



Important Prescribing Information

October 23, 2024

Subject: Temporary importation of 50% and 70% Glucose Injection from the United Kingdom 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 50% Glucose Injection 3,000 mL and 70% Glucose Injection 500 mL from Baxter's manufacturing facility in Thetford, United Kingdom. FDA has not approved these products manufactured by Baxter's Thetford 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
50% Glucose Injection	3,000 mL	FKB0257B	4	0338-9787-01
70% Glucose Injection	500 mL	FKB0273B	20	0338-9785-01

It is important to note the following:

- **The imported Glucose Injection products are NOT directly interchangeable with FDA-approved Dextrose Injection USP.** Protocols, order entry, and compounding systems will need to be adjusted.
- Dextrose USP is a hydrated form of glucose. The imported Glucose Injection product is labeled based on the anhydrous form of glucose. **Therefore, the imported product, 70% Glucose Injection, is NOT equivalent to the FDA-approved product, 70% Dextrose Injection USP, on an energy content per mL basis.**
The caloric content of 70% Glucose Injection is 2,800 kcal/L whereas the caloric content of 70% Dextrose Injection, USP is 2,380 kcal/L.

- 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 the 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.
- **The imported products do not contain barcodes on the unit label.** 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 and concentration are being used in all systems and processes and administered to individual patients.
- 70% Dextrose for Injection USP is available only by prescription in the U.S. However, the imported products 50% Glucose Injection and 70% Glucose Injection do not have the statement "Rx only" on the labeling.

Additional key differences in the labeling between the FDA-approved product and the imported products are stated in the product comparison table at the end of this letter as follows:

Table 1 Key differences between FDA-approved 70% Dextrose Injection USP, imported 70% Glucose Injection and imported 50% Injection

Table 2 Label images of FDA-approved 70% Dextrose Injection USP, imported 70% Glucose Injection and imported 50% Glucose Injection

Please refer to the UK prescribing information as follows for any pharmaceutical calculations of a final product that uses concentrated Glucose Injection:

- 70% Glucose Injection (click [here](#)) – Local product name in the UK: Glucose 70% w/v Concentrate for solution for infusion
- 50% Glucose Injection (click [here](#)) – Local product name in the UK: Glucose 50% w/v Concentrate for solution for infusion

Please refer to the FDA-approved prescribing information for 70% Dextrose Injection USP:

- 70% Dextrose Injection USP (click [here](#))

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/>).

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,

*Electronically signed by: Lee
Ann Schuette
Reason: I approve this
document
Date: Oct 23, 2024 08:49 CDT*
Lee Ann Schuette

Lee Ann Schuette

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

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Table 1 Key differences between FDA-approved 70% Dextrose Injection USP, imported 70% Glucose Injection and imported 50% Injection




	US FDA-approved product	Imported product from the UK	Imported product from the UK
Product name	70% Dextrose Injection USP	Glucose 70% w/v Concentrate for solution for infusion	Glucose 50% w/v Concentrate for solution for infusion
Label Volume	2,000 mL	500 mL	3,000 mL
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.	Glucose 70% w/v is for use in admixtures to provide temporary relief from the symptoms of increased intracranial pressure and hypoglycaemic coma and is also indicated for the supplementation of energy in parenteral nutrition.	Glucose 50% w/v is for use in admixtures to provide temporary relief from the symptoms of increased intracranial pressure and hypoglycaemic coma and is also indicated for the supplementation of energy in parenteral nutrition.
Active ingredients	Each 1,000 mL contains 700 g Dextrose Hydrus USP	Each 1,000 mL contains 700 g Anhydrous Glucose	Each 1,000 mL contains 500 g Anhydrous Glucose
Caloric content	Each 1,000 mL contains 2,380 kcal (calculated)	Each 1,000 mL contains 2,800 kcal (calculated)	Each 1,000 mL contains 2,000 kcal (calculated)
Additional information	pH is 4.0 (3.2 to 6.5) Osmolarity 3,530 mOsmol/L (calc)	pH is 3.2 – 5.5 Osmolarity 3,885 mOsmol/L	pH is 3.2 – 5.5 Osmolarity 2,775 mOsmol/L
Storage conditions	Store at room temperature 25°C/77°F. Protect from freezing.	Do not store above 25°C/77°F	Do not store above 25°C/77°F
Container type	VIAFLEX (PVC)	VIAFLEX (PVC)	VIAFLEX (PVC)
Administration port closures	Pull off port protector (blue color) 	Twist-off port protector (blue color) 	Twist-off port protector (blue color) 

Table 2 Label images of FDA-approved 70% Dextrose Injection USP, imported 70% Glucose Injection and imported 50% Glucose Injection

US FDA-approved product	Imported product from the UK	Imported product from the UK
70% Dextrose Injection USP	Glucose 70% w/v Concentrate for solution for infusion	Glucose 50% w/v Concentrate for solution for infusion
Label Color: Blue (fully) . Barcode not shown.	Label Color: Black	Label Color: Black
<p>LOT EXP</p> <p>280296 2000 mL NDC 0338-0719-06 DIN 02014874</p> <p>DEXTROSE 1800 Injection 1600 USP 1400</p> <p>70% 1200</p> <p>Pharmacy Bulk Package Not For Direct Infusion Must Be Diluted 1000</p> <p>Rx Only 800</p> <p>EACH 100 mL CONTAINS 70 g DEXTROSE HYDROUS USP IN WATER FOR INJECTION USP PH 4.0 (0.2 to 6.5) SPECIFIC GRAVITY 1.24 (CALC) HYPERTONIC OSMOLARITY 3539 mOsm/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 STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT PROTECT FROM FREEZING</p> <p>VIAFLEX CONTAINER PL 146 PLASTIC</p> <p>Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA DISTRIBUTED IN CANADA BY MADE IN USA BAXTER CORPORATION MISSISSAUGA ON L5N 9C2</p> <p>BAXTER PL 146 AND VIAFLEX ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>70% 200</p>	<p>Code B0273 500 ml</p> <p>Baxter</p> <p>Glucose 70% w/v Concentrate for solution for infusion</p> <p>1 - VIAFLEX container Hypertonic -1 Free from bacterial endotoxins</p> <p>Formula per 1000 ml - Anhydrous Glucose 700 g 70% - Water for Injections -2 HCl for pH adjustment -2 Megajoules (approx) 11.8 (2800 kcal) -</p> <p>Dilute before use – bulk source container Not for direct intravenous infusion</p> <p>3 - For use under medical supervision -3 For intravenous use following dilution under aseptic conditions Check compatibility with other admixture components before use Keep out of the sight and reach of children Do not store above 25°C Do not use unless solution is clear and container is undamaged</p> <p>4 - Single use only Do not store partially used containers -4 Discard any unused portion, waste materials and all associated devices Do not administer simultaneously with blood or, before or after, using the same transfusion equipment Discontinue infusion if adverse reaction occurs</p> <p>POM Baxter Healthcare Ltd PL 00116/0272 Caxton Way Thetford TH-35-01-931 ① Norfolk IP24 3SE UK Lot Expiry</p>	<p>Code B0257 3000 ml</p> <p>Baxter</p> <p>Glucose 50% w/v Concentrate for solution for infusion</p> <p>VIAFLEX container Hypertonic - Free from bacterial endotoxins</p> <p>Formula per 1000 ml - Anhydrous Glucose 500 g 50% - Water for Injections - HCl for pH adjustment - Megajoules (approx) 8.4 (2000 kcal) -</p> <p>Dilute before use – bulk source container Not for direct intravenous infusion</p> <p>For use under medical supervision For intravenous use following dilution under aseptic conditions Check compatibility with other admixture components before use Keep out of the sight and reach of children Do not store above 25°C Do not use unless solution is clear and container is undamaged Single use only Do not store partially used containers Discard any unused portion, waste materials and all associated devices Do not administer simultaneously with blood or, before or after, using the same transfusion equipment Discontinue infusion if adverse reaction occurs</p> <p>POM Baxter Healthcare Ltd PL 00116/0271 Caxton Way Thetford TH-35-01-934 ① Norfolk IP24 3SE UK LOT EXP</p>