON MALEXANIET HUDERAWARS OF BAUTER HUTERATIONAL NO. BEAUTER HER MATORIAL NO.
Baxter Baxter Lathcare Corporation CLINTEC NUTRITION DIVISION DEERFIELD IL 60015 USA	Baxter Corporation Mississauga ON L5N 0C2 07-25-77-318

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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)	
Administration port closures	Administration port only; Pull off port protector (blue color)	Contains medication port and administration port; Pull off port protector (blue color)	

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Table 4 Label images of FDA-approved and imported 70% Dextrose 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	
280296 2000 mL NDC 0338-0719-06 DIN 02014874 DEXTROSE 1800	JB0297 3000 mL DIN 02014874 2700 70% Dextrose Injection USP Dextrose à 70% USP, Injectable (DEXTROSE 70%) 2400	
Injection USP T600	Pharmacy Use Only / Dilute Before Infusing Pour Usage Par La Pharmacy cie Seulement / Diluer Avant La Perfusion (01)00809080000654 Not for Direct Infusion /	
Pharmacy Bulk Package Not For Direct Infusion Rx Only Must Be Diluted	Ne pas utiliser pour perfuser directement HYPERTONIC / HYPERTONIQUE CONTAINS NO MORE THAN 25 µg/L OF ALUMINUM/ NE CONTIENT PAS PLUS DE 25 µg/L DALUMINIUM APPROX mOsmol/L - 3530 APPROX pH 4.0 INTRAVENOUS FLUID AND NUTRIENT REPLENISHMENT / RECHARGE LIQUIDIENNE ET NUTRIMENT PAR	
EACH 100 mL CONTAINS 70 g DEXTROSE HYDROUS USP IN WATER FOR INJECTION USP pH 4.0 (2.2 to 6.5) SPECIFIC GRAVITY 1.24 (CALC) HYPERTONIC OSMOLARITY 3530 m0smol/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	INJECTION INTRAVEINEUSE PER 100 mL DEXTROSE HYDROUS USP - 70 g / WATER FOR INJECTION USP qs PAR 100 mL DEXTROSE HYDRATE USP - 70 g / EAU POUR INJECTION USP qs 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	
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 AFFER INITIAL ENTRY DISCARD CONTAINER AND UNUSED CONTENTS STORE UNIT IN MOISTURE BARRIER OVERWRAP AT	JAUNE AMBRE ET CELA NAFFECTE PAS L'EFFICACITE AFFIX ACCOMPANYING LABEL FOR DATE AND TIME OF ENTRY / APPOSER UNE ET IQUETTE 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	
ROOM TEMPERATURE (25°C/77°E) UNTIL READY TO USE AVOID EXCESSIVE HEAT PROTECT FROM FREEZING VIAFLEX CONTAINER PL 146 PLASTIC BAXTER HEALTHCARE CORPORATION DEERFIELD II. 60015 USA MADE IN USA MADE IN USA MISSISSADO NILS NO.C2	CAUTIONS SQUEEZE AND INSPECT BAG / SEE DIRECTIONS FOR USE / STORE AT 15°C TO 25°C ATTENTIONS PRESSER ET INSPECTER LE SAC / VOIR MODE D'EMPLOI / GARDER ENTRE 15°C ET 25°C NONPYROGENIC / STERILE / APYROGENE / STÉRILE PRESCRIBING INFORMATION AVAILABLE ON REQUEST / INFORMATION POSOLOGIQUE DISPONIBLE SUR DEMANDE	
BAXTER PL 146 AND VIAFLEX ARE TRADEMARKS OF BAXTER NTERNATIONAL INC 700 200	VIAFLEX PVC CONTAINER/CONTENANT DE PVC BAXTER AND VIAFLEX ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER ET VIAFLEX SONT DES MARQUES DE COMMERCE DE BAXTER INTERNATIONAL INC Baxter Baxter Corporation Mississauga ON L5N 0C2 300 Ayex 88-70-20-462	

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