

DIANEAL LOW CALCIUM WITH DEXTROSE- sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution
Vantive US Healthcare LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

DIANEAL Low Calcium with Dextrose

Health Care Provider Letter

IMPORTANT PRESCRIBING INFORMATION

DATE: October 21, 2024

Subject: Temporary importation of DIANEAL Low Calcium Peritoneal Dialysis Solution (2000 mL) 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 Peritoneal Dialysis Solution (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 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 Guangzhou, China and is marketed in China. At this time, importation or distribution of DIANEAL Low Calcium Peritoneal Dialysis Solution (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 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 Peritoneal Dialysis Solution (Lactate-G 1.5%)	2000 mL	6AB9766	8	0941-0686-01 (bag) 0941-0686-08 (carton)
DIANEAL Low Calcium Peritoneal Dialysis Solution (Lactate-G 2.5%)	2000 mL	6AB9776	8	0941-0690-01 (bag) 0941-0690-08 (carton)
DIANEAL Low Calcium Peritoneal Dialysis Solution (Lactate-G 4.25%)	2000 mL	6AB9796	8	0941-0694-01 (bag) 0941-0694-08 (carton)

It is important to note the following:

- **DIANEAL Low Calcium Peritoneal Dialysis Solution contains 1.24 mmol/L (2.5 mEq/L) calcium compared to DIANEAL PD-2 Peritoneal Dialysis Solution which contains 1.75 mmol/L (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 US-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 manufactured in U.S. Please refer to the FDA-approved DIANEAL Peritoneal Dialysis Solution Prescribing Information for reference.
- DIANEAL Low Calcium Peritoneal Dialysis Solution imported from China will only be available in 2000 mL fill volume for CAPD so there will need to be adaptation to the PD prescription for some patients.
- The Luer-lock connector functions the same and is fully compatible with peritoneal dialysis sets marketed in the United States. 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. China imported product has the same color-coded pull rings for 1.5% (yellow) and green (2.5%) dextrose concentrations as U.S. manufactured product. The pull ring for 4.25% dextrose concentration fluid is orange in China imported product and red in U.S. manufactured product. The container label in China imported product is in Chinese but key product characteristics are in English – solution type, volume, expiry date and dextrose 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 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. Please note that the imported solutions bags do not have barcodes.
- 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 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
- **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/drugs/nda/021221Orig1s001/BLA_021221Orig1s001.pdf).

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 21, 2024 14:17
CDT

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

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Attachments:
Product Comparison Tables 1 and 2

Table 1. Key differences of DIANEAL Peritoneal Dialysis 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	<p>DIANEAL Low Calcium Peritoneal Dialysis Solution (Lactate-G 1.5%)</p> <p>DIANEAL Low Calcium Peritoneal Dialysis Solution (Lactate-G 2.5%)</p> <p>DIANEAL Low Calcium Peritoneal Dialysis Solution (Lactate-G 4.25%)</p>	<p>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5 % Dextrose</p> <p>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose</p>	<p>DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose</p>
Labeled Fill Volume	2000 mL	1500 mL 2000 mL 2500 mL 3000 mL	2000 mL 2500 mL 3000 mL
Container Type	PVC Twin Bag	UltraBag Container (PVC)	UltraBag Container (PVC)
Bags Per Carton	8	1500 mL: 8 2000 mL: 6 2500 mL: 5 3000 mL: 4	2000 mL: 6 2500 mL: 5 3000 mL: 4
Indications	Acute and chronic renal failure patients who require continuous ambulatory peritoneal dialysis treatment because non-dialysis treatment is ineffective.	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	<p>1.5% Dextrose: Dextrose Hydrus 1.5 g / 100 mL</p> <p>2.5% Dextrose: Dextrose Hydrus 2.5 g / 100 mL</p> <p>4.25% Dextrose: Dextrose Hydrus 4.25 g / 100 mL</p>	<p>1.5% Dextrose: Dextrose Hydrus, USP 1.5 g / 100 mL</p> <p>2.5% Dextrose: Dextrose Hydrus, USP 2.5 g / 100 mL</p> <p>4.25% Dextrose: Dextrose Hydrus, USP 4.25 g / 100 mL</p>	<p>1.5% Dextrose: Dextrose Hydrus, USP 1.5 g / 100 mL</p> <p>2.5% Dextrose: Dextrose Hydrus, USP 2.5 g / 100 mL</p> <p>4.25% Dextrose: Dextrose Hydrus, USP 4.25 g / 100 mL</p>
Active Ingredient - Electrolytes	Sodium Chloride 538 mg / 100 mL Sodium Lactate 448 mg / 100 mL Calcium Chloride 18.3 mg / 100 mL Magnesium Chloride, 5.1 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 / 100 mL 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 mmol/L (equivalent to 132 mEq/L) Calcium 1.24 mmol/L (equivalent to 2.48 mEq/L) Magnesium 0.25 mmol/L (equivalent to 0.5 mEq/L) Chloride 95 mmol/L (equivalent to 95 mEq/L) Lactate 40 mmol/L (equivalent to 40 mEq/L)	Sodium 132 mEq/L Calcium 2.5 mEq/L Magnesium 0.5 mEq/L Chloride 95 mEq/L Lactate 40 mEq/L	Sodium 132 mEq/L Calcium 3.5 mEq/L Magnesium 0.5 mEq/L Chloride 96 mEq/L Lactate 40 mEq/L
pH	5.2 (4.5 to 6.5)	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
Additional Information	<p>1.5% Dextrose: Osmolarity 344 mOsmol/L (Calc)</p> <p>2.5% Dextrose: Osmolarity 395 mOsmol/L (Calc)</p> <p>4.25% Dextrose Osmolarity 483 mOsmol/L (Calc)</p>	<p>1.5% Dextrose: Osmolarity 344 mOsmol/L (Calc)</p> <p>2.5% Dextrose: Osmolarity 395 mOsmol/L (Calc)</p> <p>4.25% Dextrose Osmolarity 483 mOsmol/L (Calc)</p>	<p>1.5% Dextrose: Osmolarity 346 mOsmol/L (Calc)</p> <p>2.5% Dextrose: Osmolarity 396 mOsmol/L (Calc)</p> <p>4.25% Dextrose: Osmolarity 485 mOsmol/L (Calc)</p>

	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	Dialysate will freeze in an environment below 0°C. Do not bend or shake the container when it is frozen. Allow it to thaw naturally and shake it thoroughly before use.	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 ring cap color-coded to solution dextrose concentration: <ul style="list-style-type: none"> • Yellow = 1.5% dextrose • Green = 2.5% dextrose • Orange = 4.25% dextrose 	<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 	<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
Label Language	Container label is in Chinese. Product identification characteristics are visual in English (Volume, production and expiry date, dextrose concentration, calcium concentration)	English	English

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 US 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 or other safety-related information.

Import Product (Guangzhou, China) 2000 mL DIANEAL Low Calcium	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																				
<p>生产日期 产品批号 有效期至</p> <p>6AB9766 2L (大约80ml 增量)</p> <p>Baxter Dianeal PD-4 双联双袋</p> <p>低钙腹膜透析液(乳酸盐-G1.5%) Low Calcium Peritoneal Dialysis Solution(Lactate-G1.5%)</p> <p>【规格】 含 1.5% 葡萄糖</p> <p>【成份】(本品每100 ml含) 离子浓度 (mmol/L)</p> <table border="0"> <tr> <td>含水葡萄糖</td> <td>1.5 g</td> <td>钠</td> <td>132</td> </tr> <tr> <td>氯化钠</td> <td>538 mg</td> <td>钙</td> <td>1.24</td> </tr> <tr> <td>氯化钙</td> <td>18.3 mg</td> <td>镁</td> <td>0.25</td> </tr> <tr> <td>氯化镁</td> <td>5.1 mg</td> <td>氯</td> <td>95</td> </tr> <tr> <td>乳酸钠</td> <td>448 mg</td> <td>乳酸根</td> <td>40</td> </tr> </table> <p>【性状】本品为无菌、无热原的无色或微黄色的澄明溶液 pH值 5.2 (4.5 至 6.5) 渗透压 (理论值) 344 mOsmol/L 【适应症】低钙腹膜透析液适用于因非透析治疗无效而需要连续不间断性腹膜透析治疗的急性及慢性肾功能衰竭患者 【用法用量】【不良反应】【禁忌】详见说明书 【注意事项】除去外包装后，用均匀的力量挤压透析袋以检查是否存在渗漏，如果一旦发现渗漏，应停止使用此袋溶液。本品应一次性使用，其它详见说明书 【贮藏】密封保存 【批准文号】国药准字H20023569 【上市许可持有人】广州百特医疗用品有限公司 【注册地址】广州经济技术开发区东区丰基工业区燕园路 【生产企业】广州百特医疗用品有限公司 【生产地址】广州经济技术开发区东区丰基工业区燕园路 CONTAINER PL-146 Baxter, Dianeal, 双联双袋及BAXTER INTERNATIONAL INC. 在中国的注册商標</p>	含水葡萄糖	1.5 g	钠	132	氯化钠	538 mg	钙	1.24	氯化钙	18.3 mg	镁	0.25	氯化镁	5.1 mg	氯	95	乳酸钠	448 mg	乳酸根	40	<p>5B9766 2000 mL NDC 041-042-02 (APPROX 80 mL EXCESS)</p> <p>Baxter</p> <p>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>EACH 100 mL CONTAINS: 1.5 g DEXTROSE HYDROUS USP 338 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</p> <p>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</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (20°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> <p>UltraBag 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</p> <p>MADE IN USA US PAT NOS 436049 436733 440186 417390</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 1.5% Dextrose</p>	<p>5B9866 2000 mL NDC 041-042-02 (APPROX 80 mL EXCESS)</p> <p>Baxter</p> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>EACH 100 mL CONTAINS: 1.5 g DEXTROSE HYDROUS USP 338 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 20.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.8 TO 6.5)</p> <p>mEq/L: SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40</p> <p>OSMOLARITY - 345 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</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (20°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> <p>UltraBag 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</p> <p>MADE IN USA US PAT NOS 436049 436733 440186 417390</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">PD-2 1.5% Dextrose</p>
含水葡萄糖	1.5 g	钠	132																			
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乳酸钠	448 mg	乳酸根	40																			

Import Product (Guangzhou, China) 2000 mL DIANEAL Low Calcium	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																				
<p>生产日期</p> <p>产品批号</p> <p>有效期至</p> <p>6AB9776 2L(大约80ml 增量)</p> <p>Baxter Dianeal PD-4 双联双袋</p> <p>低钙腹膜透析液(乳酸盐-G2.5%) Low Calcium Peritoneal Dialysis Solution(Lactate-G2.5%)</p> <p>【规格】 含 2.5% 葡萄糖</p> <p>【成份】(本品每100 ml含) 离子浓度 (mmol/L)</p> <table border="0"> <tr> <td>含水葡萄糖</td> <td>2.5 g</td> <td>钠</td> <td>132</td> </tr> <tr> <td>氯化钠</td> <td>538 mg</td> <td>钙</td> <td>1.24</td> </tr> <tr> <td>氯化钙</td> <td>18.3 mg</td> <td>镁</td> <td>0.25</td> </tr> <tr> <td>氯化镁</td> <td>5.1 mg</td> <td>氯</td> <td>95</td> </tr> <tr> <td>乳酸钠</td> <td>448 mg</td> <td>乳酸根</td> <td>40</td> </tr> </table> <p>【性状】本品为无色、无热原的无色或微黄色的澄明溶液 pH值 5.2 (4.5 至 6.5) 渗透压 (理论值) 395 mOsmol/L 【适应症】低钙腹膜透析液适用于因非透析治疗无效而需要连续不卧床性腹膜透析治疗的急性及慢性肾功能衰竭患者 【用法用量】 【不良反应】 【禁忌】 详见说明书 【注意事项】 除去外袋后，用均匀的力量挤压透析袋以检查是否存在渗漏，如果一旦发现渗漏，应停止使用此袋溶液；本品应一次性使用；其它详见说明书 【贮藏】 密封保存 【批准文号】 国药准字H20023567 【上市许可持有人】 广州百特医疗用品有限公司 【注册地址】 广州经济技术开发区东基工业区燕园路 【生产企业】 广州百特医疗用品有限公司 【生产地址】 广州经济技术开发区东基工业区燕园路 CONTAINER PL-146 Baxter, Dianeal, 双联双袋是BAXTER INTERNATIONAL INC.在中国的注册商标</p>	含水葡萄糖	2.5 g	钠	132	氯化钠	538 mg	钙	1.24	氯化钙	18.3 mg	镁	0.25	氯化镁	5.1 mg	氯	95	乳酸钠	448 mg	乳酸根	40	<p>5B9776 2000 mL NDC 6941-6430-02 (APPROX 90 mL EXCESS)</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)</p> <p>mmol/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 395 mOsmol/L (CALC)</p> <p>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</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR</p> <p>DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>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</p> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA</p> <p>MADE IN USA</p> <p>US PAT NOS 4340049 4346703 4439188 4573980</p>	<p>5B9876 2000 mL NDC 0841-0427-02 (APPROX 90 mL EXCESS)</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 5.06 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)</p> <p>mmol/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 395 mOsmol/L (CALC)</p> <p>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</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR</p> <p>DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>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</p> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA</p> <p>MADE IN USA</p> <p>US PAT NOS 4340049 4346703 4439188 4573980</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">PD-2 2.5% Dextrose</p>
含水葡萄糖	2.5 g	钠	132																			
氯化钠	538 mg	钙	1.24																			
氯化钙	18.3 mg	镁	0.25																			
氯化镁	5.1 mg	氯	95																			
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Import Product (Guangzhou, China) 2000 mL DIANEAL Low Calcium	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																				
<p>生产日期</p> <p>产品批号</p> <p>有效期至</p> <p>6AB9796 2L(大约80ml 增量)</p> <p>Baxter Dianeal PD-4 可纸可袋</p> <p>低钙腹膜透析液(乳酸盐-G4.25%) Low Calcium Peritoneal Dialysis Solution(Lactate-G4.25%)</p> <p>【规格】 含 4.25% 葡萄糖</p> <p>【成份】(本品每100 ml含) 离子浓度 (mmol/L)</p> <table border="0"> <tr> <td>含水葡萄糖</td> <td>4.25 g</td> <td>钠</td> <td>132</td> </tr> <tr> <td>氯化钠</td> <td>538 mg</td> <td>钙</td> <td>1.24</td> </tr> <tr> <td>氯化钙</td> <td>18.3 mg</td> <td>镁</td> <td>0.25</td> </tr> <tr> <td>氯化钾</td> <td>5.1 mg</td> <td>氯</td> <td>95</td> </tr> <tr> <td>乳酸钠</td> <td>448 mg</td> <td>乳酸根</td> <td>40</td> </tr> </table> <p>【性状】 本品为无菌、无热原的无色或微黄色的透明溶液 pH值 5.2 (4.5 至 6.5) 渗透压 (理论值) 483 mOsmol/L 【适应症】 低钙腹膜透析液适用于因非透析治疗无效而需要连续不卧床性腹膜透析治疗的急性及慢性肾功能衰竭患者 【用法用量】 【不良反应】 【禁忌】 详见说明书 【注意事项】 除去外包装后,用均匀的力量挤压透析袋以检查是否存在渗漏,如果一旦发现渗漏,应停止使用此袋溶液; 本品为一次性使用; 其它详见说明书 【贮藏】 密封保存 【批准文号】 国药准字H20023568 【上市许可持有人】 广州百特医疗用品有限公司 【注册地址】 广州经济技术开发区东区东基工业区燕园路 【生产企业】 广州百特医疗用品有限公司 【生产地址】 广州经济技术开发区东区东基工业区燕园路 CONTAINER: PL-146 Baxter, Dianeal, 壹佰及壹佰BAXTER INTERNATIONAL INC.及中国总代理百特</p>	含水葡萄糖	4.25 g	钠	132	氯化钠	538 mg	钙	1.24	氯化钙	18.3 mg	镁	0.25	氯化钾	5.1 mg	氯	95	乳酸钠	448 mg	乳酸根	40	<p>5B9796 2000 mL NDC 6911-0433-52 (APPROX 80 mL EXCESS)</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 (4.9 TO 6.5)</p> <p>mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 483 mOsmol/L (CALC)</p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION</p> <p>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</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (20°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 4573990</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 4.25% Dextrose</p>	<p>5B9896 2000 mL NDC 6941-0429-52 (APPROX 80 mL EXCESS)</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 26.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.9 TO 6.5)</p> <p>mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 485 mOsmol/L (CALC)</p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION</p> <p>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</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (20°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 4573990</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">PD-2 4.25% Dextrose</p>
含水葡萄糖	4.25 g	钠	132																			
氯化钠	538 mg	钙	1.24																			
氯化钙	18.3 mg	镁	0.25																			
氯化钾	5.1 mg	氯	95																			
乳酸钠	448 mg	乳酸根	40																			

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Manufacturing Date

Lot Number

EXP

6AB9766

2L (APPROX 80ml EXCESS)

Baxter

Dianeal PD-4 Ultrabag

Low Calcium Peritoneal Dialysis Solution (Lactate-G1.5%)

[Strengths] Containing 1.5% glucose

[Ingredients] (Each 100 ml contains) Ionic concentration(mmol/L)

Dextrose Hydrous	1.5g	Sodium	132
Sodium Chloride	538mg	Calcium	1.24
Calcium Chloride	18.3mg	Magnesium	0.25
Magnesium Chloride	5.1mg	Chloride	95
Sodium Lactate	448mg	Lactate	40

[Characters]This product is a sterile, Nonpyrogen, Colorless or slightly yellow, Clear solution, pH 5.2 (4.5 to 6.5)

Calculated osmolarity(theoretical value) 344 mOsmol/L

[Indications] Low-calcium peritoneal dialysis solutions are indicated for use in acute and chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate

[Usage and Dosage] [Adverse Reactions]

[Contraindications] See instructions for details

[Precautions] After removing the outer bag, squeeze the dialysis bag with uniform force to check for leakage,

If leakage is found, stop using the solution;

This product should be used once;

For other details, please refer to the instructions

[Storage] Keep sealed

[Approval License Number] GYZZ H20023569

[Approval License Holder] BAXTER HEALTHCARE(GUANGZHOU) Co., Ltd

[Legal Address] Jiaoyuan Road, Dongji industrial District, GETDD,Guangzhou, P.R. China

[Manufacturer] BAXTER HEALTHCARE(GUANGZHOU) Co., Ltd

[Manufacturing Address] Jiaoyuan Road, Dongji industrial District GETDD,Guangzhou, P.R. China

CONTAINER PL-146

Baxter, Dianeal, Ultrabag are registered trademarks of BAXTER INTERNATIONAL INC. in China

Manufacturing Date

Lot Number

EXP

6AB9766 2L (APPROX 80ml EXCESS)

BaxterLogo Dianeal PD-4 Ultrabag

Low Calcium Peritoneal Dialysis Solution (Lactate-G1.5%)

[Strengths]Containing 1.5% glucose

[Ingredients](Each 100 ml contains) Ionic concentration(mmol/L)

Dextrose Hydrous	1.5 g	Sodium	132
Sodium Chloride	538mg	Calcium	1.24
Calcium Chloride	18.3mg	Magnesium	0.25

Magnesium Chloride	5.1mg	Chloride	95
Sodium Lactate	448mg	Lactate	40

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CONTAINER PL-146

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Low Calcium Peritoneal Dialysis Solution (Lactate-G1.5%)

[Specification] Contain 1.5% Dextrose

6AB9766

Lot G0000000 2LX 8 Bags

Manu. Date 0000-00-00 PD-4 UltraBag

Valid in 0000-00



Low Calcium Peritoneal Dialysis Solution (Lactate-G1.5%)

[Specification] Contain 1.5% Dextrose 6AB9766

Lot G00000000 2LX 8 Bags

Manu. Date 0000-00-00 PD-4 UltraBag

Valid in 0000-00

Barcode

6 9 3 7 7 6 5 3 0 0 2 3 3 >

S/N 0000

Manufacturing Date

Lot Number

EXP

6AB9776

2L (APPROX 80ml EXCESS)

Baxter

Dianeal PD-4 UltraBag

Low Calcium Peritoneal Dialysis Solution (Lactate-G2.5%)

[Strengths] Containing 2.5% glucose

[Ingredients] (Each 100 ml contains) Ionic concentration(mmol/L)

Dextrose Hydrous	2.5g	Sodium	132
Sodium Chloride	538mg	Calcium	1.24
Calcium Chloride	18.3mg	Magnesium	0.25
Magnesium Chloride	5.1mg	Chloride	95
Sodium Lactate	448mg	Lactate	40

[Characters] This product is a sterile, Nonpyrogen, Colorless or slightly yellow, Clear solution pH 5.2 (4.5 to 6.5)

Calculated osmolarity(theoretical value) 395 mOsmol/L

[Indications] Low-calcium peritoneal dialysis solutions are indicated for use in acute and chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate

[Usage and Dosage] [Adverse Reactions]

[Contraindications] See instructions for details

[Precautions] After removing the outer bag, squeeze the dialysis bag with uniform force to check for leakage,

If leakage is found, stop using the solution;

This product should be used once;

For other details, please refer to the instructions

[Storage] Keep sealed

[Approval License Number] GYZZ H20023567

[Approval License Holder] BAXTER HEALTHCARE(GUANGZHOU) Co., Ltd

[Legal Address] Jiaoyuan Road, Dongji industrial District, GETDD,Guangzhou, P.R. China

[Manufacturer] BAXTER HEALTHCARE(GUANGZHOU) Co., Ltd

[Manufacturing Address] Jiaoyuan Road, Dongji industrial District GETDD,Guangzhou, P.R. China

CONTAINER PL-146

Baxter, Dianeal, UltraBag are registered trademarks of BAXTER INTERNATIONAL INC. in China

Manufacturing Date

Lot Number

EXP

6AB9776 2L (APPROX 80ml EXCESS)

BaxterLogo Dianeal PD-4 Ultrabag

Low Calcium Peritoneal Dialysis Solution (Lactate-G2.5%)

[Strengths]Containing 2.5% glucose

[Ingredients](Each 100 ml contains) Ionic concentration(mmol/L)

Dextrose Hydrus	2.5 g	Sodium	132
Sodium Chloride	538mg	Calcium	1.24
Calcium Chloride	18.3mg	Magnesium	0.25
Magnesium Chloride	5.1mg	Chloride	95
Sodium Lactate	448mg	Lactate	40

[Characters]This product is a sterile, Nonpyrogen, Colorless or slightly yellow, Clear solution, pH 5.2 (4.5 to 6.5)

Calculated osmolarity(theoretical value) 395 mOsmol/L

[Indications]Low-calcium peritoneal dialysis solutions are indicated for use in acute and chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate

[Usage and Dosage] [Adverse Reactions]

[Contraindications] See instructions for details

[Precautions]After removing the outer bag, squeeze the dialysis bag with uniform force to check for leakage,

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[Manufacturing Address]Jiaoyuan Road, Dongji industrial District GETDD,Guangzhou, P.R. China

CONTAINER PL-146

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Low Calcium Peritoneal Dialysis Solution (Lactate-G2.5%)

[Specification] Contain 1.5% Dextrose

6AB9776

Lot G00000000 2LX 8 Bags

Manu. Date 0000-00-00 PD-4 UltraBag

Valid in 0000-00



Low Calcium Peritoneal Dialysis Solution (Lactate-G2.5%)

[Specification] Contain 1.5% Dextrose 6AB9776

Lot G00000000 2LX 8 Bags

Manu. Date 0000-00-00 PD-4 UltraBag

Valid in 0000-00

Barcode

6 9 3 7 7 6 5 3 0 0 2 4 0 >

S/N 0000

Manufacturing Date

Lot Number

EXP

6AB9796

2L (APPROX 80ml EXCESS)

Baxter

Dianeal PD-4 Ultrabag

Low Calcium Peritoneal Dialysis Solution (Lactate-G4.25%)

[Strengths] Containing 4.25% glucose

[Ingredients] (Each 100 ml contains) Ionic concentration(mmol/L)

Dextrose Hydrous	4.25g	Sodium	132
Sodium Chloride	538mg	Calcium	1.24
Calcium Chloride	18.3mg	Magnesium	0.25
Magnesium Chloride	5.1mg	Chloride	95
Sodium Lactate	448mg	Lactate	40

[Characters] This product is a sterile, Nonpyrogen, Colorless or slightly yellow, Clear solution, pH 5.2 (4.5 to 6.5)

Calculated osmolarity(theoretical value) 483 mOsmol/L

[Indications] Low-calcium peritoneal dialysis solutions are indicated for use in acute and chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate

[Usage and Dosage] [Adverse Reactions]

[Contraindications] See instructions for details

[Precautions] After removing the outer bag, squeeze the dialysis bag with uniform force to check for leakage, If leakage is found, stop using the bag solution;

This product should be used once;

For other details, please refer to the instructions

[Storage] Keep sealed

[Approval License Number] GYZZ H20023568

[Approval License Holder] BAXTER HEALTHCARE(GUANGZHOU) Co., Ltd

[Legal Address] Jiaoyuan Road, Dongji industrial District, GETDD, Guangzhou, P.R. China

[Manufacturer] BAXTER HEALTHCARE(GUANGZHOU) Co., Ltd

[Manufacturer Address] Jiaoyuan Road, Dongji industrial District GETDD, Guangzhou, P.R. China

CONTAINER PL-146

Baxter, Dianeal, Ultrabag are registered trademarks of BAXTER INTERNATIONAL INC. in China

Manufacturing Date

Lot Number

EXP

6AB9796 2L (APPROX 80ml EXCESS)

BaxterLogo Dianeal PD-4 Ultrabag

Low Calcium Peritoneal Dialysis Solution (Lactate-G4.25%)

[Strengths] Containing 4.25% glucose

[Ingredients] (Each 100 ml contains) Ionic concentration(mmol/L)

Dextrose Hydrous	4.25 g	Sodium	132
Sodium Chloride	538mg	Calcium	1.24

Calcium Chloride	18.3mg	Magnesium	0.25
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Sodium Lactate	448mg	Lactate	40

[Characters]This product is a sterile, Nonpyrogen, Colorless or slightly yellow, Clear solution, pH 5.2 (4.5 to 6.5)

Calculated osmolarity(theoretical value) 483 mOsmol/L

[Indications]Low-calcium peritoneal dialysis solutions are indicated for use in acute and chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate

[Usage and Dosage] [Adverse Reactions]

[Contraindications] See instructions for details

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For other details, please refer to the instructions

[Storage]Keep sealed

[Approval License Number]GYZZ H20023568

[Approval License Holder]BAXTER HEALTHCARE(GUANGZHOU) Co., Ltd

[Legal Address]Jiaoyuan Road, Dongji industrial District, GETDD, Guangzhou, P.R. China

[Manufacturer]BAXTER HEALTHCARE(GUANGZHOU) Co., Ltd

[Manufacturing Address]Jiaoyuan Road, Dongji industrial District GETDD,Guangzhou, P.R. China

CONTAINER PL-146

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Low Calcium Peritoneal Dialysis Solution (Lactate-G4.25%)

[Specification] Contain 1.5% Dextrose

6AB9796

Lot G00000000 2L X 8 Bags

Manu. Date 0000-00-00 PD-4 UltraBag

Valid in 0000-00



Low Calcium Peritoneal Dialysis Solution (Lactate-G4.25%)

[Specification] Contain 1.5% Dextrose 6AB9796

Lot G00000000 2LX 8 Bags

Manu. Date 0000-00-00 PD-4 UltraBag

Valid in 0000-00

Barcode

6 9 3 7 7 6 5 3 0 0 2 5 7 >

S/N 0000

DIANEAL LOW CALCIUM WITH DEXTROSE

sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0941-0686
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7R0OK)	DEXTROSE MONOHYDRATE	1.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	538 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	SODIUM LACTATE	448 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	18.3 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0686-08	8 in 1 CARTON	11/01/2024	11/30/2026
1	NDC:0941-0686-01	2000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		11/01/2024	11/30/2026

DIANEAL LOW CALCIUM WITH DEXTROSE

sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0941-0690
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	2.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	538 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	SODIUM LACTATE	448 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	18.3 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0690-08	8 in 1 CARTON	11/01/2024	09/30/2026
1	NDC:0941-0690-01	2000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Marketing Category	Monograph Citation	Date	Date
Unapproved drug for use in drug shortage		11/01/2024	09/30/2026

DIANEAL LOW CALCIUM WITH DEXTROSE

sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0941-0694
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	4.25 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	538 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	SODIUM LACTATE	448 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	18.3 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0694-08	8 in 1 CARTON	11/01/2024	09/30/2026
1	NDC:0941-0694-01	2000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		11/01/2024	09/30/2026

Labeler - Vantive US Healthcare LLC (119181963)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare (Guangzhou) Co., Ltd		421040114	manufacture(0941-0686, 0941-0690, 0941-0694) , analysis(0941-0686, 0941-0690, 0941-0694) , label(0941-0686, 0941-0690, 0941-0694) , pack(0941-0686, 0941-0690, 0941-0694) , sterilize(0941-0686, 0941-0690, 0941-0694)

Revised: 5/2025

Vantive US Healthcare LLC