Important Prescribing Information

December 18, 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:

- Dextrose injection products contain the hydrated form of glucose. The Glucose injection products contain the anhydrous form of glucose. While both Dextrose and Glucose injection products are manufactured from chemically identical glucose ingredients, the difference between the hydrous and anhydrous forms results in Glucose injection products NOT being equivalent in caloric content, osmolality, and specific gravity to Dextrose injection products (see table below).

	Dextrose 50%	Glucose 50%
Caloric content (kcal/L)	1,710	2,000
Osmolarity (mOsm/L)	2,520	2,775
Specific Gravity	1.170	1.185

- Baxter has worked proactively to prepare the Training Materials For Baxter Medical Information page (Baxter Resources for Products Authorized for Temporary Importation) to help support customers:
    - Webinars:
        - Dextrose, USP vs Glucose – What are the differences?
        - How to operationalize Glucose for Compounding?
    - Step by Step guide to adding Glucose 50% into ExactaMix and Abacus

- The Glucose 50% product is the equivalent of 55% Dextrose USP, and the Glucose 70% product is the equivalent of 77% Dextrose USP.

- Protocols, order entry, and compounding systems will need to be adjusted.

- 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.

- 50% Dextrose for Injection USP and 70% Dextrose for Injection USP are 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% Glucose 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 (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/).

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 15:40 CST

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

Table 1 Key differences between 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
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 Hydrous	Each 1,000 mL contains 700 g **Anhydrous** Glucose equivalent to **770 g** Dextrose Hydrous	Each 1,000 mL contains 500 g **Anhydrous** Glucose equivalent to **550 g** Dextrose Hydrous
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 mOsm/L** (calc)	pH is 3.2 – 5.5 Osmolarity **3,885 mOsm/L**	pH is 3.2 – 5.5 Osmolarity **2,775 mOsm/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