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

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

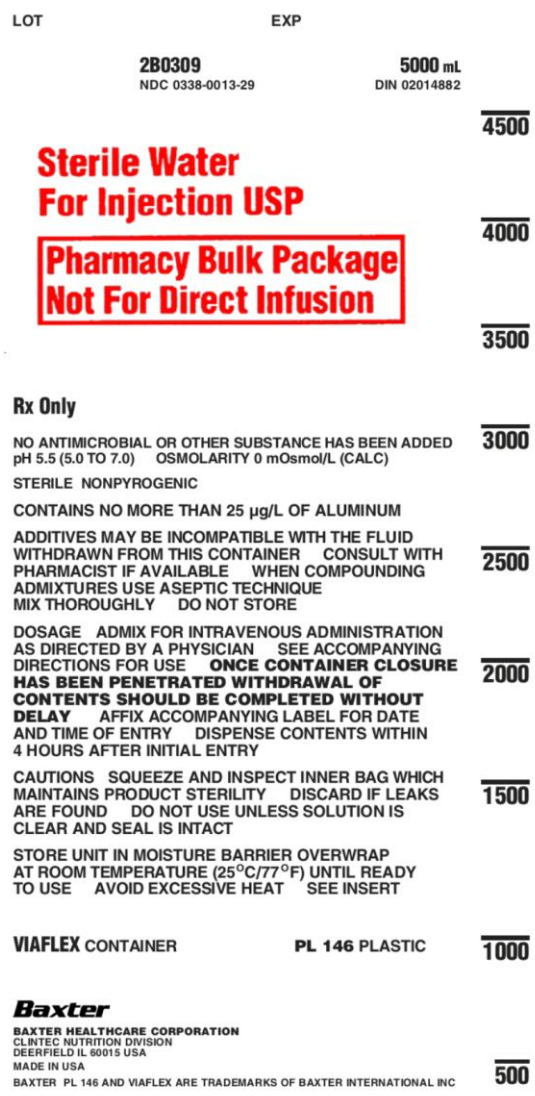
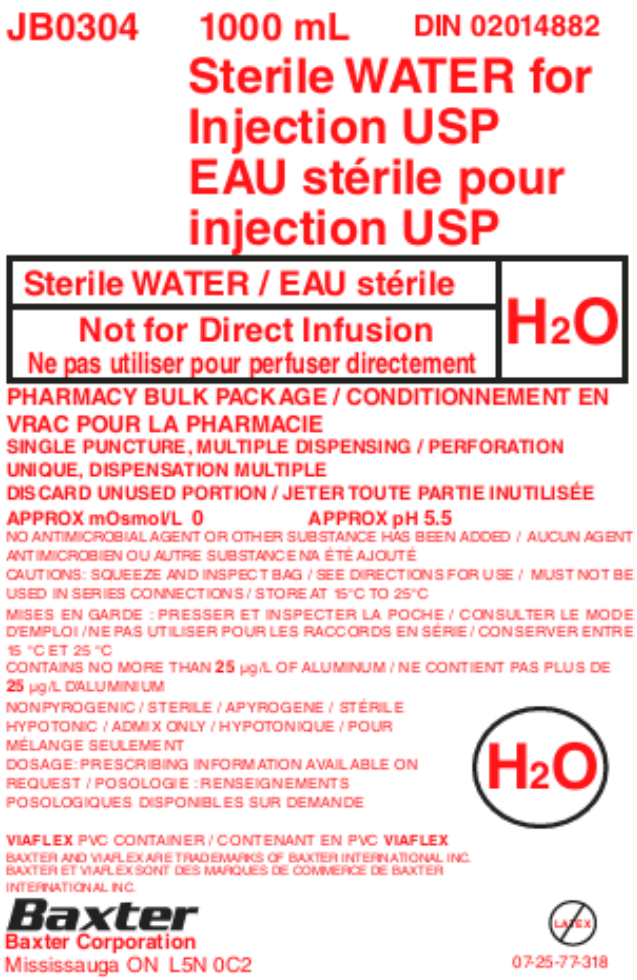
FDA-approved product	Imported product from Canada
Sterile Water for Injection USP	Sterile Water for Injection USP
Label Color: Red and Black. Barcode not shown.	Label Color: Red (fully). White 2D Barcode not shown.
	

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