STERILE WATER- water injection, solution
Baxter Healthcare Company

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.

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sterile water for injection

Health Care Provider Letter

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

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

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

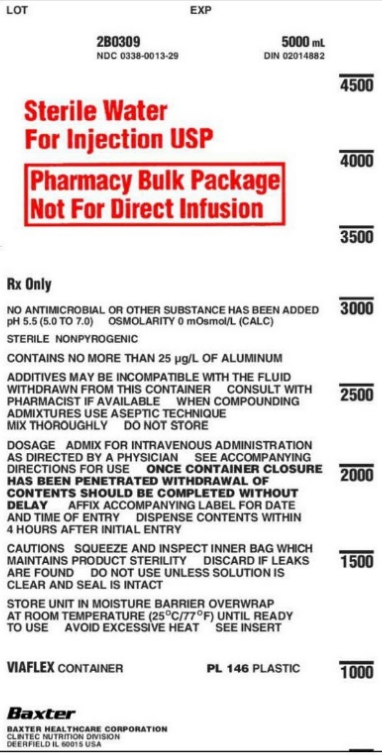
FDA approved product	Imported product from Canada
Sterile Water for Injection USP	Sterile Water for Injection USP
Label Color: Red and Black. Barcode not shown.	Label Color: Red (fully). White 2D Barcode not shown.
	

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

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
	

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

JB0304 **1000 mL** **DIN 02014882**

Sterile WATER for Injection USP
EAU stérile pour injection USP

Sterile WATER / EAU stérile

Not for Direct Infusion
Ne pas utiliser pour perfuser directement

H_2O

PHARMACY BULK PACKAGE / CONDITIONNEMENT EN VRAC POUR LA PHARMACIE

SINGLE PUNCTURE, MULTIPLE DISPENSING / PERFORATION UNIQUE, DISPENSATION MULTIPLE

DISCARD UNUSED PORTION / JETER TOUTE PARTIE INUTILISÉE

APPROX mOsmol/L 0 **APPROX pH 5.5**

NO ANTIMICROBIAL AGENT OR OTHER SUBSTANCE HAS BEEN ADDED / AUCUN AGENT ANTIMICROBIEN OU AUTRE SUBSTANCE N'A ÉTÉ AJOUTÉ

CAUTIONS: SQUEEZE AND INSPECT BAG / SEE DIRECTIONS FOR USE / MUST NOT BE USED IN SERIES CONNECTIONS / STORE AT 15°C TO 25°C

MISES EN GARDE : PRESSER ET INSPECTER LA POCHE / CONSULTER LE MODE D'EMPLOI / NE PAS UTILISER POUR LES RACCORDS EN SÉRIE / CONSERVER ENTRE 15 °C ET 25 °C

CONTAINS NO MORE THAN **25** µg/L OF ALUMINUM / NE CONTIENT PAS PLUS DE **25** µg/L D'ALUMINIUM

NONPYROGENIC / STERILE / APYROGENE / STÉRILE

HYPOTONIC / ADMIX ONLY / HYPOTONIQUE / POUR MÉLANGE SEULEMENT

DOSAGE: PRESCRIBING INFORMATION AVAILABLE ON REQUEST / POSOLOGIE : RENSEIGNEMENTS POSOLOGIQUES DISPONIBLES SUR DEMANDE

H_2O

VIAFLEX PVC CONTAINER / CONTENANT EN PVC **VIAFLEX**

Baxter
Baxter Corporation
Mississauga ON L5N 0C2

LATEX

07-25-77-318

JB-03-04 12 - 1000 mL units
Store at 15° C to 25° C

Sterile Water For Injection USP

LOT:WWWWWWWWW EXP: 2099 99

(01)00808000528

Pharmacy Bulk

Container Label

JB0304 1000 mL DIN 02014882

Sterile WATER for
Injection USP
EAU stérile pour
injection USP

Sterile WATER / EAU stérile
Not for Direct Infusion
Ne pas utilizer pour perfuser directment
H_2O

PHARMACY BULK PACKAGE / CONDITIONNEMENT EN
VRAC POUR LA PHARMACIE
SINGLE PUNCTURE, MULTIPLE DISPENSING / PERFORATION
UNIQUE, DISPENSATION MULTIPLE
DISCARD UNUSED PORTION / JETER TOUTE PARTIE INUTILISÉE

APPROX mOsmol/L 0 APPROX pH 5.5

NO ANTIMICROBIAL AGENT OR OTHER SUBSTANCE HAS BEEN ADDED / AUCUN AGENT ANTIMICROBIEN OU AUTRE SUBSTANCE NA ÉTÉ AJOUTÉ

CAUTIONS: SQUEEZE AND INSPECT BAG / SEE DIRECTIONS FOR USE / MUST NOT BE USED IN SERIES CONNECTIONS / STORE AT 15°C ET 25°C

MISES EN GARD : PRESSER ET INSPECTOR LA POCHE / CONSULTER LE MODE D'ÉMPLOI / NE PAS UTILISER POUR LES RACCORDS EN SÉRIE / CONSERVER ENTRE 15°C ET 25°C

CONTAINS NO MORE THAN **25** µg/L OF ALUMINUM / NE CONTINENT PAS PLUS DE **25** µg/L D'ALUMINIUM

NONPYROGENIC / STERILE / APYROGENE / STÉRILE
HYPOTONIC / ADMIX ONLY / HYPTONIQUE / POUR MÉLANGE SUELEMENT

DOSAGE: PRESCRIBING INFORMATION AVAILABLE ON REQUEST / POSOLOGIE : RENSEIGNEMENTS POSOLOGIQUES DISPONIBLES SUR DEMANDE

H_2O Label

VIAFLEX PVC CONTAINER / CONTENANT EN PVC **VIAFLEX**
BAXTER AND VIAFLEX TRADEMARKS OF BAXTER INTERNATIONAL, INC.
BAXTER ET VIAFLEX SONT DES MARQUES DE COMMERCE DE BAXTER INTERNATIONAL, INC.

Baxter Logo
Baxter Corporation
Mississauga ON L5N 0C2

No Latex Label
07-25-77-318

JB-03-04
12 – 1000 mL units
Store at 15°C to 25°C

Sterile Water for Injection USP

Lot: WWWWWWWWW EXP: 2099 99

2DBarcode
(01)20809080000528

Pharmacy Bulk

STERILE WATER

water injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9782
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	100 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0338-9782-12	12 in 1 CARTON	10/18/2024	
1	NDC:0338-9782-01	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 shortage		10/18/2024	

Labeler - Baxter Healthcare Company (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Corporation		205087968	ANALYSIS(0338-9782) , LABEL(0338-9782) , MANUFACTURE(0338-9782) , STERILIZE(0338-9782) , PACK(0338-9782)