

IMPORTANT PRESCRIBING INFORMATION

DATE: November 4, 2024

Subject: Temporary importation of DIANEAL PD4 Solution for Peritoneal Dialysis from Ireland 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 (U.S.) market, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import DIANEAL PD4 Solution for Peritoneal Dialysis from Baxter's manufacturing facility in Castlebar, Ireland. FDA has not approved this product manufactured by Baxter's Castlebar, Ireland 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 PD4 Solution for Peritoneal Dialysis for use in Automated Peritoneal Dialysis (APD) therapy as described in the table below. This product is manufactured by Baxter's manufacturing facility in Castlebar, Ireland and is marketed in the United Kingdom and other countries within the European Union (EU). At this time, importation or distribution of DIANEAL peritoneal dialysis solution 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 Castlebar, Ireland:

Product Name and Description	APD Container Volume	Product Code	Bags per Carton	NDC Code
DIANEAL PD4 Glucose 1.36% w/v / 13.6 mg/mL Solution for Peritoneal Dialysis	5000 mL	FPB5215R	2 bags	NDC 0941-0727-01 (bag) NDC 0941-0727-02 (carton)
DIANEAL PD4 Glucose 2.27% w/v / 22.7 mg/mL Solution for Peritoneal Dialysis	5000 mL	FPB5225R	2 bags	NDC 0941-0729-01 (bag) NDC 0941-0729-02 (carton)
DIANEAL PD4 Glucose 3.86% w/v / 38.6 mg/mL Solution for Peritoneal Dialysis	5000 mL	FPB5235R	2 bags	NDC 0941-0731-01 (bag) NDC 0941-0731-02 (carton)

It is important to note the following:

- DIANEAL PD4 Dextrose Solution for Peritoneal Dialysis manufactured in the EU is labeled to reflect glucose anhydrous content of 1.36%, 2.27% and 3.86%. DIANEAL PD-2 and DIANEAL Low Ca (2.5 mEq/L) peritoneal dialysis solution with Dextrose are labeled to reflect dextrose hydrous of 1.5%, 2.5% and 4.25%.

These solutions have identical dextrose concentrations for clinical use and boxes are color coded in the same way – yellow (1.36%/1.5%), green (2.27%/2.5%) and red/orange (3.86%/4.25%).

- **Dianeal PD4 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 Ireland-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 European-manufactured DIANEAL PD4 and U.S.-manufactured DIANEAL Low Calcium (2.5mEq/) Peritoneal Dialysis Solution (see Table 1, below). As such, clinical practice for usage, administration, and dosage for Dianeal Dextrose PD-4 APD solution (manufactured in EU) products is the same as with Dianeal Dextrose PD-2 and Dianeal Dextrose Low Ca (2.5 MEQ/L) (manufactured in U.S). Please refer to the FDA-approved Dianeal Peritoneal Dialysis Solution Prescribing Information for reference.
- Dianeal PD4 Solution for Peritoneal Dialysis imported from the EU 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 Ireland 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 Ireland imported product has a blue protective tip protector which is the same for all dextrose concentrations. The frangible is green in the Ireland imported product but blue in U.S. 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 PD4 Solution for Peritoneal Dialysis imported carton labeling includes barcodes; however, **the barcodes may not register accurately in the U.S. scanning systems.** There are no barcodes on the solution containers of the Ireland imported product. Institutions should manually input the product into their systems to confirm 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 is being used in all systems and processes and administered to individual patients.

Before prescribing, healthcare providers should be aware of some key differences in the container packaging and labeling between the DIANEAL PD4 Solution for Peritoneal Dialysis products manufactured in EU and DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution manufactured in U.S.

Key differences are highlighted in the following Product Comparison Tables:

- 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

- **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/) (<https://productfeedback.baxter.com/>).

Please refer to the FDA approved prescribing information for DIANEAL Peritoneal Dialysis Solution at [DailyMed \(nih.gov\)](https://www.accessdata.fda.gov/drugsatfda_docs/nda/021221Orig1s001.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,


Electronically signed by:
Geovana Basso
Reason: Ok.
Date: Nov 4, 2024 16:39
CST

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

	Imported Product from Ireland – DIANEAL PD4	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD2
Product name	<p>DIANEAL PD4 Glucose 1.36%* w/v / 13.6 mg/mL * 1.36% glucose anhydrous is equivalent to 1.5% dextrose hydrous</p> <p>DIANEAL PD4 Glucose 2.27%* w/v / 22.7 mg/mL * 2.27% glucose anhydrous is equivalent to 2.5% dextrose hydrous</p> <p>DIANEAL PD4 Glucose 3.86%* w/v / 38.6 mg/mL* 3.86% glucose anhydrous is equivalent to 4.25% dextrose hydrous</p>	<p>DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose</p>	<p>DIANEAL PD2 Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>DIANEAL PD2 Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>DIANEAL PD2 Peritoneal Dialysis Solution with 4.25% Dextrose</p>
Labeled Fill Volume	5000 mL	5000 mL and 6000 mL fill volumes available	5000 mL and 6000 mL fill volumes available
Container Type	Flexible PVC container with luer-lock connector	AMBU-FLEX II PVC container with luer-lock connector	AMBU-FLEX II PVC container with luer-lock connector
Bags per carton	2 bags	2 bags	2 bags
Indications	<p>Dianeal PD4 is indicated whenever peritoneal dialysis is employed, including:</p> <ol style="list-style-type: none"> 1. Acute and chronic renal failure; 2. Severe water retention; 3. Electrolyte disorders; 4. Drug intoxication, when a more adequate therapeutic alternative is not available. <p>Dianeal PD4 is particularly useful for the control of serum calcium and phosphate levels in renal failure patients receiving calcium or magnesium-containing phosphate binder.</p>	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)	<p>1.36% Glucose: Glucose Anhydrous 13.6 g/L (1.36 g/100 mL)</p> <p>2.27% Glucose: Glucose Anhydrous 22.7 g/L (2.27 g/100 mL)</p> <p>3.86% Glucose: Glucose Anhydrous 38.6 g/L (3.86 g/100 mL)</p>	<p>1.5% Dextrose: Dextrose Hydrous, USP 1.5 g/100 mL</p> <p>2.5% Dextrose: Dextrose Hydrous, USP 2.5 g/100 mL</p> <p>4.25% Dextrose: Dextrose Hydrous, USP 4.25 g/100 mL</p>	<p>1.5% Dextrose: Dextrose Hydrous, USP 1.5 g/100 mL</p> <p>2.5% Dextrose: Dextrose Hydrous, USP 2.5 g/100 mL</p> <p>4.25% Dextrose: Dextrose Hydrous, USP 4.25 g/100 mL</p>

	Imported Product from Ireland – DIANEAL PD4	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD2
Active Ingredients - Electrolytes	Sodium Chloride 5.38 g /L (538 mg/100 mL) Sodium Lactate 4.48 g /L (448 mg/100 mL) Calcium Chloride 0.184 g /L (18.4 mg/100 mL) Magnesium Chloride 0.051 g /L (5.1 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
Electrolyte Content per Liter	Sodium 132 mmol/L (equivalent to 132 mEq/L) Calcium 1.25 mmol/L (equivalent to 2.5 mEq/L) Magnesium 0.25 mmol/L (equivalent to 0.5 mEq/L) Chloride 95 mmol/L (equivalent to 95 mEq/L) Lactate 40 mmol/L (equivalent to 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	5.0 – 6.0	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
Additional Information	1.36% Glucose Anhydrous: Osmolarity 344 mOsmol/L 2.27% Glucose Anhydrous: Osmolarity 395 mOsmol/L (Calc) 3.86% Glucose Anhydrous: Osmolarity 483 mOsmol/L (Calc)	1.5% Dextrose: Osmolarity 344 mOsmol/L (Calc) 2.5% Dextrose: Osmolarity 395 mOsmol/L (Calc) 4.25% Dextrose Osmolarity 483 mOsmol/L (Calc)	1.5% Dextrose: Osmolarity 346 mOsmol/L (Calc) 2.5% Dextrose: Osmolarity 396 mOsmol/L (Calc) 4.25% Dextrose: Osmolarity 485 mOsmol/L (Calc)
Storage Conditions	Do not store above 25°C Do not refrigerate or freeze.	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	24 months









	Imported Product from Ireland – DIANEAL PD4	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD2
Container Closure System			
Container Closure			
Container Closure Differences	<ul style="list-style-type: none"> One green frangible at luer connector Blue protective tip protector 	<ul style="list-style-type: none"> One blue frangible at luer connector Pull ring cap color-coded to solution dextrose concentration: <ul style="list-style-type: none"> Yellow = 1.5% dextrose Green = 2.5% dextrose Red = 4.25% dextrose 	<ul style="list-style-type: none"> One blue frangible at luer connector Pull ring cap color-coded to solution dextrose concentration: <ul style="list-style-type: none"> Yellow = 1.5% dextrose Green = 2.5% dextrose Red = 4.25% dextrose

Table 2. Comparison of 5000 mL DIANEAL PD Solution Container Labels

Comparative container labels are presented below for the 5000 mL fill volume. Labels for the U.S. 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. Note, both Baxter and Vantive-branded labels are presented, which represent all imported lot labeling scenarios during this transition.







Imported Product from Ireland 5000 mL DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																					
<p>Lot: Baxter FPB5215R 5000 mL DIANEAL PD4 Glucose 1,36% w/v / 13,6 mg/ml Solution for Peritoneal Dialysis</p> <table border="1"> <thead> <tr> <th>Formula</th><th>g/l</th><th>Osmolality</th></tr> </thead> <tbody> <tr> <td>Anhydrous Glucose</td><td>C₆H₁₂O₆ 13,6 g</td><td>344 mOsmol/l</td></tr> <tr> <td>Sodium Chloride</td><td>NaCl 5,38 g</td><td>Na⁺ 1,32</td></tr> <tr> <td>Sodium Lactate</td><td>C₃H₅NaO₃ 4,48 g</td><td>Ca⁺⁺ 1,25</td></tr> <tr> <td>Calcium Chloride</td><td>CaCl₂·2H₂O 0,184 g</td><td>Mg⁺⁺ 0,25</td></tr> <tr> <td>Magnesium Chloride</td><td>MgCl₂·6H₂O 0,051 g</td><td>Cl⁻ 95</td></tr> <tr> <td>Water for injections to 1000 ml</td><td>C₂H₅O₂⁻ 40</td><td></td></tr> </tbody> </table> <p>Free from Bacterial Endotoxins For Intraperitoneal Infusion Not for intravenous infusion Do not use unless the solution is clear and the container undamaged For single use only Once removed from the overpouch use immediately Discard unused solution Do not store above 25°C Do not refrigerate or freeze Keep out of the sight and reach of children</p> <p>UK: Baxter Healthcare Ltd Canon Way, Thetford, Norfolk IP24 3SE, UK POM PA 2299 / 015 / 001 PL 00116 / 0230 IE and MT: Baxter Holding B.V. Kobaalweg 49 3542CE Utrecht Netherlands MA 1277 / 01001 CB-35-04-010</p>	Formula	g/l	Osmolality	Anhydrous Glucose	C ₆ H ₁₂ O ₆ 13,6 g	344 mOsmol/l	Sodium Chloride	NaCl 5,38 g	Na ⁺ 1,32	Sodium Lactate	C ₃ H ₅ NaO ₃ 4,48 g	Ca ⁺⁺ 1,25	Calcium Chloride	CaCl ₂ ·2H ₂ O 0,184 g	Mg ⁺⁺ 0,25	Magnesium Chloride	MgCl ₂ ·6H ₂ O 0,051 g	Cl ⁻ 95	Water for injections to 1000 ml	C ₂ H ₅ O ₂ ⁻ 40		<p>L5B4826  5000 mL NDC 0941-0409-07 (APPROX 150 mL EXCESS)</p> <p>Baxter</p> <p>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>EACH 100 mL CONTAINS 1.5 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 LACTATE - 40 CHLORIDE - 95 OSMOLALITY - 344 mOsmol/L (CALC) 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 FOR INTRAPERITONEAL ADMINISTRATION ONLY</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION Rx ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> <p>Ambu-Flex II CONTAINER PL 146 PLASTIC BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>	<p>L5B5193  5000 mL NDC 0941-0411-07 (APPROX 150 mL EXCESS)</p> <p>Baxter</p> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>EACH 100 mL CONTAINS 1.5 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 OSMOLALITY - 346 mOsmol/L (CALC) 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 FOR INTRAPERITONEAL ADMINISTRATION ONLY CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION Rx ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> <p>Ambu-Flex II CONTAINER PL 146 PLASTIC BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>
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Baxter Version

Low Calcium 1.5% Dextrose

PD-2 1.5% Dextrose

Imported Product from Ireland 5000 mL DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																								
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Baxter Version

Low Calcium 2.5% Dextrose

PD-2 2.5% Dextrose

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Lot

Cd Exp

Vantive

FPB5235R

5000 ml

DIANEAL PD4

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Solution for Peritoneal Dialysis

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Vantive Limited

Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

POM

PL 58711/0004

CB-35-05-237

US FDA Approved Product

DIANEAL Low Calcium PD Solution

US FDA Approved Product

DIANEAL PD-2 PD Solution

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