

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://dailymed.nlm.nih.gov/).

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
<div data-bbox="170 588 506 634"> <p>2500ml (APPROX 90ml EXCESS) 3000ml NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="170 640 292 661"> <p>6AB9768E</p> </div> <div data-bbox="170 667 506 735"> <p>Baxter Dianeal® Low Calcium(2.5mEq/L) Peritoneal Dialysis Solution With 1.5% Dextrose</p> </div> <div data-bbox="170 735 479 842"> <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 96 LACTATE 40 OSMOLARITY 344 mOsmol/L(CALC) STERILE NON PYROGENIC</p> </div> <div data-bbox="170 846 454 875"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="170 879 474 949"> <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</p> </div> <div data-bbox="170 947 474 1016"> <p>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</p> </div> <div data-bbox="170 1014 341 1035"> <p>請儲存於攝氏25度以下</p> </div> <div data-bbox="170 1035 448 1056"> <p>UltraBag™ CONTAINER PL-146* PLASTIC</p> </div> <div data-bbox="170 1056 459 1125"> <p>MANUFACTURED BY BAXTER HEALTHCARE (GUANGZHOU) CO LTD GUANGZHOU CHINA (AN AFFILIATE OF BAXTER WORLD TRADE INC USA) HK-62710</p> </div> <div data-bbox="170 1123 498 1140"> <p>DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN</p> </div> <div data-bbox="170 1140 378 1157"> <p>用法 請依照醫生指示使用</p> </div> <div data-bbox="170 1157 378 1173"> <p>Prescription Drug 處方藥物</p> </div> <div data-bbox="170 1173 313 1190"> <p>Manufacturer Address:</p> </div> <div data-bbox="170 1190 420 1222"> <p>Jiaoyuan Road, Dongji Industrial District, GETDD,Guangzhou, P.R. China</p> </div> <div data-bbox="479 793 506 1050" style="writing-mode: vertical-rl; transform: rotate(180deg);"> <p>Low Calcium 1.5% Dextrose</p> </div>	<div data-bbox="634 579 995 630"> <p>589768  2500 mL NDC 0941-0424-53 (APPROX 90 mL EXCESS) 3000 mL NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="634 642 737 665"> <p>Baxter</p> </div> <div data-bbox="634 678 914 785"> <p>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose</p> </div> <div data-bbox="634 791 920 896"> <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) STERILE NONPYROGENIC</p> </div> <div data-bbox="634 900 914 930"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="634 934 899 987"> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY DOSAGE AS DIRECTED BY A PHYSICIAN</p> </div> <div data-bbox="634 984 925 1026"> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> </div> <div data-bbox="634 1026 862 1062"> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> </div> <div data-bbox="634 1062 683 1077"> <p>Rx ONLY</p> </div> <div data-bbox="634 1077 912 1129"> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> </div> <div data-bbox="634 1131 928 1150"> <p>UltraBag CONTAINER PL 146 PLASTIC</p> </div> <div data-bbox="634 1150 893 1180"> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> </div> <div data-bbox="634 1182 837 1215"> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p> </div> <div data-bbox="634 1226 805 1251"> <p>US PAT NOS 4340049 4346703 4439188 4573980</p> </div> <div data-bbox="966 758 995 1115" style="writing-mode: vertical-rl; transform: rotate(180deg);"> <p>Low Calcium 1.5% Dextrose</p> </div>	<div data-bbox="1092 569 1453 619"> <p>589868  2500 mL NDC 0941-0425-53 (APPROX 90 mL EXCESS) 3000 mL NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="1092 632 1196 655"> <p>Baxter</p> </div> <div data-bbox="1092 667 1373 747"> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose</p> </div> <div data-bbox="1092 766 1380 871"> <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> <div data-bbox="1092 882 1373 911"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="1092 921 1359 974"> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY DOSAGE AS DIRECTED BY A PHYSICIAN</p> </div> <div data-bbox="1092 972 1386 1014"> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> </div> <div data-bbox="1092 1014 1323 1050"> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> </div> <div data-bbox="1092 1050 1143 1064"> <p>Rx ONLY</p> </div> <div data-bbox="1092 1066 1370 1117"> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> </div> <div data-bbox="1092 1119 1386 1140"> <p>UltraBag CONTAINER PL 146 PLASTIC</p> </div> <div data-bbox="1092 1140 1351 1169"> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> </div> <div data-bbox="1092 1171 1297 1203"> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p> </div> <div data-bbox="1092 1213 1265 1239"> <p>US PAT NOS 4340049 4346703 4439188 4573980</p> </div> <div data-bbox="1425 758 1455 1050" style="writing-mode: vertical-rl; transform: rotate(180deg);"> <p>PD-2 1.5% Dextrose</p> </div>

<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>
<div data-bbox="181 352 521 405"> <p>2500ml 6AB9778E (APPROX 90ml EXCESS) 3000mL NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="181 405 302 432"> <p>Baxter</p> </div> <div data-bbox="181 436 508 501"> <p>Dianeal® Low Calcium(2.5mEq/L) Peritoneal Dialysis Solution With 2.5% Dextrose</p> </div> <div data-bbox="181 499 487 611"> <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> </div> <div data-bbox="181 611 466 642" data-label="Text"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="181 646 482 785"> <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</p> </div> <div data-bbox="181 781 357 802" data-label="Text"> <p>請儲存於攝氏25度以下</p> </div> <div data-bbox="181 800 457 821" data-label="Text"> <p>UltraBag™ CONTAINER PL-146® PLASTIC</p> </div> <div data-bbox="181 819 469 890" data-label="Text"> <p>MANUFACTURED BY BAXTER HEALTHCARE (GUANGZHOU) CO LTD GUANGZHOU CHINA (AN AFFILIATE OF BAXTER WORLD TRADE INC USA) HK-62709</p> </div> <div data-bbox="181 886 506 905" data-label="Text"> <p>DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN</p> </div> <div data-bbox="181 903 386 921" data-label="Text"> <p>用法 請依照醫生指示使用</p> </div> <div data-bbox="181 919 380 938" data-label="Text"> <p>Prescription Drug 處方藥物</p> </div> <div data-bbox="181 936 329 955" data-label="Text"> <p>Manufacturer Address:</p> </div> <div data-bbox="181 953 436 987" data-label="Text"> <p>Jiaoyuan Road, Dongji Industrial District, GETDD, Guangzhou, P.R. China</p> </div> <div data-bbox="487 537 509 798" data-label="Text"> <p>Low Calcium 2.5% Dextrose</p> </div>	<div data-bbox="643 386 992 434"> <p>5B9778 (APPROX 90 mL EXCESS) NDC 0941-0430-53 2500 mL 3000 mL NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="643 441 745 466"> <p>Baxter</p> </div> <div data-bbox="643 472 906 567"> <p>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</p> </div> <div data-bbox="643 567 932 644"> <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> </div> <div data-bbox="643 644 932 726" data-label="Text"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="643 730 932 777" data-label="Text"> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY DOSAGE AS DIRECTED BY A PHYSICIAN</p> </div> <div data-bbox="643 774 888 819" data-label="Text"> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR</p> </div> <div data-bbox="643 816 837 833" data-label="Text"> <p>DISCARD UNUSED PORTION</p> </div> <div data-bbox="643 833 691 852" data-label="Text"> <p>Rx ONLY</p> </div> <div data-bbox="643 850 899 896" data-label="Text"> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C / 77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> </div> <div data-bbox="643 900 878 919" data-label="Text"> <p>UltraBag CONTAINER PL 146 PLASTIC</p> </div> <div data-bbox="643 917 860 953" data-label="Text"> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> </div> <div data-bbox="643 953 837 984" data-label="Text"> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA</p> </div> <div data-bbox="643 984 709 1001" data-label="Text"> <p>MADE IN USA</p> </div> <div data-bbox="643 1001 812 1026" data-label="Text"> <p>US PAT NOS 4340049 4346703 4439188 4573980</p> </div> <div data-bbox="964 554 992 907" data-label="Text"> <p>Low Calcium 2.5% Dextrose</p> </div>	<div data-bbox="1096 348 1448 399"> <p>5B9878 (APPROX 90 mL EXCESS) NDC 0941-0427-53 2500 mL 3000 mL NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="1096 407 1201 432"> <p>Baxter</p> </div> <div data-bbox="1096 451 1369 527"> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</p> </div> <div data-bbox="1096 537 1375 588"> <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)</p> </div> <div data-bbox="1096 585 1375 623"> <p>mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 396 mOsmol/L (CALC) STERILE NONPYROGENIC</p> </div> <div data-bbox="1096 646 1369 676" data-label="Text"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="1096 686 1357 735" data-label="Text"> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY DOSAGE AS DIRECTED BY A PHYSICIAN</p> </div> <div data-bbox="1096 732 1382 774" data-label="Text"> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> </div> <div data-bbox="1096 774 1320 791" data-label="Text"> <p>DO NOT USE UNLESS SOLUTION IS CLEAR</p> </div> <div data-bbox="1096 791 1248 808" data-label="Text"> <p>DISCARD UNUSED PORTION</p> </div> <div data-bbox="1096 808 1149 825" data-label="Text"> <p>Rx ONLY</p> </div> <div data-bbox="1096 825 1369 871" data-label="Text"> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> </div> <div data-bbox="1096 873 1382 892" data-label="Text"> <p>UltraBag CONTAINER PL 146 PLASTIC</p> </div> <div data-bbox="1096 890 1347 921" data-label="Text"> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> </div> <div data-bbox="1096 921 1295 949" data-label="Text"> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA</p> </div> <div data-bbox="1096 949 1166 963" data-label="Text"> <p>MADE IN USA</p> </div> <div data-bbox="1096 963 1266 989" data-label="Text"> <p>US PAT NOS 4340049 4346703 4439188 4573980</p> </div> <div data-bbox="1416 533 1451 785" data-label="Text"> <p>PD-2 2.5% Dextrose</p> </div>

<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>
<div data-bbox="159 373 545 424"> <p>6AB9798E 2500ml (APPROX 90ml EXCESS) 3000ml NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="159 428 298 455"> <p>Baxter</p> </div> <div data-bbox="159 464 545 535"> <p>Dianeal® Low Calcium(2.5mEq/L) Peritoneal Dialysis Solution With 4.25% Dextrose</p> </div> <div data-bbox="159 535 545 640"> <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> </div> <div data-bbox="159 642 545 674"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="159 676 545 886"> <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> </div> <div data-bbox="159 886 545 970"> <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> </div> <div data-bbox="159 972 545 1014"> <p>DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN 用法 請依照醫生指示使用</p> </div> <div data-bbox="159 1014 545 1087"> <p>Prescription Drug 處方藥物 Manufacturer Address: Jiaoyuan Road, Dongji Industrial District, GETDD,Guangzhou, P.R. China</p> </div> <div data-bbox="521 632 545 930" style="writing-mode: vertical-rl; transform: rotate(180deg);"> <p>Low Calcium 4.25% Dextrose</p> </div>	<div data-bbox="605 380 1008 430"> <p>5B9798 2500 mL (APPROX 90 mL EXCESS) 3000 mL NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="605 451 721 478"> <p>Baxter</p> </div> <div data-bbox="605 489 917 609"> <p>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose</p> </div> <div data-bbox="605 617 917 728"> <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> </div> <div data-bbox="605 732 917 764"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="605 768 917 999"> <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> </div> <div data-bbox="605 1001 917 1129"> <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> </div> <div data-bbox="980 596 1008 1020" style="writing-mode: vertical-rl; transform: rotate(180deg);"> <p>Low Calcium 4.25% Dextrose</p> </div>	<div data-bbox="1073 359 1471 409"> <p>5B9898 2500 mL (APPROX 90 mL EXCESS) 3000 mL NOMINAL SIZE CONTAINER</p> </div> <div data-bbox="1073 428 1187 455"> <p>Baxter</p> </div> <div data-bbox="1073 476 1380 564"> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose</p> </div> <div data-bbox="1073 579 1380 672"> <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 - 95 LACTATE - 40 OSMOLARITY - 485 mOsmol/L (CALC) STERILE NONPYROGENIC</p> </div> <div data-bbox="1073 701 1380 732"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <div data-bbox="1073 743 1380 968"> <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> </div> <div data-bbox="1073 970 1380 1098"> <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> </div> <div data-bbox="1443 581 1471 879" style="writing-mode: vertical-rl; transform: rotate(180deg);"> <p>PD-2 4.25% Dextrose</p> </div>