

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 22, 2024

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

Dear Healthcare Professional,

Due to a potential shortage of DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution in the United States (US) market, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import DIANEAL PD-4 Low Calcium Peritoneal Dialysis Solution (2000 mL) from Baxter's manufacturing facility in Amata, Thailand. FDA has not approved these products manufactured by Baxter's Amata, Thailand facility.

You may be provided with additional letters for other DIANEAL imported peritoneal dialysis solutions you receive. Please read each letter in its entirety because each letter may contain different, product-specific information.

Baxter has initiated temporary importation of DIANEAL PD-4 Low Calcium Peritoneal Dialysis solution for use in Continuous Ambulatory Peritoneal Dialysis (CAPD) therapy as described in the table below. This product is manufactured by Baxter's manufacturing facility in Amata, Thailand and is marketed in Thailand and India. At this time, importation or distribution of DIANEAL PD-4 Low Calcium Peritoneal Dialysis solution in the United States, by any entity other than Baxter or its authorized distributor(s) is considered a violation of the Federal Food, Drug, and Cosmetic Act and is subject to enforcement by the FDA.

Effective immediately, and during this temporary period, Baxter will offer the following imported products from Baxter's facility in Amata, Thailand:

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

It is important to note the following:

- DIANEAL PD-4 Low Calcium Peritoneal Dialysis Solution contains 1.25 mmol/L (2.5 mEq/L) of calcium compared to DIANEAL PD-2 Peritoneal Dialysis Solution with Dextrose which contains 1.75 mmol/L (3.5 mEq/L) of calcium. Patients receiving Thailand-imported DIANEAL solution should have their serum calcium levels monitored for the development of hypocalcemia.

- There are no other clinically relevant differences in the DIANEAL drug composition between the US-manufactured and Thailand-manufactured product (see Table 1, below). As such, clinical practice for usage, administration, and dosage for the Thailand imported products is the same as with the DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose manufactured in US. Please refer to the FDA-approved DIANEAL Peritoneal Dialysis Solution with Dextrose Full Prescribing Information for reference.
- The DIANEAL PD-4 Low Calcium Peritoneal Dialysis Solution with Dextrose imported from Thailand will only be available in 2000 mL fill volume for CAPD so there will be a need to adapt the PD prescription for some patients.
- The Luer-lock connector on the Thailand imported product functions the same as and is fully compatible with peritoneal dialysis sets marketed in the United States. The Thailand imported product has a single green frangible near the Y connector which is broken at the same time during flush phase as the corresponding blue frangible in US product. **There is an online clamp on the drain line in Thailand-imported product, so patients only need to use one external clamp on the infusion line compared to two external clamps for US product.** See Table 1 for more details of product differences.
- The Thailand imported product include barcodes on the shipping carton; however, the **barcodes may not register accurately in the US scanning systems.** There are no barcodes on the solution containers of the imported product. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients. For example, institutions should consider manually inputting the product into their systems and confirm that barcode systems do not provide incorrect information when the product is scanned.
- DIANEAL Low Calcium Peritoneal Dialysis Solutions are available only by prescription in the U.S. However, the imported products do not have the statement "Rx only" on the labeling. The shipping carton labels include both English and Thai language.

Before prescribing, healthcare providers should be aware of some key differences in the container packaging and labeling between the Thailand imported product and FDA approved product which are stated in the product comparison tables at the end of this letter as follows:

- Table 1: Key differences of DIANEAL Peritoneal Dialysis Solution for CAPD therapy
- Table 2: Label images of DIANEAL 2000 mL CAPD product presentations

Reporting Adverse Events

To report adverse events associated with these imported products, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of these imported products may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **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.

If you have any questions about the information contained in this letter or the use of imported DIANEAL Low Calcium Peritoneal Dialysis Solution, please contact Baxter's Medical Information Service at 1-888-736-2543.

To place an order, please contact Baxter's Center for Home Care Services by calling 1-800-284-4060.

Sincerely,

Geovana Basso
Electronically signed by:
Geovana Basso
Reason: OK
Date: Oct 22, 2024 09:28
CDT

Geovana Basso, M.D.
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

	Thailand Imported Product DIANEAL PD-4 Low Calcium	US FDA-Approved Product DIANEAL Low Calcium	US FDA-Approved Product DIANEAL PD-2
Product name	DIANEAL PD-4 Low Calcium with 1.5% Dextrose DIANEAL PD-4 Low Calcium with 2.5% Dextrose DIANEAL PD-4 Low Calcium with 4.25% Dextrose	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose
Labeled Fill Volume	2000 mL	1500 mL 2000 mL 2500 mL 3000 mL	2000 mL 2500 mL 3000 mL
Container Type	TwinBag containers (PVC)	UltraBag Container (PVC)	UltraBag Container (PVC)
Bags per carton	6	1500 mL: 8 2000 mL: 6 2500 mL: 5 3000 mL: 4	2000 mL: 6 2500 mL: 5 3000 mL: 4
Indications	1.5% and 2.5% Dextrose: Dianeal PD-4 Peritoneal dialysis solutions is indicated for use in chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate 4.25% Dextrose: Dianeal Peritoneal dialysis solutions in TwinBag containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.	DIANEAL peritoneal dialysis solutions are indicated for patients in acute or chronic renal failure.	DIANEAL peritoneal dialysis solutions are indicated for patients in acute or chronic renal failure.
Active Ingredients -Dextrose	1.5% Dextrose: Dextrose Hydrus, USP 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrus, USP 2.5 g / 100 mL 4.25% Dextrose: Dextrose Hydrus 4.25 g / 100 mL	1.5% Dextrose: Dextrose Hydrus, USP 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrus, USP 2.5 g / 100 mL 4.25% Dextrose: Dextrose Hydrus, USP 4.25 g / 100 mL	1.5% Dextrose: Dextrose Hydrus, USP 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrus, USP 2.5 g / 100 mL 4.25% Dextrose: Dextrose Hydrus, USP 4.25 g / 100 mL
Active Ingredient - Electrolytes	Sodium Chloride, USP 538 mg / 100 mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 18.3 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL	Sodium Chloride, USP 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 18.3 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL	Sodium Chloride, USP 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 25.7 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL
Electrolyte Content per Liter	Sodium 132 mEq/L Calcium 2.5 mEq/L Magnesium 0.5 mEq/L Chloride 95 mEq/L Lactate 40 mEq/L	Sodium 132 mEq/L Calcium 2.5 mEq/L Magnesium 0.5 mEq/L Chloride 95 mEq/L Lactate 40 mEq/L	Sodium 132 mEq/L Calcium 3.5 mEq/L Magnesium 0.5 mEq/L Chloride 96 mEq/L Lactate 40 mEq/L

	Thailand Imported Product DIANEAL PD-4 Low Calcium	US FDA-Approved Product DIANEAL Low Calcium	US FDA-Approved Product DIANEAL PD-2
pH	<p>1.5% Dextrose & 2.5% Dextrose: 5.2 (4.0 to 6.5)</p> <p>4.25% Dextrose 5.2 (4.5 to 6.5)</p>	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>
Storage Conditions	Store below 30°C	Store at room temperature (25°C/77°F) Brief exposure up to 40°C does not adversely affect the product.	Store at room temperature (25°C/77°F) Brief exposure up to 40°C does not adversely affect the product.
Expiration Dating	24 months	18 months	18 months
Container Closure System			
Container Closure Differences	<ul style="list-style-type: none"> Only one green frangible near the Y connector broken before FLUSH. There is one in-line clamp on the drain line. One other external clamp will be needed. Solution line contains fluid. Pull ring cap is 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 Two external clamps are needed. Solution line does not contain fluid. Pull ring cap is 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 Two external clamps are needed Solution line does not contain fluid Pull ring cap is color-coded to solution dextrose concentration: <ul style="list-style-type: none"> Yellow = 1.5% dextrose Green = 2.5% dextrose Red = 4.25% dextrose

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

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

<p>Thailand Imported Product DIANEAL PD-4 Low Calcium 2,000 mL</p>	<p>US FDA-Approved Product DIANEAL Low Calcium PD Solution</p>	<p>US FDA-Approved Product DIANEAL PD-2 PD Solution</p>
<p style="text-align: right;">THB9766 2000 ml</p> <p>Baxter</p> <p>Dianeal® PD-4 Low Calcium 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 (4.9 TO 6.5) mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40 OSMOLARITY 344 mOsm/L(CALC) STERILE NON PYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION KEEP OUT OF REACH OF CHILDREN AVOID EXCESSIVE HEAT SEE INSERT INDICATED FOR CHRONIC RENAL FAILURE PATIENTS BEING MAINTAINED ON PERITONEAL DIALYSIS DIRECTION TO BE USED AS DIRECTED BY THE PHYSICIAN</p> <p>STORAGE BELOW 30°C REG NO. JA 1259 THS1107</p> <p>MANUFACTURED BY: BAXTER MANUFACTURING (THAILAND) CO. LTD. RAYONG, THAILAND</p>	<p>5B9766 2000 mL (APPROX 90 mL EXCESS) NDC 581-905-02</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 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)) mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 344 mOsm/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</p> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4340049 4346703 4420188 4579980</p>	<p>5B9866 2000 mL (APPROX 90 mL EXCESS) NDC 581-905-02</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 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP (pH 5.2 (4.9 TO 6.5)) mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 348 mOsm/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</p> <p>BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4340049 4346703 4420188 4579980</p>

Low Calcium 1.5% Dextrose

PD-2 1.5% Dextrose

<p>Thailand Imported Product DIANEAL PD-4 Low Calcium 2,000 mL</p>	<p>US FDA-Approved Product DIANEAL Low Calcium PD Solution</p>	<p>US FDA-Approved Product DIANEAL PD-2 PD Solution</p>
<p style="text-align: right;">THB9776 2000 mL</p> <p>Baxter</p> <p>Dianeal® PD-4 Low Calcium with 2.5% Dextrose</p> <p>EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP 536 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE DIHYDRATE USP 5.38 mg MAGNESIUM CHLORIDE HEXAHYDRATE USP pH 5.2 (4.0 TO 6.5) mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40 OSMOLALITY 395 mOsmol/L(CALC) STERILE NON PYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION KEEP OUT OF REACH OF CHILDREN AVOID EXCESSIVE HEAT SEE INSERT INDICATED FOR CHRONIC RENAL FAILURE PATIENTS BEING MAINTAINED ON PERITONEAL DIALYSIS</p> <p>DIRECTION TO BE USED AS DIRECTED BY THE PHYSICIAN STORAGE BELOW 30°C</p> <p>REG NO. 2A 95/59 THRS1109 </p> <p>MANUFACTURED BY: BAXTER MANUFACTURING (THAILAND) CO., LTD. RAYONG, THAILAND</p>	<p style="text-align: right;">5B9776   2000 mL NDC 0941-0430-32 (APPROX 95 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 536 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE USP 5.38 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 OSMOLALITY - 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</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 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 4348049 4348703 4439188 4573980</p>	<p style="text-align: right;">5B9876   2000 mL NDC 0941-0421-32 (APPROX 95 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 536 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 3.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5) mEq/L SODIUM - 132 CALCIUM - 1.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLALITY - 391 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</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 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 4348049 4348703 4439188 4573980</p>

Low Calcium 2.5% Dextrose

PD-2 2.5% Dextrose

<p>Thailand Imported Product DIANEAL PD-4 Low Calcium 2,000 mL</p>	<p>US FDA-Approved Product DIANEAL Low Calcium PD Solution</p>	<p>US FDA-Approved Product DIANEAL PD-2 PD Solution</p>
<p>Baxter THB9796IP 2000 ml</p> <p>Peritoneal Dialysis Solution Low Calcium with 4.25% Dextrose-IP Dianeal® PD-4 Low Calcium</p> <p>EACH 1000 mL CONTAINS: 4.25 g DEXTROSE HYDROUS USP 538 mg SODIUM CHLORIDE 448 mg SODIUM LACTATE 19.3 mg CALCIUM CHLORIDE DIHYDRATE 5.38 mg MAGNESIUM CHLORIDE HEXAHYDRATE pH 5.2 (4.5 TO 6.5) mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40 OSMOLARITY 483 mOsmol/L (CALC) STERILE NON PYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>FOR INTRAPERITONEAL ADMINISTRATION ONLY CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION KEEP OUT OF REACH OF CHILDREN AVOID EXCESSIVE HEAT INDICATED FOR CHRONIC RENAL FAILURE PATIENTS BEING MAINTAINED ON PERITONEAL DIALYSIS</p> <p>INDICATIONS, ADMINISTRATION AND COMPLETE INFORMATION - REFER PACKAGE INSERT</p> <p>STORAGE: 18°C (63°F) - 25°C (77°F) SHA RES NO. 2A 50759 THB97132 (A)</p> <p>NAME AND ADDRESS OF MANUFACTURER: BAXTER MANUFACTURING (THAILAND) CO. LTD. 7398 MOO 8 MAEYANGPORN, PLUMKADANG, RAYONG, THAILAND 21140</p> <p>Name and Address of Importer: Baxter (India) Pvt. Ltd. No. 279-1A, 1B, 255/42B, Block C, Ground Floor, Gulshan, 4th Avenue, Opposite to Vegetarian Village, Madhavaram Red Hills Road Puzhal village, Ambattur Taluk, Tiruvallur District, Chennai - 600060 Tamil Nadu, India</p> <p>Import License Number: ILFF-000400 RC/FF-002173</p> <p>Telephone no., email address (in case of consumer complaint, Safety Reporting or Queries): Consumer Care No.: 0124-4020200 Consumer Care email ID: Customerservice_SHS_india@baxter.com</p>	<p>5B9796 2000 mL SEC 991-0413-52 (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 19.3 mg CALCIUM CHLORIDE USP 5.38 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</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</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 (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</p> <p>US PAT NOS 4360849 4346783 4439188 4573680</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 4.25% Dextrose</p>	<p>5B9896 2000 mL MOC 991-0429-52 (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 25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.5 TO 6.5) mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 95 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</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</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 (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</p> <p>US PAT NOS 4360849 4346783 4439188 4573680</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">PD-2 4.25% Dextrose</p>

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL



Baxter

THB9766



2000 ml

**Dianeal® PD-4 Low Calcium
with 1.5% Dextrose**

EACH 100ml CONTAINS 1.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
18.3 mg CALCIUM CHLORIDE USP
5.08 mg MAGNESIUM CHLORIDE USP
pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95
LACTATE 40 **OSMOLARITY** 344 mOsmol/L(CALC)
STERILE NON PYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY
CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION

KEEP OUT OF REACH OF CHILDREN
AVOID EXCESSIVE HEAT SEE INSERT
INDICATED FOR CHRONIC RENAL FAILURE PATIENTS
BEING MAINTAINED ON PERITONEAL DIALYSIS
DIRECTION TO BE USED AS DIRECTED BY THE PHYSICIAN

STORAGE BELOW 30°C
MANUFACTURED BY: **BAXTER MANUFACTURING (THAILAND) CO., LTD.**
REG NO. 2A 12/59 THRS1107 (BH)
RAYONG, THAILAND

BaxterLogo

THB9766

2000 ml

Dianeal® PD-4 Low Calcium
with 1.5% Dextrose

EACH 100ml CONTAINS1.5 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
pH5.2 (4.0 to 6.5)
mEq/LSODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95
LACTATE 40 **OSMOLARITY**344 mOsmol/L(CALC)
STERILE NON PYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY
CAUTIONSSQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION

KEEP OUT OF REACH OF CHILDREN
AVOID EXCESSIVE HEAT SEE INSERT

pH 5.2 (4.0-6.5)

Reg No. 2A 12/59

Manufacturing by
Baxter Manufacturing (Thailand) Co., Ltd.
Rayong, Thailand

Sterile, Nonpyrogenic Solution
Store below 30°C

Batch No. A20A007

MFD. 7 Jan 2020

EXP. 7 Jan 2022

Barcode

00002

(01)50085412528217(10)A20A007(17)220107

 **Baxter** THB9776
2000 ml

**Dianeal® PD-4 Low Calcium
with 2.5% Dextrose**

EACH 100 ml CONTAINS 2.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg
CALCIUM CHLORIDE DIHYDRATE USP 5.08 mg MAGNESIUM
CHLORIDE HEXAHYDRATE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95
LACTATE 40 **OSMOLARITY** 395 mOsmol/L(CALC)
STERILE NON PYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY
CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION KEEP OUT OF REACH OF CHILDREN
AVOID EXCESSIVE HEAT SEE INSERT
INDICATED FOR CHRONIC RENAL FAILURE PATIENTS
BEING MAINTAINED ON PERITONEAL DIALYSIS

DIRECTION TO BE USED AS DIRECTED BY THE PHYSICIAN
STORAGE BELOW 30°C

REG NO. 2A 95/59 THRS1109 

MANUFACTURED BY:
BAXTER MANUFACTURING (THAILAND) CO., LTD.
RAYONG, THAILAND

BaxterLogo

THB9776

2000 ml

Dianeal® PD-4 Low Calcium
with 2.5% Dextrose

EACH 100 ml CONTAINS 2.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg
CALCIUM CHLORIDE DIHYDRATE USP 5.08 mg MAGNESIUM

CHLORIDE HEXAHYDRATE USP **pH**5.2 (4.0 to 6.5)
mEq/LSODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95
LACTATE 40 **OSMOLARITY**395 mOsmol/L(CALC)
STERILE NON PYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY

CAUTIONSSQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION KEEP OUT OF REACH OF CHILDREN

AVOID EXCESSIVE HEAT SEE INSERT
INDICATED FOR CHRONIC RENAL FAILURE PATIENTS
BEING MAINTAINED ON PERITONEAL DIALYSIS

DIRECTIONTO BE USED AS DIRECTED BY THE PHYSICIAN
STORAGEBELOW 30°C

REG NO.2A 95/59
THRS1109
BG Symbol

MANUFACTURED BY:
BAXTER MANUFACTURING (THAILAND) CO. LTD.
RAYONG, THAILAND

น้ำยาล้างไตทางช่องท้อง
2.5% เดกซ์โทรส พีดี-4 แคลเซียมต่ำ

PD-4
2.5%
เดกซ์โทรส

Dianeal PD-4 Low Calcium with 2.5% Dextrose

THB9776

6 X 2000 mL

Each 100 ml contains

Sterile, Nonpyrogenic Solution

Dextrose Hydrus USP 2.5 g

Store below 30 °C

Sodium Chloride USP 538 mg

กรุณาหลีกเลี่ยงแสงแดด

Sodium Lactate 448 mg

เก็บไว้ที่อุณหภูมิต่ำกว่า 30 องศาเซลเซียส

Calcium Chloride Dihydrate USP 18.3 mg

Batch No. **A20A023**

Magnesium Chloride Hexahydrate USP 5.08 mg

pH 5.2 (4.0-6.5) Reg No. 2A 95/59

MFD. **10 Jan 2020**

Manufacturing by

EXP. **10 Jan 2022**

Baxter Manufacturing (Thailand) Co., Ltd.

ยาสำเนา

Rayong, Thailand



00001

ขายในตรา

PD-4

2.5%

Dianeal PD-4 Low Calcium with 2.5% Dextrose

THB9776

6 X 2000 mL

Each 100 ml contains

Dextrose Hydrus USP 2.5 g

Sodium Chloride USP 538 mg

Sodium Lactate 448 mg

Calcium Chloride Dihydrate USP 18.3 mg

Magnesium Chloride Hexahydrate USP 5.08 mg

pH 5.2 (4.0-6.5)

Reg No. 2A 95/59

Manufacturing by

Baxter Manufacturing (Thailand) Co., Ltd.

Rayong, Thailand

Sterile, Nonpyrogenic Solution

Store below 30°C

Batch No. A20A023

MFD. 10 Jan 2020

EXP. 10 Jan 2022

Barcode
00001

(01)500854 12528224(10)A20A023(17)220110



Peritoneal Dialysis Solution Low Calcium with 4.25% Dextrose-IP

Dianeal® PD-4 Low Calcium

EACH 100ml CONTAINS 4.25 g DEXTROSE HYDROUS 538 mg SODIUM CHLORIDE
448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE DIHYDRATE 5.08 mg
MAGNESIUM CHLORIDE HEXAHYDRATE **pH 5.2 (4.5 TO 6.5) mEq/L**
SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40
OSMOLARITY 483 mOsmol/L(CALC) STERILE NON PYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN

FOR INTRAPERITONEAL ADMINISTRATION ONLY

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION
KEEP OUT OF REACH OF CHILDREN AVOID EXCESSIVE HEAT
INDICATED FOR CHRONIC RENAL FAILURE PATIENTS
BEING MAINTAINED ON PERITONEAL DIALYSIS

INDICATION/ADMINISTRATION AND COMPLETE INFORMATION – REFER PACKAGE INSERT

STORAGE BELOW 30°C THA REG NO. 2A 93/59

THRS1131 (AA)

NAME AND ADDRESS OF MANUFACTURER:

BAXTER MANUFACTURING (THAILAND) CO.,LTD.
7/398 MOO 6 MABYANGPORN, PLUAKDAENG, RAYONG, THAILAND 21140

Name and Address of Importer:

Baxter (India) Pvt. Ltd., No. 219-1A, 1B,225/4B, Block C, Ground Floor,
Kothari ware house, Opposite to Vegetarian Village, Madhavaram
Red Hills Road Puzhal village, Ambattur Taluk, Tiruvallur District,
Chennai - 600060 Tamil Nadu, India

Import License Number: IL/FF-000400 RC/FF-002173

Telephone no., email address (in case of consumer complaint, Safety Reporting or Queries):

Consumer Care No.: 0124-4603200

Consumer Care email ID: Customerservice_SHS_India@baxter.com

BaxterLogo
THB9796IP
2000 ml

Peritoneal Dialysis Solution Low Calcium with
4.5% Dextrose-IP
Dianeal® PD-4 Low Calcium

EACH 100 ml CONTAINS4.25 g DEXTROSE HYDROUS 538 mg SODIUM CHLORIDE
448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE DIHYDRATE 5.08 mg
MAGNESIUM CHLORIDE HEXAHYDRATE **pH5.2 (4.5 to 6.5) mEq/L**
SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40
OSMOLARITY483 mOsmol/L(CALC) STERILE NON PYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN

FOR INTRAPERITONEAL ADMINISTRATION ONLY

CAUTIONSSQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION

KEEP OUT OF REACH OF CHILDREN AVOID EXCESSIVE HEAT
INDICATED FOR CHRONIC RENAL FAILURE PATIENTS
BEING MAINTAINED ON PERITONEAL DIALYSIS

**INDICATION/ADMINISTRATION AND COMPLETE INFORMATION -REFER PACKAGE
INSERT**

STORAGEBELOW 30°C
THA REG NO.2A 93/59
THRS1131
AA Symbol

NAME AND ADDRESS OF MANUFACTURER:
BAXTER MANUFACTURING (THAILAND) CO., LTD.
7/398 MOO 6 MABYANGPORN, PLUAKDAENG, RAYONG, THAILAND 21140

Name and Address of Importer:
Baxter (India) Pvt. Ltd., No. 219-1A, 1B,225/4B, Block C, Ground Floor,
Kothari ware house, Opposite to Vegetarian Village, Madhavaram
Red Hills Road Puzhal village, Ambattur Taluk, Tiruvallur District,
Chennai - 600060 Tamil Nadu, India

Import License Number:IL/FF-000400 RC/FF-002173

Telephone no., email address (in case of consumer complaint, Safety Reporting or
Queries):

Consumer Care No.: 0124-4603200

Consumer Care email ID: Customerservice_SHS_India@baxter.com

**PERITONEAL DIALYSIS SOLUTION LOW
CALCIUM WITH 4.25 % DEXTROSE-IP**

**PD-4
4.25%
DEXTROSE**

(Dianeal® PD-4)
THB9796IP

Each 100 ml contains
Dextrose Hydrous 4.25 g
Sodium Chloride 538 mg
Sodium Lactate 448 mg
Calcium Chloride Dihydrate 18.3 mg
Magnesium Chloride Hexahydrate 5.08 mg

pH 5.2 (4.5-6.5)

Manufactured by
BAXTER MANUFACTURING (THAILAND) CO.,LTD.,
7/398 MOO 6 MABYANGPORN, PLUAKDAENG,
RAYONG, THAILAND, 21140
NAME AND ADDRESS OF IMPORTER:
Baxter (India) Pvt. Ltd. No. 219-1A, 1B,225/4B, Block C,
Ground Floor, Kothari ware house, Opposite to Vegetarian Village,
Madhavaram Red Hills Road Puzhal village, Ambattur Taluk,
Tiruvallur District, Chennai - 600060 TAMILNADU, India

IMPORT LICENSE NUMBER: IL/FF-000400 RC/FF-002173

Sterile, Nonpyrogenic Solution

Store below 30 °C

Batch No. A99M999

Mfg.Date 99 Mar 9999

Exp.Date 99 Mar 9999

MRP Rs. 9999.99(incl. of all taxes)

Net Quantity - 6 U X 2000 mL.

NAME, ADDRESS, TELEPHONE NO., EMAIL ADDRESS
(IN CASE OF CONSUMER COMPLAINT, SAFETY REPORTING OR QUERIES):
Baxter (India) Private Limited, 5th Floor, Tower A, Building No. 9,
DLF Cyber City, DLF Phase III, Gurgaon -122002/ Haryana, India
Consumer Care No.: 0124-4603200
Consumer Care email ID: Customerservice_SHS_India@baxter.com

Rev.01



(01)8859656197969(01)X21SXXX(17)231120

00001

PEITONEAL DIALYSIS SOLUTION LOW

CALCIUM WITH 4.25% DEXTROSE-IP

PD-4
4.25%
DEXTROSE

(Dianeal® PD-4)
THB9796IP

Each 100 ml contains
Dextrose Hydrous 4.25 g
Sodium Chloride 538 mg
Sodium Lactate 448 mg
Calcium Chloride Dihydrate 18.3 mg
Magnesium Chloride Hexahydrate 5.08 mg

pH 5.2 (4.5-6.5)

Manufactured by
BAXTER MANUFACTURING (THAILAND) CO., LTD.,
7/398 MOO 6 MABYANGPORN, PLUAKDAENG,
RAYONG, THAILAND, 21140

NAME AND ADDRESS OF IMPORTER:

Baxter (India) Pvt. Ltd. No. 219-1A, 1B, 225/4B, Block C,
Ground Floor, Kothari ware house, Opposite to Vegetarian Village,
Madhavaran Red Hills Road Puzhal village, Ambattur Taluk,
Tiruvallur District, Chennai – 600060 TAMILNADU, India

IMPORT LICENSE NUMBER: IL/FF-000400 RC/RF-002173

Sterile, Nonpyrogenic Solution
Store below 30°C

Batch No. A99A999
MFD. 99 Mar 9999
EXP. 99 Mar 9999

MRP Rs. 9999.99(incl. of all taxes)
Net Quality – 6 U X 2000 mL.

NAME, ADDRESS, TELEPHONE NO., EMAIL ADDRESS
(IN CASE OF CONSUMER COMPLAINT, SAFETY REPORTING OR QUERIES):

Baxter (India) Private Limited, 5thFloor, Tower A, Building No. 9,
DLF Cyber City, DLF Phase III, Gurgaon – 122002/ Haryana, India
Consumer Care No.: 0124-4603200
Consumer Care email ID: Customerservice_SHS_India@baxter.com
Rev.01

Barcode
00001

(01)8859656197969(10)X21SXXX(17)231120

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:0941-0711
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	1.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, 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	5.08 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:0941-0711-06	6 in 1 CARTON	10/23/2024	10/17/2026
1	NDC:0941-0711-01	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		10/23/2024	10/17/2026

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:0941-0713
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Route of Administration	INTRAPERITONEAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7R0OK)	DEXTROSE MONOHYDRATE	2.5 g in 100 mL	
	SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, 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	5.08 mg in 100 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KOOR)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0713-06	6 in 1 CARTON	10/23/2024	10/15/2026
1	NDC:0941-0713-01	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		10/23/2024	10/15/2026	

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:0941-0715
Route of Administration	INTRAPERITONEAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7R00K)	DEXTROSE MONOHYDRATE	4.25 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, 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	5.08 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:0941-0715-06	6 in 1 CARTON	10/23/2024	04/21/2025
1	NDC:0941-0715-01	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		10/23/2024	04/21/2025

Labeler - Vantive US Healthcare LLC (119181963)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Manufacturing (Thailand) Co., Ltd		661742706	analysis(0941-0711, 0941-0713, 0941-0715) , manufacture(0941-0711, 0941-0713, 0941-0715) , label(0941-0711, 0941-0713, 0941-0715) , pack(0941-0711, 0941-0713, 0941-0715) , sterilize(0941-0711, 0941-0713, 0941-0715)

Revised: 5/2025

Vantive US Healthcare LLC