

## IMPORTANT PRESCRIBING INFORMATION

DATE: October 23, 2024

**Subject: Temporary importation of DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose from Singapore 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 with 4.25% Dextrose 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 Low Calcium (2.5 mEq/L) Peritoneal Dialysis solution with 4.25% Dextrose from Baxter's manufacturing facility in Woodlands, Singapore. FDA has not approved this product manufactured by Baxter's Woodlands, Singapore 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 Low Calcium (2.5 mEq/L) Peritoneal Dialysis solution with 4.25% Dextrose for use in Automated Peritoneal Dialysis (APD) therapy as described in the table below. This product is manufactured by Baxter's manufacturing facility in Woodlands, Singapore and is marketed in Thailand. At this time, importation or distribution of this DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis solution with 4.25% Dextrose 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 products from Baxter's facility in Woodlands, Singapore:

Product Name and Description	APD Container Volume	Product Code	Bags per Carton	NDC Code
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	5000 mL	FNB5203GN	2 bags	NDC (Bag): 0941-0705-01 NDC (Carton): 0941-0705-02

**It is important to note the following:**

- **DIANEAL Low Calcium with 4.25% Dextrose Solution for Peritoneal Dialysis contains 1.25 mmol/L (2.5mEq/L) of calcium compared to DIANEAL PD-2 Peritoneal Dialysis Solution with Dextrose which contains 1.75 mmol/L (3.5 mEq/L) of calcium.** Patients receiving Singapore-imported DIANEAL solution should have their serum calcium levels monitored for the development of hypocalcemia.
- There are no other clinically relevant differences in the drug composition between the US-manufactured and Singapore-manufactured DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25%

Dextrose (see Table 1, below). As such, clinical practice for usage, administration, and dosage is the same as with DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution manufactured in US. Please refer to the FDA-approved Dianeal Peritoneal Dialysis Solution with Dextrose Full Prescribing Information for reference

- DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose imported from Singapore will only be available in 5000 mL volume for APD, so there will be a need to adapt the PD prescription for some patients.
- The Luer-lock connector on the Singapore imported product functions the same as and is fully compatible with peritoneal dialysis sets marketed in the United States. However, the US product has color-coded pull rings covering the luer to identify the dextrose concentration, while the Singapore imported product has a blue protective tip protector which is the same for all dextrose concentrations. The frangible is green in the Singapore imported product, but blue in US product. Users of the 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.
- DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis solution with 4.25% Dextrose imported from Singapore, includes barcodes on the shipping carton; however, the **barcodes may not register accurately in the US scanning systems**. There are no barcodes on the solution containers of the imported product. Alternative procedures should be followed to assure that the correct drug product is being used 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.
- DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose is available only by prescription in the U.S. However, the imported products do not have the statement “Rx only” on the labeling.

Before prescribing, healthcare providers should be aware of some key differences in the container packaging and labeling between the Singapore imported product and FDA approved product 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: Comparison of 5000 mL DIANEAL PD Solution Container Labeling

## Reporting Adverse Events

To report adverse events associated with the imported product, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of the imported product 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](http://www.fda.gov/medwatch/report.htm)
- **Regular mail or Fax**: Download form [www.fda.gov/MedWatch/getforms.htm](http://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 \(https://productfeedback.baxter.com/\)](https://productfeedback.baxter.com/).

**Please refer to the FDA approved full prescribing information for DIANEAL Peritoneal Dialysis Solution at [DailyMed \(nih.gov\)](https://www.accessdata.fda.gov/drugsatfda_docs/nda/020122Orig1s010/DAI_020122Orig1s010.pdf).**

If you have any questions about the information contained in this letter or the use of imported DIANEAL Solution for Peritoneal Dialysis, 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: Oct 23, 2024 08:35  
CDT

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







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**Attachments:**

Product Comparison Tables 1 and 2


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

	<b>Imported Product from Singapore DIANEAL Low Calcium</b>	<b>US FDA Approved DIANEAL Low Calcium</b>	<b>US FDA Approved DIANEAL PD2</b>
<b>Product name</b>	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose
<b>Labeled Fill Volume</b>	5000 mL	5000 mL and 6000 mL fill volumes available	5000 mL and 6000 mL fill volumes available
<b>Container Type</b>	AMBU-FLEX III PVC container with luer-lock connector	AMBU-FLEX II PVC container with luer-lock connector	AMBU-FLEX II PVC container with luer-lock connector
<b>Bags per carton</b>	2 bags	2 bags	2 bags
<b>Indications</b>	DIANEAL Low Calcium peritoneal dialysis solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis	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.
<b>Active Ingredient – Dextrose (Glucose)</b>	<b>4.25% Dextrose:</b> Dextrose Hydrous, USP 4.25 g/100 mL	<b>4.25% Dextrose:</b> Dextrose Hydrous, USP 4.25 g / 100 mL	<b>4.25% Dextrose:</b> Dextrose Hydrous, USP 4.25 g / 100 mL
<b>Active Ingredients - Electrolytes</b>	Sodium Chloride, USP 538 mg / 100 mL 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 / 100 mL 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
<b>Electrolyte Content per Liter</b>	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 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
<b>pH</b>	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
<b>Additional Information</b>	<b>4.25% Dextrose:</b> Osmolarity 483 mOsmol/L (Calc)	<b>4.25% Dextrose:</b> Osmolarity 483 mOsmol/L (Calc)	<b>4.25% Dextrose</b> Osmolarity 485 mOsmol/L (Calc)
<b>Label Color and Languages:</b>	Red font  Multi-lingual including English	Black font  English	Black font  English

	Imported Product from Singapore DIANEAL Low Calcium	US FDA Approved DIANEAL Low Calcium	US FDA Approved DIANEAL PD2
<b>Storage Conditions</b>	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
<b>Expiration Dating</b>	24 months	24 months	24 months
<b>Container Closure System</b>			
<b>Container Closure</b>			
<b>Container Closure Differences</b>	<ul style="list-style-type: none"> <li>• One green frangible at luer connector</li> <li>• Blue protective tip connector</li> </ul>	<ul style="list-style-type: none"> <li>• One blue frangible at luer connector</li> <li>• Pull ring cap color-coded to solution dextrose concentration: <ul style="list-style-type: none"> <li>▪ Red = 4.25% dextrose</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• One blue frangible at luer connector</li> <li>• Pull ring cap color-coded to solution dextrose concentration: <ul style="list-style-type: none"> <li>▪ Red = 4.25% dextrose</li> </ul> </li> </ul>

**Table 2. Comparison of 5000 mL DIANEAL PD Solution with 4.25% Dextrose Container Labels**

Comparative container labels are presented below for the 5000 mL fill volume. Labels for the US approved 6000 mL solution fill volume differ only by product code / NDC / Fill Volume / Barcode. There are no differences in composition or other safety-related information.

Imported Product from Singapore 5000 mL DIANEAL Low Calcium (2.5 mEq/L)	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution
<p><b>FNB5203</b> <span style="float: right;">ยาเส้นน้ำยา 5000 mL</span></p> <p><b>Baxter</b></p> <p><b>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose</b></p> <p>EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5) mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40 OSMOLARITY 483 mOsmol/L (CALC)</p> <p>STERILE NONPYROGENIC STORE BELOW 30°C SEE INSERT</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p><b>WARNING</b> EXTENSIVE USE OF THIS SOLUTION DURING ONE PERITONEAL DIALYSIS PROCEDURE CAN RESULT IN SIGNIFICANT REMOVAL OF WATER FROM THE PATIENT FOR INTRAPERITONEAL ADMINISTRATION ONLY</p> <p><b>CAUTIONS</b> SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION KEEP OUT OF REACH OF CHILDREN</p> <p><b>BAXTER HEALTHCARE SA, SINGAPORE BRANCH</b> AMBU-FLEX CONTAINER PL-146 2 WOODLANDS INDUSTRIAL PARK D STREET 2 SINGAPORE 737778 (AN AFFILIATE OF BAXTER HEALTHCARE CORPORATION USA) SINGAPORE SING625P THAILAND 2C65/45 PHILIPPINES DR-XY20804 BRUNEI BRU12120968NP HONG KONG HK-35010 VIETNAM VN-21179-18 MALAYSIA MAL09062144AZ BAXTER HEALTHCARE (MALAYSIA) SDN. BHD. B-21-3A, THE ASCENT, PARADIGM, 1, JLN SS7/26A, 47301 PJ, SELANGOR DIRECTIONS TO BE USED AS DIRECTED BY PHYSICIAN 用法: 請依照醫生指示使用 JAUHI DARIPADA KANAK-KANAK ยาอันตราย Controlled medicine/Ubat terkawal</p> <p><b>"百特"含4.25%葡萄糖低鈣(2.5mEq/L) 腹膜透析液</b></p> <p>本藥限由醫師使用 衛署藥輸字第 022298 號 百特醫療產品股份有限公司 台北市敦化南路2段95號28樓</p> <p><b>다이아닐 저칼슘 피디액 4.25%</b> 전문의약품 / 분류번호 349</p> <p>원료약품의 분량: 100 ml 중 포도당알수화물(USP) 4.25g 염화나트륨(USP) 538mg 젖산나트륨(USP) 448mg 염화칼슘(USP) 18.3mg 염화마그네슘(USP) 5.08mg (총나트륨으로서 132mEq/L 총칼슘으로서 2.5mEq/L 총마그네슘으로서 0.5mEq/L) 총염화물로서 95mEq/L 총젖산으로서 40mEq/L) 효능 및 효과: 급 만성신부전 환자의 복막투석액 성상 / 용법 및 용량: 점부로서 참조 (주의-부작용) 포장단위: 5000 ml/백 저장방법: 밀봉용기 냉암소 보관 제조번호 / 사용기한: 별도 표시</p> <p>제조처: Baxter Healthcare SA, Singapore Branch (싱가포르) 수입자: (주)박스텍 서울시 중구 대동 10 한국관광공사빌딩 5층 TEL 0262-7100 DIANEAL, AMBU-FLEX &amp; PL-146 are trademarks of Baxter International Inc.</p> <p></p>	<p><b>L5B5203</b> <span style="float: right;">5000 mL (APPROX 150 mL EXCESS)</span></p> <p><b>Baxter</b></p> <p><b>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose</b></p> <p>EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)</p> <p>mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 483 mOsmol/L (CALC)</p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY PHYSICIAN</p> <p><b>FOR INTRAPERITONEAL ADMINISTRATION ONLY</b></p> <p><b>WARNING</b> EXTENSIVE USE OF THIS SOLUTION DURING ONE PERITONEAL DIALYSIS PROCEDURE CAN RESULT IN SIGNIFICANT REMOVAL OF WATER FROM THE PATIENT</p> <p><b>CAUTIONS</b> SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE</p> <p>AVOID EXCESSIVE HEAT SEE INSERT</p> <p><b>Ambu-Flex II</b> CONTAINER PL 146 PLASTIC</p> <p>BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p><b>BAXTER HEALTHCARE CORPORATION</b> DEERFIELD IL 60015 USA MADE IN USA</p>	<p><b>L5B5195</b> <span style="float: right;">5000 mL (APPROX 150 mL EXCESS)</span></p> <p><b>Baxter</b></p> <p><b>Dianeal PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose</b></p> <p>EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)</p> <p>mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 485 mOsmol/L (CALC)</p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY PHYSICIAN</p> <p><b>FOR INTRAPERITONEAL ADMINISTRATION ONLY</b></p> <p><b>WARNING</b> EXTENSIVE USE OF THIS SOLUTION DURING ONE PERITONEAL DIALYSIS PROCEDURE CAN RESULT IN SIGNIFICANT REMOVAL OF WATER FROM THE PATIENT</p> <p><b>CAUTIONS</b> SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE</p> <p>AVOID EXCESSIVE HEAT SEE INSERT</p> <p><b>Ambu-Flex II</b> CONTAINER PL 146 PLASTIC</p> <p>BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p><b>BAXTER HEALTHCARE CORPORATION</b> DEERFIELD IL 60015 USA MADE IN USA</p>

Low Calcium 4.25% Dextrose

PD-2 4.25% Dextrose