

## IMPORTANT PRESCRIBING INFORMATION

DATE: October 22, 2024

**Subject: Temporary importation of DIANEAL PD-4 Low Calcium Peritoneal Dialysis Solutions with Dextrose 1.5%, 2.5%, and 4.25% (2000 mL) from Thailand for use in Continuous Ambulatory Peritoneal Dialysis to address drug shortages**

Dear Healthcare Professional,

Due to a potential 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-4 Low Calcium Peritoneal Dialysis Solution (2000 mL) from Baxter's manufacturing facility in Amata, Thailand. FDA has not approved these products manufactured by Baxter's Amata, Thailand 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-4 Low Calcium Peritoneal Dialysis solution for use in Continuous Ambulatory Peritoneal Dialysis (CAPD) therapy as described in the table below. This product is manufactured by Baxter's manufacturing facility in Amata, Thailand and is marketed in Thailand and India. At this time, importation or distribution of DIANEAL PD-4 Low Calcium 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 Amata, Thailand:

Thailand Imported Product Name and Description	CAPD Fill Volume	Product Code	Bags per Carton	NDC Code
DIANEAL PD-4 Low Calcium with 1.5% Dextrose	2000 mL	THB9766	6 bags	0941-0711-01 (bag) 0941-0711-06 (carton)
DIANEAL PD-4 Low Calcium with 2.5% Dextrose	2000 mL	THB9776	6 bags	0941-0713-01 (bag) 0941-0713-06 (carton)
DIANEAL PD-4 Low Calcium with 4.25 % Dextrose	2000 mL	THB9796IP	6 bags	0941-0715-01 (bag) 0941-0715-06 (carton)

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

- **DIANEAL PD-4 Low Calcium Peritoneal Dialysis Solution contains 1.25 mmol/L (2.5 mEq/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 Thailand-imported DIANEAL solution should have their serum calcium levels monitored for the development of hypocalcemia.

- There are no other clinically relevant differences in the DIANEAL drug composition between the US-manufactured and Thailand-manufactured product (see Table 1, below). As such, clinical practice for usage, administration, and dosage for the Thailand imported products is the same as with the DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose manufactured in US. Please refer to the FDA-approved DIANEAL Peritoneal Dialysis Solution with Dextrose Full Prescribing Information for reference.
- The DIANEAL PD-4 Low Calcium Peritoneal Dialysis Solution with Dextrose imported from Thailand will only be available in 2000 mL fill volume for CAPD so there will be a need to adapt the PD prescription for some patients.
- The Luer-lock connector on the Thailand imported product functions the same as and is fully compatible with peritoneal dialysis sets marketed in the United States. The Thailand imported product has a single green frangible near the Y connector which is broken at the same time during flush phase as the corresponding blue frangible in US product. **There is an online clamp on the drain line in Thailand-imported product, so patients only need to use one external clamp on the infusion line compared to two external clamps for US product.** See Table 1 for more details of product differences.
- The Thailand imported product include 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 Peritoneal Dialysis Solutions are available only by prescription in the U.S. However, the imported products do not have the statement “Rx only” on the labeling. The shipping carton labels include both English and Thai language.

Before prescribing, healthcare providers should be aware of some key differences in the container packaging and labeling between the Thailand 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 CAPD therapy
- Table 2: Label images of DIANEAL 2000 mL CAPD product presentations

### 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.**

If you have any questions about the information contained in this letter or the use of imported DIANEAL Low Calcium Peritoneal Dialysis Solution, 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 22, 2024 09:28  
CDT

Geovana Basso, M.D.  
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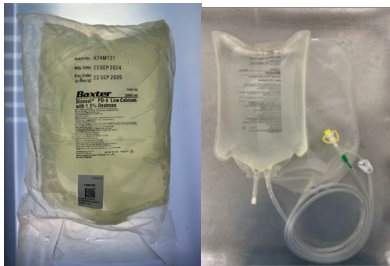


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**Attachments:**

Product Comparison Tables 1 and 2

**Table 1. Key differences of DIANEAL Peritoneal Dialysis Solution for CAPD therapy**

	<b>Thailand Imported Product DIANEAL PD-4 Low Calcium</b>	<b>US FDA-Approved Product DIANEAL Low Calcium</b>	<b>US FDA-Approved Product DIANEAL PD-2</b>
<b>Product name</b>	DIANEAL PD-4 Low Calcium with 1.5% Dextrose DIANEAL PD-4 Low Calcium with 2.5% Dextrose DIANEAL PD-4 Low Calcium with 4.25% Dextrose	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5 % Dextrose  DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose  DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose  DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose  DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose
<b>Labeled Fill Volume</b>	2000 mL	1500 mL 2000 mL 2500 mL 3000 mL	2000 mL 2500 mL 3000 mL
<b>Container Type</b>	TwinBag containers (PVC)	UltraBag Container (PVC)	UltraBag Container (PVC)
<b>Bags per carton</b>	6	1500 mL: 8 2000 mL: 6 2500 mL: 5 3000 mL: 4	2000 mL: 6 2500 mL: 5 3000 mL: 4
<b>Indications</b>	<b>1.5% and 2.5% Dextrose:</b> Dianeal PD-4 Peritoneal dialysis solutions is indicated for use in chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate  <b>4.25% Dextrose:</b> Dianeal Peritoneal dialysis solutions in TwinBag containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.	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 Ingredients -Dextrose</b>	<b>1.5% Dextrose:</b> Dextrose Hydrus, USP 1.5 g / 100 mL <b>2.5% Dextrose:</b> Dextrose Hydrus, USP 2.5 g / 100 mL <b>4.25% Dextrose:</b> Dextrose Hydrus 4.25 g / 100 mL	<b>1.5% Dextrose:</b> Dextrose Hydrus, USP 1.5 g / 100 mL <b>2.5% Dextrose:</b> Dextrose Hydrus, USP 2.5 g / 100 mL <b>4.25% Dextrose:</b> Dextrose Hydrus, USP 4.25 g / 100 mL	<b>1.5% Dextrose:</b> Dextrose Hydrus, USP 1.5 g / 100 mL <b>2.5% Dextrose:</b> Dextrose Hydrus, USP 2.5 g / 100 mL <b>4.25% Dextrose:</b> Dextrose Hydrus, USP 4.25 g / 100 mL
<b>Active Ingredient - 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 / 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
<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

	Thailand Imported Product DIANEAL PD-4 Low Calcium	US FDA-Approved Product DIANEAL Low Calcium	US FDA-Approved Product DIANEAL PD-2
<b>pH</b>	<p><b>1.5% Dextrose &amp; 2.5% Dextrose:</b> 5.2 (4.0 to 6.5)</p> <p><b>4.25% Dextrose</b> 5.2 (4.5 to 6.5)</p>	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
<b>Additional Information</b>	<p><b>1.5% Dextrose:</b> Osmolarity 344 mOsmol/L (Calc)</p> <p><b>2.5% Dextrose:</b> Osmolarity 395 mOsmol/L (Calc)</p> <p><b>4.25% Dextrose</b> Osmolarity 483 mOsmol/L (Calc)</p>	<p><b>1.5% Dextrose:</b> Osmolarity 344 mOsmol/L (Calc)</p> <p><b>2.5% Dextrose:</b> Osmolarity 395 mOsmol/L (Calc)</p> <p><b>4.25% Dextrose</b> Osmolarity 483 mOsmol/L (Calc)</p>	<p><b>1.5% Dextrose:</b> Osmolarity 346 mOsmol/L (Calc)</p> <p><b>2.5% Dextrose:</b> Osmolarity 396 mOsmol/L (Calc)</p> <p><b>4.25% Dextrose:</b> Osmolarity 485 mOsmol/L (Calc)</p>
<b>Storage Conditions</b>	Store below 30°C	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	18 months	18 months
<b>Container Closure System</b>			
<b>Container Closure Differences</b>	<ul style="list-style-type: none"> <li>• Only one green frangible near the Y connector broken before FLUSH.</li> <li>• There is one in-line clamp on the drain line. One other external clamp will be needed.</li> <li>• Solution line contains fluid.</li> <li>• Pull ring cap is color-coded to solution dextrose concentration:               <ul style="list-style-type: none"> <li>○ Yellow = 1.5% dextrose</li> <li>○ Green = 2.5% dextrose</li> <li>○ Red = 4.25% dextrose</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Two frangibles – one blue in “Y”-junction and one green at the sterile solution bag</li> <li>• Two external clamps are needed.</li> <li>• Solution line does not contain fluid.</li> <li>• Pull ring cap is color-coded to solution dextrose concentration:               <ul style="list-style-type: none"> <li>○ Yellow = 1.5% dextrose</li> <li>○ Green = 2.5% dextrose</li> <li>○ Red = 4.25% dextrose</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Two frangibles – one blue in “Y”-junction and one green at the sterile solution bag</li> <li>• Two external clamps are needed</li> <li>• Solution line does not contain fluid</li> <li>• Pull ring cap is color-coded to solution dextrose concentration:               <ul style="list-style-type: none"> <li>○ Yellow = 1.5% dextrose</li> <li>○ Green = 2.5% dextrose</li> <li>○ Red = 4.25% dextrose</li> </ul> </li> </ul>

**Table 2. Comparison of DIANEAL PD Solution Container Labels for CAPD**

Comparative container labels are presented below for the 2000 mL fill volume that is proposed for import. Labels for the U.S. FDA-approved 1500 mL, 2500 mL, and 3000 mL solution fill volume differ only by product code / NDC / Fill Volume / Barcode. There are no differences in composition, except for minor variations to active pharmaceutical ingredient quantities (excluding dextrose), or other safety-related information.

<p><b>Thailand Imported Product</b> <b>DIANEAL PD-4 Low Calcium</b> <b>2,000 mL</b></p>	<p><b>US FDA-Approved Product</b> <b>DIANEAL Low Calcium PD Solution</b></p>	<p><b>US FDA-Approved Product</b> <b>DIANEAL PD-2 PD Solution</b></p>
<p style="text-align: right;">THB9766 2000 ml</p> <p><b>Baxter</b></p> <p><b>Dianeal® PD-4 Low Calcium 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 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 - 344 mOsmol/L (CALC) STERILE NON-PYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION 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</p> <p>KEEP OUT OF REACH OF CHILDREN AVOID EXCESSIVE HEAT SEE INSERT INDICATED FOR CHRONIC RENAL FAILURE PATIENTS BEING MAINTAINED ON PERITONEAL DIALYSIS DIRECTION TO BE USED AS DIRECTED BY THE PHYSICIAN</p> <p>STORAGE BELOW 30°C MANUFACTURED BY: REG NO. 2A 12/59 THRS1107 BAXTER MANUFACTURING (THAILAND) CO., LTD. (BH) RAYONG, THAILAND</p>	<p style="text-align: right;">5B9766 2000 mL NDC 0941-0424-52 (APPROX 80 mL EXCESS)</p> <p><b>Baxter</b></p> <p><b>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution 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 -95 LACTATE -40 OSMOLARITY - 344 mOsmol/L (CALC) STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY DOSAGE AS DIRECTED BY A PHYSICIAN 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><b>UltraBag</b> CONTAINER PL 146 PLASTIC</p> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4340049 4346703 4439188 4573980</p>	<p style="text-align: right;">5B9866 2000 mL NDC 0941-0425-52 (APPROX 80 mL EXCESS)</p> <p><b>Baxter</b></p> <p><b>Dianeal PD-2 Peritoneal Dialysis Solution 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) STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY DOSAGE AS DIRECTED BY A PHYSICIAN 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><b>UltraBag</b> CONTAINER PL 146 PLASTIC</p> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4340049 4346703 4439188 4573980</p>

**Low Calcium 1.5% Dextrose**

**PD-2 1.5% Dextrose**

<p>Thailand Imported Product DIANEAL PD-4 Low Calcium 2,000 mL</p>	<p>US FDA-Approved Product DIANEAL Low Calcium PD Solution</p>	<p>US FDA-Approved Product DIANEAL PD-2 PD Solution</p>
<p style="text-align: right;">THB9776 2000 ml</p> <p><b>Baxter</b></p> <p><b>Dianeal® PD-4 Low Calcium with 2.5% Dextrose</b></p> <p>EACH 100 ml CONTAINS 2.5 g DEXTROSE HYDROUS USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE DIHYDRATE USP 5.08 mg MAGNESIUM CHLORIDE HEXAHYDRATE USP pH 5.2 (4.0 TO 6.5) mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40 OSMOLARITY 395 mOsmol/L(CALC) STERILE NON PYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION 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 KEEP OUT OF REACH OF CHILDREN AVOID EXCESSIVE HEAT SEE INSERT INDICATED FOR CHRONIC RENAL FAILURE PATIENTS BEING MAINTAINED ON PERITONEAL DIALYSIS</p> <p>DIRECTION TO BE USED AS DIRECTED BY THE PHYSICIAN STORAGE BELOW 30°C</p> <p>REG NO. 2A 95/59 THRS1109 (BC)</p> <p>MANUFACTURED BY: BAXTER MANUFACTURING (THAILAND) CO., LTD. RAYONG, THAILAND</p>	<p style="text-align: right;">5B9776 2000 mL NDC 0941-0430-52 (APPROX 80 mL EXCESS)</p> <p><b>Baxter</b></p> <p><b>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</b></p> <p>EACH 100 mL CONTAINS 2.5 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 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 395 mOsmol/L (CALC) STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY DOSAGE AS DIRECTED BY A PHYSICIAN</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 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><b>UltraBag</b> CONTAINER PL 146 PLASTIC BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4340049 4346703 4439188 4573980</p>	<p style="text-align: right;">5B9876 2000 mL NDC 0941-0427-52 (APPROX 80 mL EXCESS)</p> <p><b>Baxter</b></p> <p><b>Dianeal PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</b></p> <p>EACH 100 mL CONTAINS 2.5 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 - 95 LACTATE - 40 OSMOLARITY - 395 mOsmol/L (CALC) STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY DOSAGE AS DIRECTED BY A PHYSICIAN 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><b>UltraBag</b> CONTAINER PL 146 PLASTIC BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4340049 4346703 4439188 4573980</p>

**Low Calcium 2.5% Dextrose**

**PD-2 2.5% Dextrose**

<p>Thailand Imported Product <b>DIANEAL PD-4 Low Calcium</b> 2,000 mL</p>	<p>US FDA-Approved Product <b>DIANEAL Low Calcium PD Solution</b></p>	<p>US FDA-Approved Product <b>DIANEAL PD-2 PD Solution</b></p>
<p>THB9796IP <b>Baxter</b> 2000 mL</p> <p><b>Peritoneal Dialysis Solution Low Calcium with 4.25% Dextrose-IP</b> <b>Dianeal® PD-4 Low Calcium</b></p> <p>EACH 100mL CONTAINS 4.25 g DEXTROSE HYDROUS 538 mg SODIUM CHLORIDE 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE OBT-HYDRATE 5.08 mg MAGNESIUM CHLORIDE HEXAHYDRATE pH 5.2 (4.5 TO 6.5) mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40 OSMOLARITY 483 mOsmol/L (CALC) STERILE NON PYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>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 KEEP OUT OF REACH OF CHILDREN AVOID EXCESSIVE HEAT INDICATED FOR CHRONIC RENAL FAILURE PATIENTS BEING MAINTAINED ON PERITONEAL DIALYSIS</p> <p>INDICATION/ADMINISTRATION AND COMPLETE INFORMATION - REFER PACKAGE INSERT</p> <p>STORAGE BELOW 30°C THA REG NO. 2A 93/99 THRS1131 (AA)</p> <p>NAME AND ADDRESS OF MANUFACTURER: BAXTER MANUFACTURING (THAILAND) CO. LTD. 7/398 MOO 6 MABYANGPORN, PLUAKDAENG, RAYONG, THAILAND 21140</p> <p>Name and Address of Importer: Baxter (India) Pvt. Ltd., No. 219-1A, 1B, 225/4B, Block C, Ground Floor, Kothari ware house, Opposite to Vegetarian Village, Madhavaram Red Hills Road Puzhal village, Ambattur Taluk, Tiruvallur District, Chennai - 600060 Tamil Nadu, India</p> <p>Import License Number: IL/FF-000400 RC/FF-002173</p> <p>Telephone no., email address (in case of consumer complaint, Safety Reporting or Queries): Consumer Care No.- 0124-4603200 Consumer Care email ID: Customerservice_SHS_India@baxter.com</p>	<p><b>5B9796</b> 2000 mL NDC 0941-0433-52 (APPROX 80 mL EXCESS)</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) STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION <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 DOSAGE AS DIRECTED BY A PHYSICIAN <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 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><b>UltraBag</b> CONTAINER PL 146 PLASTIC BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p><b>BAXTER HEALTHCARE CORPORATION</b> DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4340049 4346703 4439188 4573980</p>	<p><b>5B9896</b> 2000 mL NDC 0941-0429-52 (APPROX 80 mL EXCESS)</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) mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 486 mOsmol/L (CALC) STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION <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 DOSAGE AS DIRECTED BY A PHYSICIAN <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 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><b>UltraBag</b> CONTAINER PL 146 PLASTIC BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p><b>BAXTER HEALTHCARE CORPORATION</b> DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4340049 4346703 4439188 4573980</p>

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