

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: November 4, 2024

Subject: Temporary importation of DIANEAL PD4 Glucose Solutions for Peritoneal Dialysis from Ireland for use in Automated 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 in the United States (US) market, Baxter Healthcare Corporation (Baxter) is coordinating with the US Food and Drug Administration (FDA) to temporarily import DIANEAL PD4 Glucose Solution for Peritoneal Dialysis from Baxter's manufacturing facility in Castlebar, Ireland. FDA has not approved this product manufactured by Baxter's Castlebar, Ireland 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 PD4 Glucose Solution for Peritoneal Dialysis for use in Automated Peritoneal Dialysis (APD) therapy as described in the table below. This product is manufactured by Baxter's manufacturing facility in Castlebar, Ireland and is marketed in the United Kingdom and other countries within the European Union (EU). At this time, importation or distribution of DIANEAL 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 Castlebar, Ireland:

Product Name and Description	APD Container Volume	Product Code	Bags per Carton	NDC Code
DIANEAL PD4 Glucose 1.36% w/v / 13.6 mg/mL Solution for Peritoneal Dialysis	2500 mL	FPB9718R	4 bags	NDC 0941-0733-01 (bag) NDC 0941-0733-04 (carton)
DIANEAL PD4 Glucose 2.27% w/v / 22.7 mg/mL Solution for Peritoneal Dialysis	2500 mL	FPB9728R	4 bags	NDC 0941-0735-01 (bag) NDC 0941-0735-04 (carton)

Throughout this document, there are references to Vantive and associated legal entities. The Vantive business is comprised of several legal entities, which collectively hold substantially all of Baxter's renal/kidney care and acute therapies businesses. These legal entities – and the global Vantive business – are wholly-owned (directly or indirectly) by Baxter International Inc., Baxter's ultimate parent entity.

It is important to note the following:

- **DIANEAL PD4 Glucose Solution for Peritoneal Dialysis contains 1.25 mmol/L (2.5mEq/L) of calcium compared to DIANEAL PD-2 Peritoneal Dialysis Solution with Dextrose which contains 1.75 mmol/L (3.5 mEq/L).** Patients receiving Castlebar-imported DIANEAL solution should have their serum calcium levels monitored for the development of hypocalcemia.
- DIANEAL PD4 Glucose Solution for Peritoneal Dialysis manufactured in Ireland are labeled to reflect glucose anhydrous content of 1.36% and 2.27%. DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose are labeled to reflect dextrose hydrous content of 1.5% and 2.5%. These solutions have identical dextrose concentrations for clinical use and boxes are color coded in the same way – yellow (1.36%/1.5%) and green (2.27%/2.5%).
- There are no other clinically relevant differences in the drug composition between the Ireland-manufactured DIANEAL PD4 Glucose Solutions for Peritoneal Dialysis and U.S.-manufactured DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution (see Table 1, below). As such, clinical practice for usage, administration, and dosage for DIANEAL PD4 Glucose APD solution (manufactured in Ireland) products is the same as with DIANEAL PD-2 and DIANEAL Low Calcium (2.5 MEQ/L) with Dextrose (manufactured in US). Please refer to the FDA-approved DIANEAL Peritoneal Dialysis Solution Prescribing Information for reference.
- DIANEAL PD4 Glucose Solution for Peritoneal Dialysis imported from Ireland will only be available in 2500 mL volume for APD, so there will be a need to adapt the PD prescription for some patients.
- The Luer-lock connector on the Ireland imported product functions the same as and is fully compatible with peritoneal dialysis sets marketed in the United States. However, the FDA-approved product has color-coded pull rings covering the luer to identify the dextrose concentration, while the Ireland imported product has a blue protective tip protector which is the same for all dextrose concentrations. The frangible is green in the Ireland imported product but blue in FDA approved product. Users of the imported product should check the product label to ensure that they are using the correct dextrose concentration. See Table 1 for more details of product differences.
- DIANEAL PD4 Glucose Solutions for Peritoneal Dialysis imported product carton labeling includes barcodes; 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 ensure that the correct drug product is being used in all systems and processes and administered to individual patients. For example, institutions should manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned.
- DIANEAL Solution for Peritoneal Dialysis is available only by prescription in the US. 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 Ireland imported product and FDA approved product which are stated in the product comparison tables at the end of this letter as follows:

Key differences are highlighted in the following Product Comparison Tables:

- Table 1: Key differences of DIANEAL Peritoneal Dialysis Solution for APD therapy
- Table 2: Comparison of 3000 mL DIANEAL PD Solution Container Labeling

Reporting Adverse Events

To report adverse events associated with the imported product, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of the imported product 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 \(nih.gov\)](http://DailyMed.nih.gov/).

If you have any questions about the information contained in this letter or the use of imported Dianeal Solution for Peritoneal Dialysis, 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: Nov 4, 2024 16:37
CST

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 Solutions for APD therapy

	Imported Product from Ireland DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium	US FDA Approved Product DIANEAL PD2
Product name	DIANEAL PD4 Glucose 1.36%* w/v / 13.6 mg/mL * 1.36% glucose anhydrous is equivalent to 1.5% dextrose hydrous DIANEAL PD4 Glucose 2.27%* w/v / 22.7 mg/mL * 2.27% glucose anhydrous is equivalent to 2.5% dextrose hydrous	DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose	DIANEAL PD2 Peritoneal Dialysis Solution with 1.5% Dextrose DIANEAL PD2 Peritoneal Dialysis Solution with 2.5% Dextrose
Labeled Fill Volume	2500 mL	2000 mL and 3000 mL fill volumes available	1000ml, 2000 mL and 3000 mL fill volumes available
Container Type	Flexible PVC container with luer-lock connector	AMBU-FLEX II PVC container with luer-lock connector	AMBU-FLEX II PVC container with luer-lock connector
Bags per Carton	4 bags	2000 mL: 6 bags 3000 mL: 4 bags	1000 mL: 12 bags 2000 mL: 6 bags 3000 mL: 4 bags
Indications	Dianeal PD4 is indicated whenever peritoneal dialysis is employed, including: 1. Acute and chronic renal failure; 2. Severe water retention; 3. Electrolyte disorders; 4. Drug intoxication, when a more adequate therapeutic alternative is not available. Dianeal PD4 is particularly useful for the control of serum calcium and phosphate levels in renal failure patients receiving calcium or magnesium-containing phosphate binder.	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 (Glucose)	1.36% Glucose: Glucose Anhydrous 13.6 g / L (1.36 g/100 mL) <i>(Note : 1.36% glucose anhydrous is equivalent to 1.5% dextrose hydrous)</i> 2.27% Glucose: Glucose Anhydrous 22.7 g / L (2.27 g/100 mL) <i>(Note: 2.27% glucose anhydrous is equivalent to 2.5% dextrose hydrous)</i>	1.5% Dextrose: Dextrose Hydrous, USP 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrous, USP 2.5 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

	Imported Product from Ireland DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium	US FDA Approved Product DIANEAL PD2
Active Ingredients - Electrolytes	Sodium Chloride 5.38 g / L <u>(538 mg/100 mL)</u> Sodium Lactate 4.48 g / L <u>(448 mg/100 mL)</u> Calcium Chloride 0.184 g / L <u>(18.4 mg/100 mL)</u> Magnesium Chloride 0.051 g / L <u>(5.1 mg/100 mL)</u>	Sodium Chloride, USP 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 18.3 mg / 100 mL Magnesium Chloride, USP 5.06 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 mmol/L <u>(equivalent to 132 mEq/L)</u> Calcium 1.25 mmol/L <u>(equivalent to 2.5 mEq/L)</u> Magnesium 0.25 mmol/L <u>(equivalent to 0.5 mEq/L)</u> Chloride 95 mmol/L <u>(equivalent to 95 mEq/L)</u> Lactate 40 mmol/L <u>(equivalent to 40 mEq/L)</u>	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	5.0 – 6.0	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
Additional Information	1.36% Glucose Anhydrous: Osmolarity 344 mOsmol/L 2.27% Glucose Anhydrous: Osmolarity 395 mOsmol/L (Calc)	1.5% Dextrose: Osmolarity 344 mOsmol/L (Calc) 2.5% Dextrose: Osmolarity 395 mOsmol/L (Calc)	1.5% Dextrose: Osmolarity 346 mOsmol/L (Calc) 2.5% Dextrose: Osmolarity 396 mOsmol/L (Calc)
Storage Conditions	Do not store above 25°C Do not refrigerate or freeze.	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	24 months	24 months

	Imported Product from Ireland DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium	US FDA Approved Product DIANEAL PD2
Container Closure System			
Container Closure			
Container Closure Differences	<ul style="list-style-type: none"> • One green frangible at luer connector • Blue protective lip protector 	<ul style="list-style-type: none"> • One blue frangible at luer connector • Pull ring cap color-coded to solution dextrose concentration: <ul style="list-style-type: none"> • Yellow = 1.5% dextrose • Green = 2.5% dextrose 	<ul style="list-style-type: none"> • One blue frangible at luer connector • Pull ring cap color-coded to solution dextrose concentration: <ul style="list-style-type: none"> • Yellow = 1.5% dextrose • Green = 2.5% dextrose

Table 2. Comparison of 2500 mL DIANEAL PD Solution Container Labels

Comparative container labels are presented below for the 2500 mL (Ireland) and 3000 mL (US) fill volume. Labels for the remaining US FDA approved 1000 mL and 2000 mL solution fill volumes differ only by product code / NDC / Fill Volume / Barcode. There are no differences in composition or other safety-related information within the same dextrose concentration and formulation. Note, both Baxter and Vantive-branded labels are presented below, which represent all imported lot labeling scenarios during this transition.

Imported Product 2500 mL DIANEAL PD4 (Ireland)	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																					
<p>Baxter FF897 18R 2500 mL DIANEAL PD4 Dextrose 1,36% w/v / 13,6 mg/ml Solution for Peritoneal Dialysis</p> <table border="1"> <thead> <tr> <th>Formula</th> <th>g/l</th> <th>mmol/l</th> </tr> </thead> <tbody> <tr> <td>Anhydrous Glucose</td> <td>C₆H₁₂O₆ 13,6 g</td> <td>35,6 mmol/l</td> </tr> <tr> <td>Sodium Chloride</td> <td>NaCl 1,36 g</td> <td>13,2</td> </tr> <tr> <td>Sodium Lactate</td> <td>C₃H₅O₂Na 1,48 g</td> <td>14,3</td> </tr> <tr> <td>Calcium Chloride</td> <td>CaCl₂·2H₂O 0,184 g</td> <td>0,71</td> </tr> <tr> <td>Magnesium Chloride</td> <td>MgCl₂·6H₂O 0,051 g</td> <td>0,19</td> </tr> <tr> <td>Water for Injection to 2500 mL</td> <td></td> <td>1000</td> </tr> </tbody> </table> <p>Free From Substantial Contaminants For Intraperitoneal Infusion Not for Intravenous Infusion Do not use unless the solution is clear and the container undamaged For single use only Once removed from the overwrap use immediately Discard unused portion Do not store above 25°C Do not refrigerate or freeze Keep out of the light and reach of children</p> <p>Baxter Healthcare Ltd Customer Service Bureau PO Box 58 28, 2790/2711/2701 PL 06716 (L25) 28, 2790/2711/2701 PL 06716 (L25) 28, 2790/2711/2701 PL 06716 (L25)</p>	Formula	g/l	mmol/l	Anhydrous Glucose	C ₆ H ₁₂ O ₆ 13,6 g	35,6 mmol/l	Sodium Chloride	NaCl 1,36 g	13,2	Sodium Lactate	C ₃ H ₅ O ₂ Na 1,48 g	14,3	Calcium Chloride	CaCl ₂ ·2H ₂ O 0,184 g	0,71	Magnesium Chloride	MgCl ₂ ·6H ₂ O 0,051 g	0,19	Water for Injection to 2500 mL		1000	<p>L589901 3000 mL <small>NDC 041-049-01 (APPROX 30 mL EXCESS)</small></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 0,85 mg MAGNESIUM CHLORIDE USP pH 5,2 (4,8 TO 6,2)</p> <p>2,5 mEq/L SODIUM - 132 CALCIUM - 2,5 MAGNESIUM - 0,5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 348 mOsmol/L (CALC)</p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION</p> <p>USE AS DIRECTED BY 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 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>Ambu-Flex II CONTAINER PL 146 PLASTIC BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 1.5% Dextrose</p>	<p>L585169 3000 mL <small>NDC 041-041-01 (APPROX 150 mL EXCESS)</small></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 5,36 mg MAGNESIUM CHLORIDE USP pH 5,2 (4,8 TO 6,2)</p> <p>1,5 mEq/L SODIUM - 132 CALCIUM - 2,5 MAGNESIUM - 0,5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 348 mOsmol/L (CALC)</p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY 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 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>Ambu-Flex II CONTAINER PL 146 PLASTIC BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">PD-2 1.5% Dextrose</p>
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Water for Injection to 1000 mL		Ca ⁺⁺ 40																					

Imported Product 2500 mL DIANEAL PD4 (Ireland)	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																					
<p>Baxter FP897288 2500 mL</p> <p>DIANEAL PD4 (Dextrose) 2,27% w/v / 22,7 mg/ml Solution for Peritoneal Dialysis</p> <table border="1"> <thead> <tr> <th>Formula</th> <th>g/l</th> <th>mmol/l</th> </tr> </thead> <tbody> <tr> <td>Infusion Dextrose</td> <td>C₆H₁₂O₆ 22,7 g</td> <td>595 mmol/L</td> </tr> <tr> <td>Sodium Chloride</td> <td>NaCl 5,38 g</td> <td>92 mmol/L</td> </tr> <tr> <td>Sodium Lactate</td> <td>C₃H₅O₂Na 4,48 g</td> <td>64 mmol/L</td> </tr> <tr> <td>Calcium Chloride</td> <td>CaCl₂·2H₂O 0,184 g</td> <td>0,25 mmol/L</td> </tr> <tr> <td>Magnesium Chloride</td> <td>MgCl₂·6H₂O 0,201 g</td> <td>0,75 mmol/L</td> </tr> <tr> <td>Water for Injection to 1000 mL</td> <td></td> <td>Ca⁺⁺ 40</td> </tr> </tbody> </table> <p><small>Free from Bacterial Endotoxins For Intraperitoneal Infusion Not for Intravenous Infusion Do not use unless the solution is clear and the container undamaged For single use only Once removed from the packaging use immediately Discard unused solution Do not store above 25°C Do not refrigerate or freeze Keep out of the sight and reach of children</small></p> <p><small>Baxter Healthcare Ltd Dunfermline, Fife KY11 1DQ © 2005 Baxter Building UK, Kilmoryie St 2022 Dundee, Scotland UK 1277/01/002 18-03-05-01</small></p>	Formula	g/l	mmol/l	Infusion Dextrose	C ₆ H ₁₂ O ₆ 22,7 g	595 mmol/L	Sodium Chloride	NaCl 5,38 g	92 mmol/L	Sodium Lactate	C ₃ H ₅ O ₂ Na 4,48 g	64 mmol/L	Calcium Chloride	CaCl ₂ ·2H ₂ O 0,184 g	0,25 mmol/L	Magnesium Chloride	MgCl ₂ ·6H ₂ O 0,201 g	0,75 mmol/L	Water for Injection to 1000 mL		Ca ⁺⁺ 40	<p>L5B9902 3000 mL NDC 0941-0457-02 (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><small>EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP 528 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE USP 0.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (5.0 TO 6.0) mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 368 mOsm/L (CALC)</small></p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY 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 Rx ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (20°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> <p>Ambu-Flex II CONTAINER PL 146 PLASTIC BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>	<p>L5B5179 3000 mL NDC 0941-0410-04 (APPROX 100 mL EXCESS)</p> <p>Baxter</p> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p><small>EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP 528 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 20.7 mg CALCIUM CHLORIDE USP 0.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.5 TO 6.5) mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 368 mOsm/L (CALC)</small></p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY 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 Rx ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (20°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> <p>Ambu-Flex II CONTAINER PL 146 PLASTIC BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>
Formula	g/l	mmol/l																					
Infusion Dextrose	C ₆ H ₁₂ O ₆ 22,7 g	595 mmol/L																					
Sodium Chloride	NaCl 5,38 g	92 mmol/L																					
Sodium Lactate	C ₃ H ₅ O ₂ Na 4,48 g	64 mmol/L																					
Calcium Chloride	CaCl ₂ ·2H ₂ O 0,184 g	0,25 mmol/L																					
Magnesium Chloride	MgCl ₂ ·6H ₂ O 0,201 g	0,75 mmol/L																					
Water for Injection to 1000 mL		Ca ⁺⁺ 40																					

Low Calcium 2.5% Dextrose

PD-2 2.5% Dextrose

Imported Product 2500 mL DIANEAL PD4 (Ireland)	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																					
<p>Vantive <small>FPB9728R</small> 2500 mL</p> <p>DIANEAL PD4 <small>Glucose 2,27% w/v / 22,7 mg/ml</small> Solution for Peritoneal Dialysis</p> <table border="1"> <thead> <tr> <th>Ingredients</th> <th>g/L</th> <th>Amount</th> </tr> </thead> <tbody> <tr> <td>Acetate Chloride</td> <td>$C_2H_3O_2^-$</td> <td>22.7 g</td> </tr> <tr> <td>Sodium Chloride</td> <td>NaCl</td> <td>1.34 g</td> </tr> <tr> <td>Sodium Lactate</td> <td>$C_3H_5O_2^-$</td> <td>4.48 g</td> </tr> <tr> <td>Calcium Chloride</td> <td>$CaCl_2 \cdot 2H_2O$</td> <td>0.184 g</td> </tr> <tr> <td>Magnesium Chloride</td> <td>$MgCl_2 \cdot 6H_2O$</td> <td>0.051 g</td> </tr> <tr> <td>Water for Injection to 1000 mL</td> <td></td> <td>1000 mL</td> </tr> </tbody> </table> <p><small>Free from: Bacterial Endotoxins For intraperitoneal infusion Not for intravenous infusion Do not use unless the solution is clear and the container undamaged. For single use only Once returned from the overpack use immediately Shaded amount solution Do not store above 25°C Do not refrigerate or freeze Keep out of the sight and reach of children</small></p> <p><small>Baxter Limited Baxter Technology Park, Worcester Business Campus, 117th Avenue, Worcester, UK, 201711-0001</small></p>	Ingredients	g/L	Amount	Acetate Chloride	$C_2H_3O_2^-$	22.7 g	Sodium Chloride	NaCl	1.34 g	Sodium Lactate	$C_3H_5O_2^-$	4.48 g	Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0.184 g	Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0.051 g	Water for Injection to 1000 mL		1000 mL		
Ingredients	g/L	Amount																					
Acetate Chloride	$C_2H_3O_2^-$	22.7 g																					
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Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0.051 g																					
Water for Injection to 1000 mL		1000 mL																					

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Lot

Exp

Baxter		FPB9718R		2500 ml	
DIANEAL PD4		Glucose 1,36% w/v / 13,6 mg/ml			
Solution for Peritoneal Dialysis					
Formula		g/l		Osmolarity	
Anhydrous Glucose	$C_6H_{12}O_6$	13,6 g	344 mOsmol/l		
Sodium Chloride	NaCl	5,38 g	mmol/l		
Sodium Lactate	$C_3H_5NaO_3$	4,48 g	Na ⁺	132	
Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0,184 g	Ca ⁺⁺	1,25	
Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0,051 g	Mg ⁺⁺	0,25	
Water for Injections to 1000 ml			Cl ⁻	95	
			$C_3H_5O_3^-$	40	
<p>Free from Bacterial Endotoxins For Intraperitoneal infusion Not for intravenous infusion Do not use unless the solution is clear and the container undamaged For single use only Once removed from the overpouch use immediately Discard unused solution Do not store above 25°C Do not refrigerate or freeze Keep out of the sight and reach of children</p>					
<p>UK: Baxter Healthcare Ltd Caxton Way Thetford Norfolk IP24 3SE UK</p>					
<p>IE and MT: Baxter Holding B.V., Kobaltweg 49, 3542CE, Utrecht, Netherlands</p>					
		<p>PA 2299/015/001 PL 00116/0230 MA 1277/01001</p>		<p>CB-35-04-620</p>	

Lot Exp

BaxterLogo FPB9718R 2500 ml

DIANEAL PD4 Glucose 1,36% w/v / 13,6 mg/ml

Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity	344mOsmol/l
Anhydrous Glucose	$C_6H_{12}O_6$	13,6 g		mmol/l
Sodium Chloride	NaCl	5,38 g	Na ⁺	1. 132

Sodium Lactate	$C_3H_5NaO_3$	4,48 g	Ca ⁺⁺	1,25
Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0,051 g	Cl ⁻	95
Water for Injections to 1000ml			$C_3H_5O_3^-$	40

Free from Bacterial Endotoxins

For Intraperitoneal infusion

Not for intravenous infusion

Do not use unless the solution is clear and the container undamaged

For single use only

Once removed from the overpouch use immediately

Discard unused solution

Do not store above 25°C

Do not refrigerate or freeze

Keep out of the sight and reach of children

UK:

Baxter Healthcare Ltd

Caxton Way Thetford Norfolk

IP24 3SE UK

IE and MT:

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POM Symbol

PA 2299/015/001

PL 00116/0230

MA 1277/01001

CB-35-04-620

FPB9718R

2500 ml x 4

Dianeal PD4 Glucose 1.36% w/v / 13,6 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	13,6 g
Sodium Chloride	5,38 g
Sodium Lactate	4,48 g
Calcium Chloride	0,184 g
Magnesium Chloride	0,051 g
Water for Injections to 1000 ml	



Single bag with Luer connector

Do not store above 25°C. Do not refrigerate or freeze.

88-46-13-208

Free from bacterial endotoxins.

For intraperitoneal infusion.

Not for intravenous use. For single use only.

Do not use unless the solution is clear and the container undamaged.

Once removed from the overpouch use immediately.

Discard unused solution. Keep out of the sight and reach of children.

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IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands

PA 2299/015/001 PL 00116/0230 MA 1277/01001

POM



(01)50085412574429(17)201200(10)8888888888

FPB9718R
2500 ml x 4

Dianeal PD4 Glucose
1.36% w/v / 13,6 mg/ml

Lot

Lot



FPB9718R 2500 ml x 4

Dianeal PD4 Glucose 1.36% w/v / 13,6 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	13,6 g
Sodium Chloride	5,38 g
Sodium Lactate	4,48 g
Calcium Chloride	0,184 g
Magnesium Chloride	0,051 g
Water for Injections to 1000 ml	

Free from bacterial endotoxins.

For intraperitoneal infusion.

Not for intravenous use. For single use only.

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PA 2299/015/001 PL 00116/0230 MA 1277/01001

POM Symbol

Lot:

Single bag with
Luer connector

Do not store above 25°C.
Do not refrigerate or
freeze.

88-46-13-208

Barcode

(01)50085412574429(17)201200(10)88B88B88B8

Dianeal PD4 Glucose FPB9718R

1.36% w/v / 13,6 mg/ml 2500 ml x 4

Lot:

Lot

Exp

Vantive		FPB9718R		2500 ml	
DIANEAL PD4		Glucose 1,36% w/v / 13,6 mg/ml			
Solution for Peritoneal Dialysis					
Formula		g/l		Osmolarity	
Anhydrous Glucose	$C_6H_{12}O_6$	13,6 g		344 mOsmol/l	
Sodium Chloride	NaCl	5,38 g		mmol/l	
Sodium Lactate	$C_3H_5NaO_3$	4,48 g		Na ⁺	132
Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0,184 g		Ca ⁺⁺	1,25
Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0,051 g		Mg ⁺⁺	0,25
Water for Injections to 1000 ml				Cl ⁻	95
				$C_3H_5O_3^-$	40
<p>Free from Bacterial Endotoxins For Intraperitoneal infusion Not for intravenous infusion Do not use unless the solution is clear and the container undamaged For single use only Once removed from the overpouch use immediately Discard unused solution Do not store above 25°C Do not refrigerate or freeze Keep out of the sight and reach of children</p>					
Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom				POM	
				PL 58711/0002	
				CB-35-05-245	

Lot Exp

Vantive Logo FPB9718R 2500 ml

DIANEAL PD4 Glucose 1,36% w/v / 13,6 mg/ml

Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity	344mOsmol/l
Anhydrous Glucose	$C_6H_{12}O_6$	13,6 g		mmol/l
Sodium Chloride	NaCl	5,38 g	Na ⁺	1. 132
Sodium Lactate	$C_3H_5NaO_3$		Ca ⁺⁺	

Sodium Lactate	$C_3H_5O_3^-$	4,48 g	Ca ⁺⁺	1,25
Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0,051 g	Cl ⁻	95
Water for Injections to 1000ml			$C_3H_5O_3^-$	40

Free from Bacterial Endotoxins

For Intraperitoneal infusion

Not for intravenous infusion

Do not use unless the solution is clear and the container undamaged

For single use only

Once removed from the overpouch use immediately

Discard unused solution

Do not store above 25°C

Do not refrigerate or freeze

Keep out of the sight and reach of children

Vantive Limited

Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

POM Symbol

PL 58711/0002

CB-35-05-245

FPB9718R

2500 ml x 4

Dianeal PD4 Glucose 1.36% w/v / 13,6 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	13,6 g
Sodium Chloride	5,38 g
Sodium Lactate	4,48 g
Calcium Chloride	0,184 g
Magnesium Chloride	0,051 g
Water for Injections to 1000 ml	

Free from bacterial endotoxins.

For intraperitoneal infusion.

Not for intravenous use. For single use only.

Do not use unless the solution is clear and the container undamaged.

Once removed from the overpouch use immediately.

Discard unused solution. Keep out of the sight and reach of children.

Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

PL 58711/0002

UK Only



Single bag with Luer connector

Do not store above 25°C.
Do not refrigerate or freeze.

88-46-13-978



(01)573324 14203561(17)201200(10)8888888888

FPB9718R
2500 ml x 4

Dianeal PD4 Glucose
1.36% w/v / 13,6 mg/ml

Lot

Lot: 

POM

FPB9718R 2500 ml x 4

Dianeal PD4 Glucose 1.36% w/v / 13,6 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	13,6 g
Sodium Chloride	5,38 g
Sodium Lactate	4,48 g
Calcium Chloride	0,184 g
Magnesium Chloride	0,051 g
Water for Injections to 1000 ml	

Free from bacterial endotoxins.

For intraperitoneal infusion.

Not for intravenous use. For single use only.

Do not use unless the solution is clear and the container undamaged.

Once removed from the overpouch use immediately.

Discard unused solution. Keep out of the sight and reach of children.

Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE
United Kingdom

PL 58711/0002

POM Symbol

Lot:

UK Only

Single bag with
Luer connector

Do not store above 25°C.

Do not refrigerate or
freeze.

88-46-13-978

Barcode

(01)57332414203561(17)201200(10)88B88B88B8

Dianeal PD4 Glucose FPB9718R

1.36% w/v / 13,6 mg/ml 2500 ml x 4

Lot:

Baxter		FPB9728R		2500 ml	
DIANEAL PD4 Glucose		2,27% w/v / 22,7 mg/ml			
Solution for Peritoneal Dialysis					
Formula		g/l		Osmolarity	
Anhydrous Glucose	$C_6H_{12}O_6$	22,7 g		395 mOsmol/l	
Sodium Chloride	NaCl	5,38 g		mmol/l	
				Na ⁺	132
Sodium Lactate	$C_3H_5NaO_3$	4,48 g		Ca ⁺⁺	1,25
Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0,184 g		Mg ⁺⁺	0,25
Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0,051 g		Cl ⁻	95
Water for Injections to 1000 ml				$C_3H_5O_3^-$	40
<p>Free from Bacterial Endotoxins For Intraperitoneal infusion Not for intravenous infusion Do not use unless the solution is clear and the container undamaged For single use only Once removed from the overpouch use immediately Discard unused solution Do not store above 25°C Do not refrigerate or freeze Keep out of the sight and reach of children</p>					
UK: Baxter Healthcare Ltd Caxton Way Thetford Norfolk IP24 3SE UK		POM		PA 2299/015/002 PL 00116/0231 MA 1277/01002	
IE and MT: Baxter Holding B.V. Kobaltweg 49 3542CE Utrecht Netherlands				CB-35-04-621	

Lot Exp

BaxterLogo FPB9728R 2500 ml

DIANEAL PD4 Glucose 2,27% w/v / 22,7 mg/ml

Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity	395mOsmol/l
Anhydrous Glucose	$C_6H_{12}O_6$	22,7 g		mmol/l
Sodium Chloride	NaCl	5,38 g	Na ⁺	1. 132

Sodium Lactate	$C_3H_5NaO_3$	4,48 g	Ca ⁺⁺	1,25
Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0,051 g	Cl ⁻	95
Water for Injections to 1000ml			$C_3H_5O_3^-$	40

Free from Bacterial Endotoxins

For Intraperitoneal infusion

Not for intravenous infusion

Do not use unless the solution is clear and the container undamaged

For single use only

Once removed from the overpouch use immediately

Discard unused solution

Do not store above 25°C

Do not refrigerate or freeze

Keep out of the sight and reach of children

UK:

Baxter Healthcare Ltd

Caxton Way Thetford Norfolk IP24 3SE UK

IE and MT:

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POM Symbol

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PL 00116/0231

MA 1277/01002

CB-35-04-621

FPB9728R

2500 ml x 4

Dianeal PD4 Glucose 2.27% w/v / 22,7 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	22,7 g
Sodium Chloride	5,38 g
Sodium Lactate	4,48 g
Calcium Chloride	0,184 g
Magnesium Chloride	0,051 g
Water for Injections to 1000 ml	



Single bag with Luer connector

Do not store above 25°C.
Do not refrigerate or freeze.

88-46-13-209

Free from bacterial endotoxins.
For intraperitoneal infusion.
Not for intravenous use. For single use only.
Do not use unless the solution is clear and the container undamaged.
Once removed from the overpouch use immediately.
Discard unused solution. Keep out of the sight and reach of children.

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IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands
PA 2299/015/002 PL 00116/0231 MA 1277/01002

POM



(01)50086412574436(17)201200(10)8888888888

Lot:



FPB9728R
2500 ml x 4

Dianeal PD4 Glucose
2.27% w/v / 22,7 mg/ml

Lot:

FPB9728R 2500 ml x 4

Dianeal PD4 Glucose 2.27% w/v / 22,7 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	22,7 g
Sodium Chloride	5,38 g
Sodium Lactate	4,48 g
Calcium Chloride	0,184 g
Magnesium Chloride	0,051 g
Water for Injections to 1000 ml	

Free from bacterial endotoxins.
For intraperitoneal infusion.
Not for intravenous use. For single use only.
Do not use unless the solution is clear and the container undamaged.
Once removed from the overpouch use immediately.
Discard unused solution. Keep out of the sight and reach of children.

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IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands

PA 2299/015/002 PL 00116/0231 MA 1277/01002

POM Symbol

Lot:

Single bag with
Luer connector

Do not store above 25°C.
Do not refrigerate or
freeze.

88-46-13-209

Barcode

(01)50085412574436(17)201200(10)88B88B88B8

Dianeal PD4 Glucose FPB9728R

2.27% w/v / 22,7 mg/ml 2500 ml x 4

Lot:

Lot

Exp

Vantive

FPB9728R

2500 ml

DIANEAL PD4 Glucose **2,27% w/v / 22,7 mg/ml**
Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity	
Anhydrous Glucose	$C_6H_{12}O_6$	22,7 g	395 mOsmol/l	
Sodium Chloride	NaCl	5,38 g	mmol/l	
			Na ⁺	132
Sodium Lactate	$C_3H_5NaO_3$	4,48 g	Ca ⁺⁺	1,25
Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0,051 g	Cl ⁻	95
Water for Injections to 1000 ml			$C_3H_5O_3^-$	40

Free from Bacterial Endotoxins
For Intraperitoneal infusion
 Not for intravenous infusion
 Do not use unless the solution is clear and the container undamaged
 For single use only
 Once removed from the overpouch use immediately
 Discard unused solution
 Do not store above 25°C
 Do not refrigerate or freeze
 Keep out of the sight and reach of children

Vantive Limited
 Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

POM

PL 58711/0003

CB-35-05-246

Lot Exp

Vantive Logo FPB9728R 2500 ml

DIANEAL PD4 Glucose 2,27% w/v / 22,7 mg/ml

Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity	395mOsmol/l
Anhydrous Glucose	$C_6H_{12}O_6$	22,7 g		mmol/l
Sodium Chloride	NaCl	5,38 g	Na ⁺	1. 132
Sodium Lactate	$C_3H_5NaO_3$		Ca ⁺⁺	

Sodium Lactate	$C_3H_5O_3^-$	4,48 g	Ca ⁺⁺	1,25
Calcium Chloride	$CaCl_2 \cdot 2H_2O$	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	$MgCl_2 \cdot 6H_2O$	0,051 g	Cl ⁻	95
Water for Injections to 1000ml			$C_3H_5O_3^-$	40

Free from Bacterial Endotoxins

For Intraperitoneal infusion

Not for intravenous infusion

Do not use unless the solution is clear and the container undamaged

For single use only

Once removed from the overpouch use immediately

Discard unused solution

Do not store above 25°C

Do not refrigerate or freeze

Keep out of the sight and reach of children

Vantive Limited

Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

POM Symbol

PL 58711/0003

CB-35-05-246

FPB9728R **2500 ml x 4**

Dianeal PD4 Glucose 2.27% w/v / 22,7 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	22,7 g
Sodium Chloride	5,38 g
Sodium Lactate	4,48 g
Calcium Chloride	0,184 g
Magnesium Chloride	0,051 g
Water for Injections to 1000 ml	

Free from bacterial endotoxins.
For intraperitoneal infusion.
Not for intravenous use. For single use only.
Do not use unless the solution is clear and the container undamaged.
Once removed from the overpouch use immediately.
Discard unused solution. Keep out of the sight and reach of children.

Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

PL 58711/0003

Lot: ⏰

UK Only



Single bag with Luer connector

Do not store above 25°C.
Do not refrigerate or freeze.

88-46-13-979

POM



(01)57332414202885 (17 201200) (10)888 888888

FPB9728R
2500 ml x 4

Dianeal PD4 Glucose
2.27% w/v / 22,7 mg/ml

Lot: ⏰

FPB9728R 2500 ml x 4

Dianeal PD4 Glucose 2.27% w/v / 22,7 mg/ml

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For intraperitoneal infusion.

Not for intravenous use. For single use only.

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Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE
United Kingdom

PL 58711/0003

POM Symbol

Lot:

UK Only

Single bag with
Luer connector

Do not store above 25°C.

Do not refrigerate or
freeze.

88-46-13-979

Barcode

(01)5733241420885(17)201200(10)88B88B88B8

Dianeal PD4 Glucose FPB9728R

2.27% w/v / 22,7 mg/ml 2500 ml x 4

Lot:

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:0941-0733	
Route of Administration	INTRAPERITONEAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7R0OK)		DEXTROSE MONOHYDRATE	1.36 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	18.4 mg in 100 mL	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)		MAGNESIUM CHLORIDE	5.1 mg in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0733-04	4 in 1 CARTON	11/06/2024	12/31/2026
1	NDC:0941-0733-01	2500 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			11/06/2024	12/31/2026

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:0941-0735	
Route of Administration	INTRAPERITONEAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	

DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7R0OK)	DEXTROSE MONOHYDRATE	2.27 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	18.4 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.1 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0735-04	4 in 1 CARTON	11/06/2024	12/31/2026
1	NDC:0941-0735-01	2500 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		11/06/2024	12/31/2026

Labeler - Vantive US Healthcare LLC (119533513)

Establishment

Name	Address	ID/FEI	Business Operations
Vantive Manufacturing Limited		986154341	analysis(0941-0733, 0941-0735) , label(0941-0733, 0941-0735) , manufacture(0941-0733, 0941-0735) , pack(0941-0733, 0941-0735) , sterilize(0941-0733, 0941-0735)

Revised: 7/2025

Vantive US Healthcare LLC