Baxter

IMPORTANT PRESCRIBING INFORMATION

DATE: November 22, 2024

Subject: Temporary importation of DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose (2000 mL) from Guangzhou, China for use in Automated Peritoneal Dialysis to address drug shortages

Dear Healthcare Professional,

Due to the current critical shortage of DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution in the United States (US) market, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose (2000 mL) from Baxter's manufacturing facility in Guangzhou, China. FDA has not approved this product manufactured by Baxter's Guangzhou, China facility.

You may be provided with additional letters for other DIANEAL imported peritoneal dialysis solutions you receive. Please read each letter in its entirety because each letter may contain different, product-specific information.

Baxter has initiated temporary importation of DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose (2000 mL) for use in Ambulatory Peritoneal Dialysis (APD) therapy as described in the table below. This product is manufactured by Baxter's manufacturing facility in Guangzhou, China and is marketed in Hong Kong. At this time, importation or distribution of DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose (2000 mL) in the United States by any entity other than Baxter or its authorized distributor(s) is considered a violation of the Federal Food, Drug, and Cosmetic Act and is subject to enforcement by the FDA.

Effective immediately, and during this temporary period, Baxter will offer the following imported product from Baxter's facility in Guangzhou, China:

China Imported Product Name and Description	APD Solution Volume	Product Code	Bags per Carton	NDC Code
DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose	2000 mL	6AB5166E	6 bags	NDC 0941-0727-01 (bag) NDC 0941-0727-06 (carton)

It is important to note the following:

- DIANEAL PD-2 with 1.5% Dextrose imported from China will only be available in 2000 mL volume for APD, so there will need to be adaptation to the PD prescription for some patients.
- There are no other clinically relevant differences in the DIANEAL drug composition between the U.S.-manufactured and China-manufactured product (see Table 1, below). As such, clinical practice for usage, administration, and dosage for the China imported product is the same as with DIANEAL PD-2 manufactured in the US. Please refer to the FDA-approved Dianeal Peritoneal Dialysis Solution Prescribing Information for reference.
- The Luer-lock connector on the China imported product functions the same as and is fully compatible with peritoneal dialysis sets marketed in the United States. However, the U.S. product has color-coded pull rings covering the luer to identify the dextrose concentration, while the China- imported product has a blue protective tip protector which is the same for all dextrose concentrations. The frangible is green in the imported product but blue in U.S. product. Users of the China imported product should check the product label to ensure that they are using the correct dextrose concentration. See Table 1 for more details of product differences.
- The China imported product may include barcodes on the shipping carton; however, the **barcodes may not register accurately in the U.S. scanning systems**. There are no barcodes on the solution containers of the China imported product. Alternative procedures should be followed to assure that the correct drug product is being used in all systems and processes and administered to individual patients. For example, institutions should consider manually inputting the product into their systems and confirm that barcode systems do not provide incorrect information when the product is scanned.

Before prescribing, healthcare providers should be aware of some key differences in the container packaging and labeling between the China imported products and the FDA-approved products which are stated in the product comparison tables at the end of this letter as follows:

- Table 1: Key differences of DIANEAL Peritoneal Dialysis Solution for APD therapy
- Table 2: Label images of DIANEAL 2000 mL APD product presentation

Reporting Adverse Events

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, please report to:
Baxter - Product Feedback Portal (https://productfeedback.baxter.com/).

Please refer to the FDA approved full prescribing information for Dianeal Peritoneal Dialysis Solution at DailyMed (nih.gov)

If you have any questions about the information contained in this letter or the use of imported DIANEAL PD-2 with 1.5% Dextrose (2000 mL), please contact Baxter's Medical Information Service at 1-888-736-2543.

To place an order, please contact Baxter's Center for Home Care Services by calling 1-800-284-4060.

Sincerely,

Geovana Basso

Electronically signed by:
Geovana Basso
Reason: ok.
Date: Nov 22, 2024 13:34 CST

Geovana Basso, M.D.
Director of Americas Medical Affairs
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

Attachments:
Product Comparison Tables 1 and 2

Table 1. Key differences of DIANEAL Peritoneal Dialysis Solutions for APD therapy

	Imported Product (Guangzhou, China) DIANEAL PD-2 1.5% Dextrose	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD-2
Product name	DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose	DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose	DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose
Labeled Fill Volume	2000 mL	2000 mL and 3000 mL solution fill volumes available	1000, 2000 mL and 3000 mL solution fill volumes available
Container Type	Ambu-Flex (PVC) container with luer-lock and blue tip connector cap	AMBU-FLEX II (PVC) container with luer-lock connector and colored pull ring caps	AMBU-FLEX II (PVC) container with luer-lock connector and colored pull ring caps
Bags per Carton	6 bags	2000 mL: 6 bags 3000 mL: 4 bags	1000 mL: 12 bags 2000 mL: 6 bags 3000 mL: 4 bags
Indications	Peritoneal dialysis is indicated for patients in acute or chronic renal failure when nondialytic medical therapy is judged to be inadequate (Vaamonde and Perez 1977). It may also be indicated in the treatment of certain fluid and electrolyte disturbances, and for patients intoxicated with certain poisons and drugs (Knepshield et al. 1977). However, for many substances other methods of detoxification have been reported to be more effective than peritoneal dialysis (Vaamonde and Perez; Chang 1977)	DIANEAL peritoneal dialysis solutions are indicated for patients in acute or chronic renal failure.	DIANEAL peritoneal dialysis solutions are indicated for patients in acute or chronic renal failure.
Active Ingredient – Dextrose (Glucose)	Dextrose Hydrous, USP 1.5g / 100mL	**1.5% Dextrose**: Dextrose Hydrous, USP 1.5g / 100mL	**1.5% Dextrose**: Dextrose Hydrous, USP 1.5g / 100mL
Active Ingredients - Electrolytes	Sodium Chloride, USP 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 25.7 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL	Sodium Chloride, USP 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 18.3 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL	Sodium Chloride, USP 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 25.7 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL
Electrolyte Content per Liter	Sodium 132 mEq/L Calcium 3.5 mEq/L Magnesium 0.5 mEq/L Chloride 96 mEq/L Lactate 40 mEq/L	Sodium 132 mEq/L Calcium 2.5 mEq/L Magnesium 0.5 mEq/L Chloride 95 mEq/L Lactate 40 mEq/L	Sodium 132 mEq/L Calcium 3.5 mEq/L Magnesium 0.5 mEq/L Chloride 96 mEq/L Lactate 40 mEq/L
pH	5.2 (4.5 to 6.5)	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
Additional Information	**1.5% Dextrose**: Osmolarity 346 mOsmol/L (Calc)	**1.5% Dextrose**: Osmolarity 344 mOsmol/L (Calc)	**1.5% Dextrose**: Osmolarity 346 mOsmol/L (Calc)

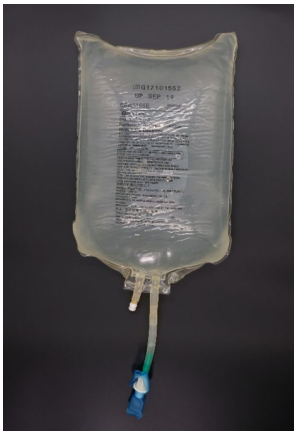
	Imported Product (Guangzhou, China) DIANEAL PD-2 1.5% Dextrose	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD-2
Storage Conditions	Store at room temperature (25°C/77°F): Brief exposure up to 40°C (104°F) does not adversely affect the product.	Store at room temperature (25°C/77°F) Brief exposure up to 40°C does not adversely affect the product	Store at room temperature (25°C/77°F) Brief exposure up to 40°C does not adversely affect the product
Expiration Dating	24 months	24 months	1000 mL: 18 months 2000 mL: 24 months 3000 mL: 24 months
Container Closure System			
Container Closure			
Container Closure Differences	• One green frangible at luer connector • Blue protective tip protector	• One blue frangible at luer connector • Pull ring cap color-coded to solution dextrose concentration: ▪ Yellow = 1.5% dextrose	• One blue frangible at luer connector • Pull ring cap color-coded to solution dextrose concentration: ▪ Yellow = 1.5% dextrose

Table 2. Label images of DIANEAL 2000 mL APD product presentations

Comparative container labels are presented below for DIANEAL Peritoneal Dialysis Solution with 1.5% Dextrose in the 2000 mL fill volume. Labels for other US approved solution fill volumes differ only by product code / NDC / Fill Volume / Barcode. There are no differences in composition or other safety-related information.

Imported Product (Guangzhou, China) 2000mL DIANEAL PD Solution	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2