

## IMPORTANT PRESCRIBING INFORMATION

DATE: December 17, 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 0941-0737-01 (bag)<br>NDC 0941-0737-06 (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](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/ndr/2014/014121Orig1s001.pdf)

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: .  
Date: Dec 18, 2024 07:13 CST

Geovana Basso, M.D.  
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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 (Guangzhou, China)<br>DIANEAL PD-2<br>1.5% Dextrose  | U.S. FDA Approved Product<br>DIANEAL Low Calcium  | U.S. FDA Approved Product<br>DIANEAL PD-2   |
|---|---|---|---|
| <b>Product name</b>                           | 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  |
| <b>Labeled Fill Volume</b>                    | 2000 mL   | 2000 mL and 3000 mL solution fill volumes available   | 1000, 2000 mL and 3000 mL solution fill volumes available   |
| <b>Container Type</b>                         | 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  |
| <b>Bags per Carton</b>                        | 6 bags  | 2000 mL: 6 bags<br>3000 mL: 4 bags  | 1000 mL: 12 bags<br>2000 mL: 6 bags<br>3000 mL: 4 bags  |
| <b>Indications</b>                            | 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 (Knepshild 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.   |
| <b>Active Ingredient – Dextrose (Glucose)</b> | Dextrose Hydrous, USP<br>1.5g / 100mL   | <b>1.5% Dextrose:</b><br>Dextrose Hydrous, USP<br>1.5g / 100mL  | <b>1.5% Dextrose:</b><br>Dextrose Hydrous, USP<br>1.5g / 100mL  |
| <b>Active Ingredients - Electrolytes</b>      | Sodium Chloride, USP 538 mg / 100mL<br>Sodium Lactate 448 mg / 100 mL<br>Calcium Chloride, USP 25.7 mg / 100 mL<br>Magnesium Chloride, USP 5.08 mg / 100 mL   | Sodium Chloride, USP 538 mg / 100mL<br>Sodium Lactate 448 mg / 100 mL<br>Calcium Chloride, USP 18.3 mg / 100 mL<br>Magnesium Chloride, USP 5.08 mg / 100 mL | Sodium Chloride, USP 538 mg / 100mL<br>Sodium Lactate 448 mg / 100 mL<br>Calcium Chloride, USP 25.7 mg / 100 mL<br>Magnesium Chloride, USP 5.08 mg / 100 mL |
| <b>Electrolyte Content per Liter</b>          | Sodium 132 mEq/L<br>Calcium 3.5 mEq/L<br>Magnesium 0.5 mEq/L<br>Chloride 96 mEq/L<br>Lactate 40 mEq/L   | Sodium 132 mEq/L<br>Calcium 2.5 mEq/L<br>Magnesium 0.5 mEq/L<br>Chloride 95 mEq/L<br>Lactate 40 mEq/L   | Sodium 132 mEq/L<br>Calcium 3.5 mEq/L<br>Magnesium 0.5 mEq/L<br>Chloride 96 mEq/L<br>Lactate 40 mEq/L   |
| <b>pH</b>                                     | 5.2 (4.5 to 6.5)  | 5.2 (4.0 to 6.5)  | 5.2 (4.0 to 6.5)  |
| <b>Additional Information</b>                 | <b>1.5% Dextrose:</b><br>Osmolarity 346 mOsmol/L (Calc)   | <b>1.5% Dextrose:</b><br>Osmolarity 344 mOsmol/L (Calc)   | <b>1.5% Dextrose:</b><br>Osmolarity 346 mOsmol/L (Calc)   |

|                                      | Imported Product (Guangzhou, China)<br>DIANEAL PD-2<br>1.5% Dextrose   | U.S. FDA Approved Product<br>DIANEAL Low Calcium  | U.S. FDA Approved Product<br>DIANEAL PD-2   |
|--------------------------------------|--|---|---|
| <b>Storage Conditions</b>            | Store at room temperature (25°C/77°F):<br>Brief exposure up to 40°C (104°F) does not adversely affect the product.                 | Store at room temperature (25°C/77°F)<br>Brief exposure up to 40°C does not adversely affect the product  | Store at room temperature (25°C/77°F)<br>Brief exposure up to 40°C does not adversely affect the product  |
| <b>Expiration Dating</b>             | 24 months  | 24 months   | 1000 mL: 18 months<br>2000 mL: 24 months<br>3000 mL: 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 protector</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>▪ Yellow = 1.5% 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>▪ Yellow = 1.5% dextrose</li> </ul> </li> </ul> |

**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)<br>2000mL DIANEAL PD Solution  | US FDA Approved Product<br>DIANEAL Low Calcium PD Solution   | US FDA Approved Product<br>DIANEAL PD-2  |
|--|--|--|
| <p><b>6AB5166E</b> <span style="float: right;">2000ml<br/>(APPROX 80ml EXCESS)</span></p> <hr/> <p><b>Baxter</b></p> <p><b>Dianeal® PD-2<br/>Peritoneal Dialysis Solution<br/>With 1.5% Dextrose</b></p> <p>EACH 100ml 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 (4.5 TO 6.5) mEq/L SODIUM 132 CALCIUM 3.5 MAGNESIUM 0.5 CHLORIDE 96 LACTATE 40 OSMOLARITY 346 mOsmol/L(CALC)<br/>STERILE NON PYROGENIC</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 5px auto;">POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</div> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY<br/><b>CAUTIONS</b> SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR<br/>DISCARD UNUSED PORTION<br/>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (UNDER 25°C) UNTIL READY TO USE<br/>AVOID EXCESSIVE HEAT SEE INSERT<br/>請儲存於攝氏25度以下</p> <p><b>Ambu-Flex™ III</b> CONTAINER PL-146® PLASTIC<br/>MANUFACTURED BY<br/>BAXTER HEALTHCARE (GUANGZHOU) CO LTD<br/>GUANGZHOU CHINA<br/>(AN AFFILIATE OF BAXTER WORLD TRADE INC USA)<br/>HK-42544<br/>DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN</p> <p><b>用法 請依照醫生指示使用</b><br/>Prescription Drug 處方藥物<br/>Manufacturer Address:<br/>Jiaoyuan Road, Dongji Industrial District,<br/>GETDD,Guangzhou, P.R. China</p> | <p><b>L5B4825</b> <span style="float: right;">2000 mL<br/>(APPROX 80 mL EXCESS)</span></p> <p><small>NDC 0941-0409-06</small></p> <hr/> <p><b>Baxter</b></p> <p><b>Dianeal<br/>Low Calcium (2.5 mEq/L)<br/>Peritoneal Dialysis Solution<br/>with 1.5% Dextrose</b></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) mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 344 mOsmol/L (CALC)<br/>STERILE NONPYROGENIC</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 5px auto;">POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</div> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY PHYSICIAN<br/><b>FOR INTRAPERITONEAL ADMINISTRATION ONLY</b><br/><b>CAUTIONS</b> SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND<br/>DO NOT USE UNLESS SOLUTION IS CLEAR<br/>DISCARD UNUSED PORTION<br/>Rx ONLY<br/>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE<br/>AVOID EXCESSIVE HEAT SEE INSERT</p> <p><b>Ambu-Flex II</b> CONTAINER PL 146 PLASTIC<br/>BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC<br/><b>BAXTER HEALTHCARE CORPORATION</b><br/>DEERFIELD IL 60015 USA<br/>MADE IN USA</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 5px auto; transform: rotate(-90deg); transform-origin: center;">Low Calcium 1.5% Dextrose</div> | <p><b>L5B5166</b> <span style="float: right;">2000 mL<br/>(APPROX 80 mL EXCESS)</span></p> <p><small>NDC 0941-0411-06</small></p> <hr/> <p><b>Baxter</b></p> <p><b>Dianeal PD-2<br/>Peritoneal Dialysis Solution<br/>with 1.5% Dextrose</b></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) mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 346 mOsmol/L (CALC)<br/>STERILE NONPYROGENIC</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 5px auto;">POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</div> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY PHYSICIAN<br/><b>FOR INTRAPERITONEAL ADMINISTRATION ONLY</b><br/><b>CAUTIONS</b> SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND<br/>DO NOT USE UNLESS SOLUTION IS CLEAR<br/>DISCARD UNUSED PORTION<br/>Rx ONLY<br/>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE<br/>AVOID EXCESSIVE HEAT SEE INSERT</p> <p><b>Ambu-Flex II</b> CONTAINER PL 146 PLASTIC<br/>BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC<br/><b>BAXTER HEALTHCARE CORPORATION</b><br/>DEERFIELD IL 60015 USA<br/>MADE IN USA</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 5px auto; transform: rotate(-90deg); transform-origin: center;">PD-2 1.5% Dextrose</div> |