

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

Baxter Healthcare Corporation

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 Solution 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 (U.S.) market, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import DIANEAL PD4 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 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	5000 mL	FPB5215R	2 bags	NDC 0941-0727-01 (bag) NDC 0941-0727-02 (carton)
DIANEAL PD4 Glucose 2.27% w/v / 22.7 mg/mL Solution for Peritoneal Dialysis	5000 mL	FPB5225R	2 bags	NDC 0941-0729-01 (bag) NDC 0941-0729-02 (carton)
DIANEAL PD4 Glucose 3.86% w/v / 38.6 mg/mL Solution for Peritoneal Dialysis	5000 mL	FPB5235R	2 bags	NDC 0941-0731-01 (bag) NDC 0941-0731-02 (carton)

It is important to note the following:

- DIANEAL PD4 Dextrose Solution for Peritoneal Dialysis manufactured in the EU is labeled to reflect glucose anhydrous content of 1.36%, 2.27% and 3.86%. DIANEAL PD-2 and DIANEAL Low Ca (2.5 mEq/L) peritoneal dialysis solution with Dextrose are labeled to reflect dextrose hydrous of 1.5%, 2.5% and 4.25%.

These solutions have identical dextrose concentrations for clinical use and boxes are color coded in the same way – yellow (1.36%/1.5%), green (2.27%/2.5%) and red/orange (3.86%/4.25%).

- **Dianeal PD4 Dextrose 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) of calcium.** Patients receiving Ireland-imported DIANEAL solution should have their serum calcium levels monitored for the development of hypocalcemia.
- There are no other clinically relevant differences in the drug composition between the European-manufactured DIANEAL PD4 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 Dextrose PD-4 APD solution (manufactured in EU) products is the same as with Dianeal Dextrose PD-2 and Dianeal Dextrose Low Ca (2.5 MEQ/L) (manufactured in U.S.). Please refer to the FDA-approved Dianeal Peritoneal Dialysis Solution Prescribing Information for reference.
- Dianeal PD4 Solution for Peritoneal Dialysis imported from the EU will only be available in 5000 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 U.S. 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 U.S. 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 Solution for Peritoneal Dialysis imported carton labeling includes barcodes; however, **the barcodes may not register accurately in the U.S. scanning systems.** There are no barcodes on the solution containers of the Ireland imported product. Institutions should manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned. 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.

Before prescribing, healthcare providers should be aware of some key differences in the container packaging and labeling between the DIANEAL PD4 Solution for Peritoneal Dialysis products manufactured in EU and DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution manufactured in U.S.

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 5000 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 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,


Electronically signed by:
Geovana Basso
Reason: Ok
Date: Nov 4, 2024 16:39
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	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD2
Product name	<p>DIANEAL PD4 Glucose 1.36%* w/v / 13.6 mg/mL * 1.36% glucose anhydrous is equivalent to 1.5% dextrose hydrous</p> <p>DIANEAL PD4 Glucose 2.27%* w/v / 22.7 mg/mL * 2.27% glucose anhydrous is equivalent to 2.5% dextrose hydrous</p> <p>DIANEAL PD4 Glucose 3.86%* w/v / 38.6 mg/mL* 3.86% glucose anhydrous is equivalent to 4.25% dextrose hydrous</p>	<p>DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose</p>	<p>DIANEAL PD2 Peritoneal Dialysis Solution with 1.5% Dextrose</p> <p>DIANEAL PD2 Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>DIANEAL PD2 Peritoneal Dialysis Solution with 4.25% Dextrose</p>
Labeled Fill Volume	5000 mL	5000 mL and 6000 mL fill volumes available	5000 mL and 6000 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	2 bags	2 bags	2 bags
Indications	<p>Dianeal PD4 is indicated whenever peritoneal dialysis is employed, including:</p> <ol style="list-style-type: none"> 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. <p>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.</p>	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)	<p>1.36% Glucose: Glucose Anhydrous 13.6 g/L (1.36 g/100 mL)</p> <p>2.27% Glucose: Glucose Anhydrous 22.7 g/L (2.27 g/100 mL)</p> <p>3.86% Glucose: Glucose Anhydrous 38.6 g/L (3.86 g/100 mL)</p>	<p>1.5% Dextrose: Dextrose Hydrous, USP 1.5 g/100 mL</p> <p>2.5% Dextrose: Dextrose Hydrous, USP 2.5 g/100 mL</p> <p>4.25% Dextrose: Dextrose Hydrous, USP 4.25 g/100 mL</p>	<p>1.5% Dextrose: Dextrose Hydrous, USP 1.5 g/100 mL</p> <p>2.5% Dextrose: Dextrose Hydrous, USP 2.5 g/100 mL</p> <p>4.25% Dextrose: Dextrose Hydrous, USP 4.25 g/100 mL</p>

	Imported Product from Ireland – DIANEAL PD4	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD2
Active Ingredients - Electrolytes	Sodium Chloride 5.38 g /L (538 mg/100 mL) Sodium Lactate 4.48 g /L (448 mg/100 mL) Calcium Chloride 0.184 g /L (18.4 mg/100 mL) Magnesium Chloride 0.051 g /L (5.1 mg/100 mL)	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 25.7 mg /100 mL Magnesium Chloride, USP 5.08 mg /100 mL
Electrolyte Content per Liter	Sodium 132 mmol/L (equivalent to 132 mEq/L) Calcium 1.25 mmol/L (equivalent to 2.5 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	5.0 – 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) 3.86% Glucose Anhydrous: Osmolarity 483 mOsmol/L (Calc)	1.5% Dextrose: Osmolarity 344 mOsmol/L (Calc) 2.5% Dextrose: Osmolarity 395 mOsmol/L (Calc) 4.25% Dextrose Osmolarity 483 mOsmol/L (Calc)	1.5% Dextrose: Osmolarity 346 mOsmol/L (Calc) 2.5% Dextrose: Osmolarity 396 mOsmol/L (Calc) 4.25% Dextrose: Osmolarity 485 mOsmol/L (Calc)
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	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. 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 tip 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 • Red = 4.25% 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 • Red = 4.25% dextrose

Table 2. Comparison of 5000 mL DIANEAL PD Solution Container Labels

Comparative container labels are presented below for the 5000 mL fill volume. Labels for the U.S. approved 6000 mL solution fill volume differ only by product code / NDC / Fill Volume / Barcode. There are no differences in composition or other safety-related information. Note, both Baxter and Vantive-branded labels are presented, which represent all imported lot labeling scenarios during this transition.

Imported Product from Ireland 5000 mL DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																					
<p>Baxter FPB52158 5000 mL DIANEAL PD4 Glucose 1,36% w/v / 13,6 mg/ml Solution for Peritoneal Dialysis</p> <table border="1"> <thead> <tr> <th>Constituent</th> <th>wt</th> <th>mmoles</th> </tr> </thead> <tbody> <tr> <td>Glucose</td> <td>13,6 g</td> <td>360</td> </tr> <tr> <td>Sodium Chloride</td> <td>NaCl 5,38 g</td> <td>92</td> </tr> <tr> <td>Sodium Lactate</td> <td>C₃H₅O₂Na 6,48 g</td> <td>62</td> </tr> <tr> <td>Sodium Citrate</td> <td>Na₃C₆H₅O₇ 0,184 g</td> <td>0,25</td> </tr> <tr> <td>Magnesium Chloride</td> <td>MgCl₂·6H₂O 0,691 g</td> <td>9</td> </tr> <tr> <td>CaCl₂</td> <td></td> <td>48</td> </tr> </tbody> </table> <p>Free from Bacterial Endotoxins Free from Heparin-based substances Not for intravenous infusion Do not use unless the solution is clear and the container undamaged For single use only Once removed from the approach use immediately Discard unused solution Do not store above 30°C Do not refrigerate or freeze Keep out of the light and reach of children</p> <p>Baxter Healthcare Ltd Letchworth, Hertfordshire, SG8 4LS UK Tel: +44 (0)1462 424000 Fax: +44 (0)1462 424001 Baxter (US) Inc., Deerfield, IL 60015, USA Tel: +1 847 398 2000 Fax: +1 847 398 2001</p>	Constituent	wt	mmoles	Glucose	13,6 g	360	Sodium Chloride	NaCl 5,38 g	92	Sodium Lactate	C ₃ H ₅ O ₂ Na 6,48 g	62	Sodium Citrate	Na ₃ C ₆ H ₅ O ₇ 0,184 g	0,25	Magnesium Chloride	MgCl ₂ ·6H ₂ O 0,691 g	9	CaCl ₂		48	<p>L5B4826 5000 mL NDC 5881-009-07 (APPROX 100 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 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.88 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 - 80 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>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY PHYSICIAN FOR INTRAPERITONEAL ADMINISTRATION ONLY</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION Rx ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (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>L5B5193 5000 mL NDC 5881-011-07 (APPROX 100 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 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.88 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)</p> <p>mEq/L: SODIUM - 132 CALCIUM - 3.5 CHLORIDE - 80 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>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY 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 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>
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<p>Baxter Version</p>	<p>Low Calcium 1.5% Dextrose</p>	<p>PD-2 1.5% Dextrose</p>																					

Imported Product from Ireland 5000 mL DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																								
<p>Vantive FPB5215R 5000 mL DIANEAL PD4 Glucose 1,36% w/v / 13,6 mg/ml</p> <p>Solution for Peritoneal Dialysis</p> <table border="1"> <thead> <tr> <th>Form</th> <th>g/L</th> <th>mg/dL</th> <th>mmol/L</th> </tr> </thead> <tbody> <tr> <td>Acetate Buffer</td> <td>C₂H₃O₂</td> <td>13,4 g</td> <td></td> </tr> <tr> <td>Sodium Chloride</td> <td>NaCl</td> <td>5,38 g</td> <td>93</td> </tr> <tr> <td>Sodium Lactate</td> <td>C₃H₅O₂</td> <td>4,42 g</td> <td>32</td> </tr> <tr> <td>Sodium Bicarbonate</td> <td>NaHCO₃</td> <td>0,184 g</td> <td>0,25</td> </tr> <tr> <td>Magnesium Chloride</td> <td>MgCl₂·6H₂O</td> <td>0,251 g</td> <td>0,95</td> </tr> </tbody> </table> <p>Wife to replace in 100 ml C₂H₃O₂ 40</p> <p>Free from Bacterial 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 solution Do not store above 25°C Do not refrigerate or freeze Keep out of the light and reach of children</p> <p>Baxter GmbH Baxter Technology Park Bielefeld Business Campus 33611 Bielefeld Germany PL 1467110000</p> <p style="text-align: center;">Vantive Version</p>	Form	g/L	mg/dL	mmol/L	Acetate Buffer	C ₂ H ₃ O ₂	13,4 g		Sodium Chloride	NaCl	5,38 g	93	Sodium Lactate	C ₃ H ₅ O ₂	4,42 g	32	Sodium Bicarbonate	NaHCO ₃	0,184 g	0,25	Magnesium Chloride	MgCl ₂ ·6H ₂ O	0,251 g	0,95		
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<p>Baxter FPB5225R 5000 mL DIANEAL PD4 Glucose 2,27% w/v / 22,7 mg/ml</p> <p>Solution for Peritoneal Dialysis</p> <table border="1"> <thead> <tr> <th>Form</th> <th>g/L</th> <th>mg/dL</th> <th>mmol/L</th> </tr> </thead> <tbody> <tr> <td>Acetate Buffer</td> <td>C₂H₃O₂</td> <td>22,7 g</td> <td></td> </tr> <tr> <td>Sodium Chloride</td> <td>NaCl</td> <td>5,38 g</td> <td>93</td> </tr> <tr> <td>Sodium Lactate</td> <td>C₃H₅O₂</td> <td>4,42 g</td> <td>32</td> </tr> <tr> <td>Sodium Bicarbonate</td> <td>NaHCO₃</td> <td>0,184 g</td> <td>0,25</td> </tr> <tr> <td>Magnesium Chloride</td> <td>MgCl₂·6H₂O</td> <td>0,251 g</td> <td>0,95</td> </tr> </tbody> </table> <p>Wife to replace in 100 ml C₂H₃O₂ 40</p> <p>Free from Bacterial 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 solution Do not store above 25°C Do not refrigerate or freeze Keep out of the light and reach of children</p> <p>Baxter Healthcare US Dexter Drive Deerfield, IL 60015, USA PL 1467110000</p> <p style="text-align: center;">Baxter Version</p>	Form	g/L	mg/dL	mmol/L	Acetate Buffer	C ₂ H ₃ O ₂	22,7 g		Sodium Chloride	NaCl	5,38 g	93	Sodium Lactate	C ₃ H ₅ O ₂	4,42 g	32	Sodium Bicarbonate	NaHCO ₃	0,184 g	0,25	Magnesium Chloride	MgCl ₂ ·6H ₂ O	0,251 g	0,95	<p>L5B5202  5000 mL NDC 591-047-05 (APPROX 100 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 130 mg SODIUM CHLORIDE USP 440 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE USP 1.99 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.5 TO 6.5)</p> <p>mEq/L SODIUM - 130 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 60 OSMOLARITY - 396 mOsm/L (CALC) 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</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</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>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 2.5% Dextrose</p>	<p>L5B5194  5000 mL NDC 591-043-07 (APPROX 100 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 130 mg SODIUM CHLORIDE USP 440 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 3.00 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.5 TO 6.5)</p> <p>mEq/L SODIUM - 130 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 60 OSMOLARITY - 396 mOsm/L (CALC) 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</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</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>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 2.5% Dextrose</p>
Form	g/L	mg/dL	mmol/L																							
Acetate Buffer	C ₂ H ₃ O ₂	22,7 g																								
Sodium Chloride	NaCl	5,38 g	93																							
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Imported Product from Ireland 5000 mL DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																					
<p>Vantive FFB5225R 5000 mL DIANEAL PD4 Glucose 2,27% w/v / 22,7 mg/ml</p> <p>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 22,7 g</td> <td>397 mEq/L</td> </tr> <tr> <td>Sodium Chloride</td> <td>NaCl 5,38 g</td> <td>Na⁺ 132</td> </tr> <tr> <td>Sodium Lactate</td> <td>C₃H₅O₃Na 4,48 g</td> <td>Ca⁺⁺ 1,25</td> </tr> <tr> <td>Calcium Chloride</td> <td>CaCl₂·2H₂O 0,184 g</td> <td>Mg⁺⁺ 0,25</td> </tr> <tr> <td>Magnesium Chloride</td> <td>MgCl₂·6H₂O 0,251 g</td> <td>Cl⁻ 95</td> </tr> <tr> <td></td> <td></td> <td>OSMOL: 440</td> </tr> </tbody> </table> <p>Free from Bacterial Endotoxins Free from Pyrogenal Substances Not for Intravenous Infusion Do not use unless the solution is clear and the container undamaged For single use only Shake container from the wraparound use immediately Store at room temperature Do not store above 25°C Do not refrigerate or freeze Keep out of the sight and reach of children</p> <p>Baxter Limited Baxter Healthcare Corporation, 11700 Center Expressway, Deerfield, IL 60015 USA PL 5871110002 08-20-08</p> <p style="text-align: center;">Vantive Version</p>	Formula	g/L	mmol/L	Anhydrous Glucose	C ₆ H ₁₂ O ₆ 22,7 g	397 mEq/L	Sodium Chloride	NaCl 5,38 g	Na ⁺ 132	Sodium Lactate	C ₃ H ₅ O ₃ Na 4,48 g	Ca ⁺⁺ 1,25	Calcium Chloride	CaCl ₂ ·2H ₂ O 0,184 g	Mg ⁺⁺ 0,25	Magnesium Chloride	MgCl ₂ ·6H ₂ O 0,251 g	Cl ⁻ 95			OSMOL: 440	<p style="text-align: center;">US FDA Approved Product DIANEAL Low Calcium PD Solution</p>	<p style="text-align: center;">US FDA Approved Product DIANEAL PD-2 PD Solution</p>
Formula	g/L	mmol/L																					
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Imported Product from Ireland 5000 mL DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																					
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Formula	g/L	mmol/L																					
Anhydrous Glucose	C ₆ H ₁₂ O ₆ 38,6 g	397 mEq/L																					
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Low Calcium 4.25% Dextrose

PD-2 4.25% Dextrose

Imported Product from Ireland 5000 mL DIANEAL PD4	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution																		
<div style="border: 1px solid black; padding: 5px;"> <p>Vantive <small>PPB5235R</small> 5000 ml DIANEAL PD4 Glucose 3,86% w/v / 38,6 mg/ml Solution for Peritoneal Dialysis</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Name</th> <th style="width: 20%;">g/l</th> <th style="width: 20%;">mmol/l</th> </tr> </thead> <tbody> <tr> <td>Infusion Volume</td> <td>$C_6H_{12}O_6$ 38,6 g</td> <td>0,57 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>$C_3H_5NaO_2$ 4,48 g</td> <td>33 mmol/l</td> </tr> <tr> <td>Sodium Citrate</td> <td>$C_6H_5Na_3O_7$ 0,184 g</td> <td>0,29 mmol/l</td> </tr> <tr> <td>Hydrochloric Acid</td> <td>H_2O 0,051 g</td> <td>0,95 mmol/l</td> </tr> </tbody> </table> <p><small>Note for injection in 5000 ml</small></p> <p><small>Free from Bacterial Endotoxins</small></p> <p><small>For intraperitoneal infusion</small></p> <p><small>Not for intravenous infusion</small></p> <p><small>Do not use unless the solution is clear and the container undamaged</small></p> <p><small>For single use only</small></p> <p><small>Check container from the company use immediately</small></p> <p><small>Obtain unused solution</small></p> <p><small>Do not store above 20°C</small></p> <p><small>Do not refrigerate or freeze</small></p> <p><small>Keep out of the sight and reach of children</small></p> <p style="text-align: right;"><small>PL 18771/2004</small></p> </div> <p style="text-align: center; font-weight: bold; margin-top: 10px;">Vantive Version</p>	Name	g/l	mmol/l	Infusion Volume	$C_6H_{12}O_6$ 38,6 g	0,57 mmol/l	Sodium Chloride	NaCl 5,38 g	92 mmol/l	Sodium Lactate	$C_3H_5NaO_2$ 4,48 g	33 mmol/l	Sodium Citrate	$C_6H_5Na_3O_7$ 0,184 g	0,29 mmol/l	Hydrochloric Acid	H_2O 0,051 g	0,95 mmol/l		
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PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Baxter FPB5215R		5000 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>			
UK: Baxter Healthcare Ltd Caxton Way Thetford Norfolk IP24 3SE UK		<div style="border: 1px solid black; padding: 2px; display: inline-block;">POM</div>	
IE and MT: Baxter Holding B.V. Kobaltweg 49 3542CE Utrecht Netherlands		PA 2299/015/001 PL 00116/0230 MA 1277/01001	
		CB-35-04-610	

Lot Exp
 Baxter Logo FPB5215R 5000 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
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Sodium Lactate	$C_3H_5NaO_3$	4,48 g	Ca ⁺⁺ 1,25

Calcium Chloride	CaCl ₂ ·2H ₂ O	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	MgCl ₂ ·6H ₂ O	0,051 g	Cl ⁻	95
Water for Injections to 1000 ml			C ₃ H ₅ O 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

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Discard unused solution

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UK:

Baxter Healthcare Ltd

Caxton Way Thetford Norfolk IP24 3SE UK

POM symbol

IE and MT:

Baxter Holding B.V. Kobaltweg 49 354CE Utrecht Netherlands

PA 2299/015/001

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MA 1277/01001

CB-35-04-610

FPB5215R

5000 ml x 2

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.

88-46-13-198

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

POM



(01)500854 12574375(17)201200(10)8888888888

FPB5215R
5000 ml x 2

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

Lot:

Lot:



FPB5215R 5000 ml x 2
Dianeal PD4 Glucose 1.36% w/v / 13,6 mg/ml
Solution for Peritoneal Dialysis

Formula	g/l
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Lot:

Single bag with
Luer connector

Do not store above 25°C.
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88-46-13-198

POM symbol

Barcode
(01)50085412574375(17)201200(10)88B88B88B8

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

Lot:

FPB5215R
5000 ml x 2

Lot

Exp

Baxter FPB5225R **5000 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	
Sodium Lactate	$C_3H_5NaO_3$	4,48 g	Na ⁺	132
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Water for Injections to 1000 ml			Cl ⁻	95
			$C_3H_5O_3^-$	40

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UK:

Baxter Healthcare Ltd

POM

Caxton Way Thetford Norfolk IP24 3SE UK

PA 2299/015/002

IE and MT:

PL 00116/0231

Baxter Holding B.V., Kobaltweg 49, 3542CE, Utrecht, Netherlands

MA 1277/01002

CB-35-04-611

Lot Exp

BaxterLogo FPB5225R 5000 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	
Sodium Lactate	$C_3H_5NaO_3$	4,48 g	Na ⁺	132
			Ca ⁺⁺	1,25

Calcium Chloride	CaCl ₂ ·2H ₂ O	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	MgCl ₂ ·6H ₂ O	0,051 g	Cl ⁻	95
Water for Injections to 1000 ml			C ₃ H ₅ O 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

POM symbol

IE and MT:

Baxter Holding B.V., Kobaltweg 49, 354CE, Utrecht, Netherlands

PA 2299/015/002

PL 00116/0231

MA 1277/01002

CB-35-04-611

FPB5225R

5000 ml x 2

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.
 88-46-13-199



FPB5225R
5000 ml x 2

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

UK: Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom
 IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands

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

POM

Lot:



FPB5225R 5000 ml x 2
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.

UK: Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom
 IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands

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

Lot:

Single bag with
Luer connector

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

88-46-13-199

POM symbol

Barcode
(01)50085412574382(17)201200(10)88B88B88B8

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

Lot:

FPB5225R
5000 ml x 2

Lot

Exp

Baxter FPB5235R **5000 ml**
DIANEAL PD4 Glucose 3,86% w/v / 38,6 mg/ml
 Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity	
Anhydrous Glucose	$C_6H_{12}O_6$	38,6 g	483 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

UK:

Baxter Healthcare Ltd
 Caxton Way Thetford Norfolk IP24 3SE UK

POM

PA 2299/015/003

IE and MT:

Baxter Holding B.V. Kobaltweg 49 3542CE Utrecht Netherlands

PL 00116/0232

MA 1277/01003

CB-35-04-612

Lot Exp
 BaxterLogo FPB5235R 5000 ml
 DIANEAL PD4 Glucose 3,86% w/v / 38,6 mg/ml
 Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity	
Anhydrous Glucose	$C_6H_{12}O_6$	38,6 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 ·2H ₂ O	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	MgCl ₂ ·6H ₂ O	0,051 g	Cl ⁻	95
Water for Injections to 1000ml			C ₃ H ₅ O 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

POM symbol

IE and MT:

Baxter Holding B.V. Kobaltweg 49 354CE Utrecht Netherlands

PA 2299/015/003

PL 00116/0232

MA 1277/01003

CB-35-04-612

FPB5235R**5000 ml x 2****Dianeal PD4 Glucose 3.86% w/v / 38,6 mg/ml****Solution for Peritoneal Dialysis**

Formula	g/l
Anhydrous Glucose	38,6 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.



Single bag with Luer connector

Do not store above 25°C.

Do not refrigerate or freeze.

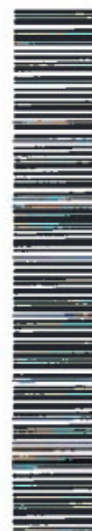
88-46-13-200

UK: Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom

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

PA 2299/015/003 PL 00116/0232 MA 1277/01003

POM



(01)50085412574399(17)201200(10)8888888888

FPB5235R
5000 ml x 2**Dianeal PD4 Glucose**
3.86% w/v / 38,6 mg/ml

Lot:

Lot:



FPB5235R 5000 ml x 2

Dianeal PD4 Glucose 3.86% w/v / 38,6 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	38,6 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.

UK: Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom

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

PA 2299/015/003 PL 00116/0232 MA 1277/01003

Lot:

Single bag with
Luer connector

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

88-46-13-200

POM symbol

Barcode

(01)50085412574399(17)201200(10)88B88B88B8

Dianeal PD4 Glucose
3.86% w/v / 38,6mg/ml

Lot:

FPB5235R
5000 ml x 2

Vantive FPB5215R **5000** 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

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 58711/0002

CB-35-05-235

Lot Exp
 Vantive Logo FPB5215R 5000 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
			Mg ⁺⁺	0,25

Magnesium Chloride	MgCl ₂ ·6H ₂ O	0,051 g	Cl ⁻	95
Water for Injections to 1000ml			C ₃ H ₅ O 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-35-05-235

FPB5215R **5000 ml x 2**

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

Lot ⏰

UK Only




Single bag with Luer connector

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

88-46-13-968

POM



(01)57332414202991 (17)201200 (10)8888888888

FPB5215R
5000 ml x 2

⏰

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

Lot

FPB5215R 5000 ml x 2
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

Lot:

Single bag with
Luer connector

Do not store above 25°C.

Do not refrigerate or
freeze.

88-46-13-968

POM symbol

Barcode

(01)57332414202991(17)201200(10)88B88B88B8

Dianeal PD4 Glucose

1.36% w/v / 13,6mg/ml

Lot:

FPB5215R

5000 ml x 2

Lot

Exp

Vantive FPB5225R **5000** 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	
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

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-35-05-236

Lot Exp

Vantive Logo FPB5225R 5000 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	Na ⁺	mmol/l
				132
Sodium Lactate	C ₃ H ₅ NaO ₃	4,48 g	Ca ⁺⁺	1,25
Calcium Chloride	CaCl ₂ ·2H ₂ O	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	MgCl ₂ ·6H ₂ O	0,051 g	Cl ⁻	95
Water for Injections to 1000ml			C ₃ H ₅ O 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-35-05-236

FPB5225R

5000 ml x 2

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	

UK Only



Single bag with Luer connector

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

88-46-13-969

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

POM



(01)57332414203073(17)201200(10)8888888888

FPB5225R
5000 ml x 2

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

Lot:

Lot:



FPB5225R 5000 ml x 2
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 58744/0003

Lot:

Single bag with
Luer connector

Do not store above 25°C.

Do not refrigerate or
freeze.

88-46-13-969

POM symbol

Barcode

(01)57332414203073(17)201200(10)88B88B88B8

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

Lot:

FPB5225R
5000 ml x 2

Vantive **FPB5235R** **5000 ml**
DIANEAL PD4 **Glucose 3,86% w/v / 38,6 mg/ml**
Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity	
Anhydrous Glucose	$C_6H_{12}O_6$	38,6 g	483 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 58711/0004

CB-35-05-237

Lot Exp
 Vantive Logo FPB5235R 5000 ml
 DIANEAL PD4 Glucose 3,86% w/v / 38,6 mg/ml
 Solution for Peritoneal Dialysis

Formula		g/l	Osmolarity
Anhydrous Glucose	$C_6H_{12}O_6$	38,6 g	395 mOsmol/l

Sodium Chloride	NaCl	5,38 g	Na ⁺	mmol/l
				132
Sodium Lactate	C ₃ H ₅ NaO ₃	4,48 g	Ca ⁺⁺	1,25
Calcium Chloride	CaCl ₂ ·2H ₂ O	0,184 g	Mg ⁺⁺	0,25
Magnesium Chloride	MgCl ₂ ·6H ₂ O	0,051 g	Cl ⁻	95
Water for Injections to 1000ml			C ₃ H ₅ O 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 58711/0004

CB-35-05-237

FPB5235R

5000 ml x 2

Dianeal PD4 Glucose 3.86% w/v / 38,6 mg/ml

Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	38,6 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 58711/0004

UK Only



Single bag with Luer connector
 Do not store above 25°C.
 Do not refrigerate or freeze.

88-46-13-970

POM



(01)57332414203004(17)201200(10)8888888888

FPB5235R
5000 ml x 2

Dianeal PD4 Glucose
3.86% w/v / 38,6 mg/ml

Lot: i

Lot



FPB5235R 5000 ml x 2
Dianeal PD4 Glucose 3.86% w/v / 38,6 mg/ml
Solution for Peritoneal Dialysis

Formula	g/l
Anhydrous Glucose	38,6 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 58711/0004

Lot:

Single bag with
Luer connector

Do not store above 25°C.

Do not refrigerate or
freeze.

88-46-13-970

POM symbol

Barcode

(01)57332414203004(17)201200(10)88B88B88B8

Dianeal PD4 Glucose
3.86% w/v / 38,6mg/ml

Lot:

FPB5235R
5000 ml x 2

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:0941-0727
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) (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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0727-02	2 in 1 CARTON	10/29/2024	
1	NDC:0941-0727-01	5000 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		10/29/2024	

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:0941-0729
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	18.4 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0729-02	2 in 1 CARTON	10/29/2024	
1	NDC:0941-0729-01	5000 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		10/29/2024	

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:0941-0731
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)	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	18.4 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0731-02	2 in 1 CARTON	10/29/2024	
1	NDC:0941-0731-01	5000 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		10/29/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare S.A.		988899845	analysis(0941-0727, 0941-0729, 0941-0731) , label(0941-0727, 0941-0729, 0941-0731) , manufacture(0941-0727, 0941-0729, 0941-0731) , pack(0941-0727, 0941-0729, 0941-0731) , sterilize(0941-0727, 0941-0729, 0941-0731)

Revised: 11/2024

Baxter Healthcare Corporation