

IMPORTANT PRESCRIBING INFORMATION

DATE: October 21, 2024

Subject: Temporary importation of DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose from China for use in Continuous Ambulatory 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, 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 Dextrose 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 Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose 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 Guangzhou, China and is marketed in Hong Kong. At this time, importation or distribution of DIANEAL Low Calcium (2.5 mEq/L) 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 Guangzhou, China:

China Imported Product Name and Description	CAPD Fill Volume	Product Code	Bags per Carton	NDC Code
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose	2500 mL	6AB9768E	4 bags	0941-0684-01 (bag) 0941-0684-04 (carton)
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose	2500 mL	6AB9778E	4 bags	0941-0688-01 (bag) 0941-0688-04 (carton)
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	2500 mL	6AB9798E	4 bags	0941-0692-01 (bag) 0941-0692-04 (carton)

It is important to note the following:

- **DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose contains 2.5 mEq/L calcium compared to DIANEAL PD-2 Peritoneal Dialysis Solution which contains 3.5 mEq/L calcium.** Patients receiving China-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 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 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose manufactured in U.S. Please refer to the FDA-approved DIANEAL Peritoneal Dialysis Solution Prescribing Information for reference.
- DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose imported from China will only be available in 2500 mL fill volume for CAPD therapy so there will need to be an adaptation to the PD prescription for some patients.
- The blue Luer-lock connector functions the same and is fully compatible with peritoneal dialysis sets marketed in the United States but is more deeply recessed than the white connector of U.S.-manufactured product and covers the end of the transfer set. China 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 U.S.-manufactured product. There two online clamps on the drain (blue clamp) and infusion (white clamp) lines in China-imported product so patients do not need to use the two external clamps needed for U.S.-manufactured product. China imported product has a green pull ring for all dextrose concentrations compared to the colored pull rings in U.S.-manufactured product which specify glucose concentration. See Table 1 for more details of product differences.
- The China imported product includes 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 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. Please note that the imported solutions bags do not have barcodes.
- DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solutions are available only by prescription in the U.S. However, the imported product does 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 China imported product and the 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 2500 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
- **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 full prescribing information for DIANEAL Peritoneal Dialysis Solution at [DailyMed \(nih.gov\)](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/014121Orig1s001.pdf).

If you have any questions about the information contained in this letter or the use of imported DIANEAL Low Calcium (2.5 mEq/L) 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 21, 2024 14:23
CDT

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

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Attachments:

Product Comparison Tables 1 and 2

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

	Imported Product (Guangzhou, China) DIANEAL Low Calcium	U.S. FDA-Approved Product DIANEAL Low Calcium	U.S. FDA-Approved Product DIANEAL PD-2
Product name	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 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
Labeled Fill Volume	2500 mL	1500 mL 2000 mL 2500 mL 3000 mL	2000 mL 2500 mL 3000 mL
Container Type	UltraBag Container (PVC)	UltraBag Container (PVC)	UltraBag Container (PVC)
Bags per Carton	4	1500 mL: 8 2000 mL: 6 2500 mL: 5 3000 mL: 4	2000 mL: 6 2500 mL: 5 3000 mL: 4
Indications	DIANEAL Low Calcium peritoneal dialysis solutions in UltraBag containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when non-dialytic 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.
Active Ingredient-Dextrose	1.5% Dextrose: Dextrose Hydrous, 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrous, 2.5 g / 100 mL 4.25% Dextrose: Dextrose Hydrous, 4.25 g / 100 mL	1.5% Dextrose: Dextrose Hydrous, USP 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrous, USP 2.5 g / 100 mL 4.25% Dextrose: Dextrose Hydrous, USP 4.25 g / 100 mL	1.5% Dextrose: Dextrose Hydrous, USP 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrous, USP 2.5 g / 100 mL 4.25% Dextrose: Dextrose Hydrous, USP 4.25 g / 100 mL
Active Ingredient - Electrolytes	Sodium Chloride, 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, 18.3 mg / 100 mL Magnesium Chloride, 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 with low calcium	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
pH	5.2 (4.5 – 6.5)	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
Additional Information	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 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)




	Imported Product (Guangzhou, China) DIANEAL Low Calcium	U.S. FDA-Approved Product DIANEAL Low Calcium	U.S. FDA-Approved Product DIANEAL PD-2
Storage Conditions	Store unit in moisture barrier overwrap at room temperature (under 25°C) until ready to use. Avoid excessive heat.	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	18 months	18 months
Container Closure System			
Container Closure Differences	<ul style="list-style-type: none"> • One green frangible at the sterile solution bag, to be broken (after drain) to allow for 'flush before fill' therapy step • Pull rings are green for all Dextrose concentrations • Blue luer connector with deeply recessed shroud covering end of transfer set • Two online clamps – a blue clamp on the infusion line and a white clamp on drain line 	<ul style="list-style-type: none"> • Two frangibles – one blue in “Y”-junction and one green at the sterile solution bag • 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 • White Luer connector • External clamps are needed to control solution flow. 	<ul style="list-style-type: none"> • Two frangibles – one blue in “Y”-junction and one green at the sterile solution bag • 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 • White Luer connector • External clamps are needed to control solution flow.
Bag Print Color	1.5% dextrose: black 2.5% dextrose: blue 4.25% dextrose: red	Black	Black

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

Comparative container labels are presented below for the 2500 mL fill volume that is proposed for import. Labels for the US approved 1500 mL, 2000 mL, and 3000 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 (Guangzhou, China) - 2500 mL DIANEAL Low Calcium	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution
<p style="text-align: center;">2500ml (APPROX 90ml EXCESS) 3000ml NOMINAL SIZE CONTAINER</p> <p>6AB9768E</p> <p style="text-align: center;">Baxter</p> <p>Dianeal® Low Calcium(2.5mEq/L) Peritoneal Dialysis Solution With 1.5% Dextrose</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 (4.5 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> <div style="border: 1px solid black; padding: 2px; width: fit-content;"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <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 STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (UNDER 25°C) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT 請儲存於攝氏25度以下 UltraBag™ CONTAINER PL-146® PLASTIC MANUFACTURED BY BAXTER HEALTHCARE (GUANGZHOU) CO LTD GUANGZHOU CHINA (AN AFFILIATE OF BAXTER WORLD TRADE INC USA) HK-62710 DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN 用法 請依照醫生指示使用 Prescription Drug 處方藥物 Manufacturer Address: Jiaoyuan Road, Dongji Industrial District, GETDD,Guangzhou, P.R. China</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; transform: rotate(-90deg); transform-origin: left top;"> <p>Low Calcium 1.5% Dextrose</p> </div>	<p style="text-align: center;">2500 mL (APPROX 90 mL EXCESS) 3000 mL NOMINAL SIZE CONTAINER</p> <p>5B9768</p> <p style="text-align: center;">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) mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 344 mOsmol/L (CALC) STERILE NONPYROGENIC</p> <div style="border: 1px solid black; padding: 2px; width: fit-content;"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <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>UltraBag CONTAINER PL 146 PLASTIC 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> <div style="border: 1px solid black; padding: 2px; width: fit-content; transform: rotate(-90deg); transform-origin: left top;"> <p>Low Calcium 1.5% Dextrose</p> </div>	<p style="text-align: center;">2500 mL (APPROX 90 mL EXCESS) 3000 mL NOMINAL SIZE CONTAINER</p> <p>5B9868</p> <p style="text-align: center;">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) mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 346 mOsmol/L (CALC) STERILE NONPYROGENIC</p> <div style="border: 1px solid black; padding: 2px; width: fit-content;"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <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>UltraBag CONTAINER PL 146 PLASTIC 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> <div style="border: 1px solid black; padding: 2px; width: fit-content; transform: rotate(-90deg); transform-origin: left top;"> <p>PD-2 1.5% Dextrose</p> </div>

<p align="center">Imported Product (Guangzhou, China) - 2500 mL DIANEAL Low Calcium</p>	<p align="center">US FDA Approved Product DIANEAL Low Calcium PD Solution</p>	<p align="center">US FDA Approved Product DIANEAL PD-2 PD Solution</p>
<p align="center">2500ml 6AB9778E (APPROX 90ml EXCESS) 3000mL NOMINAL SIZE CONTAINER</p> <p>Baxter</p> <p>Dianeal® Low Calcium(2.5mEq/L) Peritoneal Dialysis Solution With 2.5% Dextrose</p> <p>EACH 100ml 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 (4.5 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 STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (UNDER 25°C) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT 請儲存於攝氏25度以下</p> <p>UltraBag™ CONTAINER PL-146® PLASTIC MANUFACTURED BY BAXTER HEALTHCARE (GUANGZHOU) CO LTD GUANGZHOU CHINA (AN AFFILIATE OF BAXTER WORLD TRADE INC USA) HK-62709 DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN 用法 請依照醫生指示使用 Prescription Drug 處方藥物 Manufacturer Address: Jiaoyuan Road, Dongji Industrial District, GETDD, Guangzhou, P.R. China</p> <p align="center" style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 2.5% Dextrose</p>	<p align="center">5B9778 (APPROX 90 mL EXCESS) NDC 0941-0427-53 2500 mL NOMINAL SIZE CONTAINER</p> <p>Baxter</p> <p>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</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</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>UltraBag 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 align="center" style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 2.5% Dextrose</p>	<p align="center">5B9878 (APPROX 90 mL EXCESS) NDC 0941-0427-53 2500 mL NOMINAL SIZE CONTAINER</p> <p>Baxter</p> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>EACH 100 mL CONTAINS 2.5 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 - 396 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>UltraBag 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 align="center" style="writing-mode: vertical-rl; transform: rotate(180deg);">PD-2 2.5% Dextrose</p>

<p>Imported Product (Guangzhou, China) - 2500 mL DIANEAL Low Calcium</p>	<p>US FDA Approved Product DIANEAL Low Calcium PD Solution</p>	<p>US FDA Approved Product DIANEAL PD-2 PD Solution</p>
<p>6AB9798E 2500ml (APPROX 90ml EXCESS) 3000ml NOMINAL SIZE CONTAINER</p> <p>Baxter</p> <p>Dianeal® Low Calcium(2.5mEq/L) Peritoneal Dialysis Solution With 4.25% Dextrose</p> <p>EACH 100ml 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 (4.5 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>WARNING EXTENSIVE USE OF THIS SOLUTION DURING ONE PERITONEAL DIALYSIS PROCEDURE CAN RESULT IN SIGNIFICANT REMOVAL OF WATER FROM THE PATIENT 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 STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (UNDER 25°C) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT 請儲存於攝氏25度以下</p> <p>UltraBag™ CONTAINER PL-146® PLASTIC MANUFACTURED BY BAXTER HEALTHCARE (GUANGZHOU) CO LTD GUANGZHOU CHINA (AN AFFILIATE OF BAXTER WORLD TRADE INC USA) HK-62711</p> <p>DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN 用法 請依照醫生指示使用</p> <p>Prescription Drug 處方藥物 Manufacturer Address: Jiaoyuan Road, Dongji Industrial District, GETDD,Guangzhou, P.R. China</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 4.25% Dextrose</p>	<p>5B9798 2500 mL (APPROX 90 mL EXCESS) 3000 mL NOMINAL SIZE CONTAINER</p> <p>Baxter</p> <p>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose</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 WARNING 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 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>UltraBag 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="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 4.25% Dextrose</p>	<p>5B9898 2500 mL (APPROX 90 mL EXCESS) 3000 mL NOMINAL SIZE CONTAINER</p> <p>Baxter</p> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose</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 - 485 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 WARNING 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 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>UltraBag 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="writing-mode: vertical-rl; transform: rotate(180deg);">PD-2 4.25% Dextrose</p>