

IMPORTANT DRUG INFORMATION

October 2014

Subject: Temporary Importation of DIANEAL® Solution for Peritoneal Dialysis

Dear Healthcare Professional,

Due to current critical shortage of Dianeal peritoneal dialysis solutions for new and existing patients in the US market, Baxter Healthcare Corporation (Baxter) is coordinating with the Food and Drug Administration (FDA) to increase the availability of the drug. Baxter has initiated temporary importation of Dianeal peritoneal dialysis solutions manufactured at Baxter’s Castlebar, Ireland facility and marketed within the European Union (EU). The FDA has not approved this product in the United States.

Prior to its use, it is important to check for leaks by squeezing the inner bag firmly. If leaks are found, do not use solution as sterility may be impaired. Additionally, check to see that solution is clear and free of foreign matter. Solutions that are cloudy, discolored, contain visible particulate matter, or show evidence of leakage should not be used or discarded, but reported to Baxter Product Surveillance immediately. To report product quality issues, please contact Baxter Product Surveillance at 1-800-437-5176.

There are no clinically relevant differences in the composition of the European-manufactured product and the US-manufactured product (see Table 1). However, because the imported product is only available in one size (5000 ml), the number of solution bags patients use per treatment may require modification. Although the frangible, medication ports, and connection caps may appear different for the European-manufactured product, they function in a similar manner to the US-manufactured product.

Effective immediately, Baxter will offer DIANEAL PD4 Glucose Solution for Peritoneal Dialysis in flexible polyvinyl chloride bag containers in the following volume:

Automated Peritoneal Dialysis (APD) product, 5000mL container:

Product*	Product Code Number NDC number	US equivalent Product Code Number and NDC number
Dianeal PD4 Glucose 1,36% w/v 13,6 mg/ml Solution for Peritoneal Dialysis	SPB5215RC NDC 0941-0464-01	L5B4826 NDC 0941-0409-07
Dianeal PD4 Glucose 2,27% w/v 22,7 mg/ml Solution for Peritoneal Dialysis	SPB5225RC NDC 0941-0465-01	L5B5202 NDC 0941-0457-05
Dianeal PD4 Glucose 3,86% w/v 38,6 mg/ml Solution for Peritoneal Dialysis	SPB5235RC NDC 0941-0466-01	L5B5203 NDC 0941-0459-05

*Comparable to Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose manufactured in the US

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.

Dosage and Administration

Baxter’s DIANEAL PD4 with 1,36%, 2,27%, or 3,86% Glucose Solution for Peritoneal Dialysis (manufactured in EU) has the same ionic composition as Baxter’s Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5%, 2.5%, or 4.25% Dextrose products (manufactured in US). Please

note that numerical values for EU products use commas in place of decimal points for the US products. Dianeal solution concentration is expressed as % anhydrous glucose, which correlates to the following % dextrose monohydrate equivalents:

- 1.5% dextrose monohydrate (or glucose monohydrate) = 1,36% anhydrous dextrose (or anhydrous glucose)
- 2.5% dextrose monohydrate (or glucose monohydrate) = 2,27% anhydrous dextrose (or anhydrous glucose)
- 4.25% dextrose monohydrate (or glucose monohydrate) = 3,86% anhydrous dextrose (or anhydrous glucose)

As such, clinical practice for usage, administration, and dosage for DIANEAL PD4 with 1,36%, 2,27%, or 3,86% Glucose Solution for Peritoneal Dialysis (manufactured in EU) products is the same as with the Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5%, 2.5%, or 4.25% Dextrose products (manufactured in US). Please refer to the FDA-approved Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution US Package Insert for reference.

Summary of Product Differences

Before prescribing, healthcare providers should be aware of some key differences in the container packaging and labeling between the DIANEAL PD4 with Glucose Solution for Peritoneal Dialysis products (manufactured in EU) and Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose (manufactured in US).

Key differences are highlighted in the attached Product Comparison Tables as follows:

- Table 1: Dianeal Formulation Comparison (as labeled)
- Table 2: Comparison of Dianeal container labels for APD, 5000 mL

Additional differences with photographs are highlighted in the accompanying Comparison Guide, which describes differences in shipping cartons, solution bags, and labeling.

Important Notes

- Despite visual differences in the product appearance, the Luer-lock connector is the same and is fully compatible with peritoneal dialysis sets marketed in the United States.
- Prior to use, it is important to check for leaks by squeezing the inner bag firmly. If leaks are found, do not use solution as sterility may be impaired. Additionally, check to see that solution is clear and free of foreign matter. Solutions that are cloudy, discolored, contain visible particulate matter, or show evidence of leakage should not be used or discarded, but reported to Baxter Product Surveillance immediately. To report product quality issues, please contact Baxter Product Surveillance at 1-800-437-5176.
- DIANEAL PD4 with Glucose Solutions imported product and carton labeling includes barcodes; however, the barcodes may not register accurately in the US scanning systems. Institutions should manually input the product into their systems and confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

If you have any questions about the information contained in this letter or the use of DIANEAL PD4 with 1,36%, 2,27%, or 3,86% Glucose Solution for Peritoneal Dialysis products, please contact Baxter's Medical Information Service at 1-888-736-2543, Option #2. To place an order, please contact Baxter's Center for Service by calling 1-888-229-0001.

To report product quality issues, please contact Baxter Product Surveillance at 1-800-437-5176. To report

adverse events associated with Dianeal peritoneal dialysis solutions, please call Baxter at 1-866-888-2472 or fax: 1-800-759-1801. Adverse events that may be related to the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail:** use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax:** 1-800-FDA-0178 (1-800-332-0178)

Sincerely,

Mary Gellens, M.D.
Baxter Healthcare Corporation

Baxter and DIANEAL are registered trademarks of Baxter International Inc.

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

Product Comparison Tables

Table 1. Dianeal Formulation Comparison (as labeled)

	Product manufactured in EU	Product manufactured in US
Product name	DIANEAL PD4 Glucose Solution for Peritoneal Dialysis	Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose
Content	<p>1,36% w/v / 13,6 mg/ml Formula / 1000 ml: 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</p>	<p>1.5% Dextrose Each 100 mL contains: Dextrose Hydrus USP 1.5 g Sodium Chloride USP 538 mg Sodium Lactate 448 mg Calcium Chloride USP 18.3 mg Magnesium Chloride USP 5.08 mg</p>
	<p>2,27% w/v / 22,7 mg/ml Formula / 1000 ml: Anhydrous Glucose 22,7 g/l Sodium Chloride 5,38 g/l Sodium Lactate 4,48 g/l Calcium Chloride 0,184 g/l Magnesium Chloride 0,051 g/l</p>	<p>2.5% Dextrose Each 100 mL contains: Dextrose Hydrus USP 2.5 g Sodium Chloride USP 538 mg Sodium Lactate 448 mg Calcium Chloride USP 18.3 mg Magnesium Chloride USP 5.08 mg</p>
	<p>3,86% w/v / 38,6 mg/ml Formula / 1000 ml: Anhydrous Glucose 38,6 g/l Sodium Chloride 5,38 g/l Sodium Lactate 4,48 g/l Calcium Chloride 0,184 g/l Magnesium Chloride 0,051 g/l</p>	<p>4.25% Dextrose Each 100 mL contains: Dextrose Hydrus USP 4.25 g Sodium Chloride USP 538 mg Sodium Lactate 448 mg Calcium Chloride USP 18.3 mg Magnesium Chloride USP 5.08 mg</p>
Ionic composition*	Sodium 132 mmol/L Calcium 1,25 mmol/L Magnesium 0,25 mmol/L Chloride 95 mmol/L Lactate 40 mmol/L	Sodium 132 mEq/L Calcium 2.5 mEq/L Magnesium 0.5 mEq/L Chloride 95 mEq/L Lactate 40 mEq/L
Osmolarity (calculated)	1,36% Glucose: 344 mOsm/L 2,27% Glucose: 395 mOsm/L 3,86% Glucose: 483 mOsm/L	1.5% Dextrose: 344 mOsmol/L 2.5% Dextrose: 395 mOsmol/L 4.25% Dextrose: 483 mOsmol/L
Storage conditions	Do not store above 25°C.	It is recommended the product be stored at room temperature (25°C / 77°F): brief exposure up to 40°C (104°F) does not adversely affect the product.

* The ionic concentration between the two products is exactly the same though different units of measure (mmol/L vs. mEq/L) are used.

Table 2. Comparison of Dianeal container labels for APD, 5000 mL

Product manufactured in EU – 5000 mL	Product manufactured in US – 5000 mL																					
<p> </p> <p>Baxter DIANEAL PD4 Glucose Glucosa 1,36% w/v / 13,6 mg/ml 5000 ml STERILE</p> <p>Solutio ad dialysin peritonealis usum praeparata / Peritonealdialyselösung / Peritonealdialysiselemento / Solución para Diálisis Peritoneal / Διαλύμα Περιτοναϊκής Διαλύσεως (Καθάρσις)</p> <p> <table border="1"> <tr> <th>Formula / Formule / 1000 ml enthält / Sammenstilling per 1000 ml / Composición por 1000 ml / Lijvening op 1000 ml</th> <th>g/l</th> <th>Osmolality / Osmolarité / Osmolaliteit / Osmolaridade / Osmolarität / Osmolariteit / Osmolaridad / Osmolariteit</th> </tr> <tr> <td>Dextrosium (Glucosum) Anhydriyum / Anhydrius Glucose / Glucose anhydri / Glucose anhidra / Glucose wasserfrei / Waterrijge glucose</td> <td>$C_6H_{12}O_6$ 13,6 g</td> <td>344 mOsmol/l</td> </tr> <tr> <td>Natrii Chloridum / Sodium Chloride / Chlorure de Sodium / Natriumchlorid / Chlorure Sodium / Natriumchlorid</td> <td>NaCl 5,38 g</td> <td>132 mmol/l</td> </tr> <tr> <td>Natrii Lactas / Sodium Lactate / Lactate de Sodium / Natrium L (-) Lactat / Lactato Sodium / Natriumlactat</td> <td>$C_3H_5NaO_3$ 4,48 g</td> <td>Ca⁺⁺ 1,25</td> </tr> <tr> <td>Calcii Chloridum / Calcium Chloride / Chlorure de Calcium dihydrate / Calciumchlorid + 2H₂O / Calcium Chlorid 2H₂O / Calciumchloridhydrate</td> <td>$CaCl_2 \cdot 2H_2O$ 0,184 g</td> <td>Mg⁺⁺ 0,25</td> </tr> <tr> <td>Magnesi Chloridum / Magnesium Chloride / Chlorure de Magnesium hexahydrat / Magnesiumchlorid + 6H₂O / Chlorure Magnésium 6H₂O / Magnesiumchloridhexahydrat</td> <td>$MgCl_2 \cdot 6H_2O$ 0,051 g</td> <td>Cl⁻ 95</td> </tr> <tr> <td>Aqua ad injectabilia / Water for injections ad / eau pour préparations injectables epu 1000 ml / to 1000 ml / Agua para inyección en / to 1000 ml / Wasser für Injektionszwecke ad 1000 ml / Water voor injecties ad 1000 ml</td> <td>C_2H_5O 40</td> <td></td> </tr> </table> </p> <p> <p> APD PL 00116/0230 Baxter Healthcare Ltd Canby Way, Thetford, Norfolk IP24 3SE, UK MA 161/01105 </p> <p> APD 3400936630727 Baxter SA B-7800 Lesnau Su prescripção médica: 39515127F12 </p> <p> APD 646430 OZ Baxter SL Punto de Contacto: 46384 Ribarroja del Turia (Valencia) </p> <p> APD MTN 11086 FN Baxter by 281-02031 Helsinki </p> <p> APD MTN 11438 SE Baxter Medical AB SE-164 84 Kista </p> <p> APD TRK500201 B CB-35-03-352 </p> </p>	Formula / Formule / 1000 ml enthält / Sammenstilling per 1000 ml / Composición por 1000 ml / Lijvening op 1000 ml	g/l	Osmolality / Osmolarité / Osmolaliteit / Osmolaridade / Osmolarität / Osmolariteit / Osmolaridad / Osmolariteit	Dextrosium (Glucosum) Anhydriyum / Anhydrius Glucose / Glucose anhydri / Glucose anhidra / Glucose wasserfrei / Waterrijge glucose	$C_6H_{12}O_6$ 13,6 g	344 mOsmol/l	Natrii Chloridum / Sodium Chloride / Chlorure de Sodium / Natriumchlorid / Chlorure Sodium / Natriumchlorid	NaCl 5,38 g	132 mmol/l	Natrii Lactas / Sodium Lactate / Lactate de Sodium / Natrium L (-) Lactat / Lactato Sodium / Natriumlactat	$C_3H_5NaO_3$ 4,48 g	Ca ⁺⁺ 1,25	Calcii Chloridum / Calcium Chloride / Chlorure de Calcium dihydrate / Calciumchlorid + 2H ₂ O / Calcium Chlorid 2H ₂ O / Calciumchloridhydrate	$CaCl_2 \cdot 2H_2O$ 0,184 g	Mg ⁺⁺ 0,25	Magnesi Chloridum / Magnesium Chloride / Chlorure de Magnesium hexahydrat / Magnesiumchlorid + 6H ₂ O / Chlorure Magnésium 6H ₂ O / Magnesiumchloridhexahydrat	$MgCl_2 \cdot 6H_2O$ 0,051 g	Cl ⁻ 95	Aqua ad injectabilia / Water for injections ad / eau pour préparations injectables epu 1000 ml / to 1000 ml / Agua para inyección en / to 1000 ml / Wasser für Injektionszwecke ad 1000 ml / Water voor injecties ad 1000 ml	C_2H_5O 40		<p> </p> <p>L5B4826 5000 mL (APPROX 150 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 18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)</p> <p>mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.6 CHLORIDE - 95 LACTATE - 40 OSMOLALITY - 344 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</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (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</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>
Formula / Formule / 1000 ml enthält / Sammenstilling per 1000 ml / Composición por 1000 ml / Lijvening op 1000 ml	g/l	Osmolality / Osmolarité / Osmolaliteit / Osmolaridade / Osmolarität / Osmolariteit / Osmolaridad / Osmolariteit																				
Dextrosium (Glucosum) Anhydriyum / Anhydrius Glucose / Glucose anhydri / Glucose anhidra / Glucose wasserfrei / Waterrijge glucose	$C_6H_{12}O_6$ 13,6 g	344 mOsmol/l																				
Natrii Chloridum / Sodium Chloride / Chlorure de Sodium / Natriumchlorid / Chlorure Sodium / Natriumchlorid	NaCl 5,38 g	132 mmol/l																				
Natrii Lactas / Sodium Lactate / Lactate de Sodium / Natrium L (-) Lactat / Lactato Sodium / Natriumlactat	$C_3H_5NaO_3$ 4,48 g	Ca ⁺⁺ 1,25																				
Calcii Chloridum / Calcium Chloride / Chlorure de Calcium dihydrate / Calciumchlorid + 2H ₂ O / Calcium Chlorid 2H ₂ O / Calciumchloridhydrate	$CaCl_2 \cdot 2H_2O$ 0,184 g	Mg ⁺⁺ 0,25																				
Magnesi Chloridum / Magnesium Chloride / Chlorure de Magnesium hexahydrat / Magnesiumchlorid + 6H ₂ O / Chlorure Magnésium 6H ₂ O / Magnesiumchloridhexahydrat	$MgCl_2 \cdot 6H_2O$ 0,051 g	Cl ⁻ 95																				
Aqua ad injectabilia / Water for injections ad / eau pour préparations injectables epu 1000 ml / to 1000 ml / Agua para inyección en / to 1000 ml / Wasser für Injektionszwecke ad 1000 ml / Water voor injecties ad 1000 ml	C_2H_5O 40																					
<p> </p> <p>Baxter DIANEAL PD4 Glucose Glucosa 2,27% w/v / 22,7 mg/ml 5000 ml STERILE</p> <p>Solutio ad dialysin peritonealis usum praeparata / Peritonealdialyselösung / Peritonealdialysiselemento / Solución para Diálisis Peritoneal / Διαλύμα Περιτοναϊκής Διαλύσεως (Καθάρσις)</p> <p> <table border="1"> <tr> <th>Formula / Formule / 1000 ml enthält / Sammenstilling per 1000 ml / Composición por 1000 ml / Lijvening op 1000 ml</th> <th>g/l</th> <th>Osmolality / Osmolarité / Osmolaliteit / Osmolaridade / Osmolarität / Osmolariteit / Osmolaridad / Osmolariteit</th> </tr> <tr> <td>Dextrosium (Glucosum) Anhydriyum / Anhydrius Glucose / Glucose anhydri / Glucose anhidra / Glucose wasserfrei / Waterrijge glucose</td> <td>$C_6H_{12}O_6$ 22,7 g</td> <td>395 mOsmol/l</td> </tr> <tr> <td>Natrii Chloridum / Sodium Chloride / Chlorure de Sodium / Natriumchlorid / Chlorure Sodium / Natriumchlorid</td> <td>NaCl 5,38 g</td> <td>132 mmol/l</td> </tr> <tr> <td>Natrii Lactas / Sodium Lactate / Lactate de Sodium / Natrium L (+) Lactat / Lactato Sodium / Natriumlactat</td> <td>$C_3H_5NaO_3$ 4,48 g</td> <td>Ca⁺⁺ 1,25</td> </tr> <tr> <td>Calcii Chloridum / Calcium Chloride / Chlorure de Calcium dihydrate / Calciumchlorid + 2H₂O / Calcium Chlorid 2H₂O / Calciumchloridhydrate</td> <td>$CaCl_2 \cdot 2H_2O$ 0,184 g</td> <td>Mg⁺⁺ 0,25</td> </tr> <tr> <td>Magnesi Chloridum / Magnesium Chloride / Chlorure de Magnesium hexahydrat / Magnesiumchlorid + 6H₂O / Chlorure Magnésium 6H₂O / Magnesiumchloridhexahydrat</td> <td>$MgCl_2 \cdot 6H_2O$ 0,051 g</td> <td>Cl⁻ 95</td> </tr> <tr> <td>Aqua ad injectabilia / Water for injections ad / eau pour préparations injectables epu 1000 ml / to 1000 ml / Agua para inyección en / to 1000 ml / Wasser für Injektionszwecke ad 1000 ml / Water voor injecties ad 1000 ml</td> <td>C_2H_5O 40</td> <td></td> </tr> </table> </p> <p> <p> APD PL 00116/0231 Baxter Healthcare Ltd Canby Way, Thetford, Norfolk IP24 3SE, UK MA 161/01105 </p> <p> APD 3400936633797 Baxter SA B-7800 Lesnau Su prescripção médica: 39515131F12 </p> <p> APD 646431 OZ Baxter SL Punto de Contacto: 46384 Ribarroja del Turia (Valencia) </p> <p> APD MTN 11087 FN Baxter by 281-02031 Helsinki </p> <p> APD MTN 11439 SE Baxter Medical AB SE-164 84 Kista </p> <p> APD TRK500201 B CB-35-03-352 </p> </p>	Formula / Formule / 1000 ml enthält / Sammenstilling per 1000 ml / Composición por 1000 ml / Lijvening op 1000 ml	g/l	Osmolality / Osmolarité / Osmolaliteit / Osmolaridade / Osmolarität / Osmolariteit / Osmolaridad / Osmolariteit	Dextrosium (Glucosum) Anhydriyum / Anhydrius Glucose / Glucose anhydri / Glucose anhidra / Glucose wasserfrei / Waterrijge glucose	$C_6H_{12}O_6$ 22,7 g	395 mOsmol/l	Natrii Chloridum / Sodium Chloride / Chlorure de Sodium / Natriumchlorid / Chlorure Sodium / Natriumchlorid	NaCl 5,38 g	132 mmol/l	Natrii Lactas / Sodium Lactate / Lactate de Sodium / Natrium L (+) Lactat / Lactato Sodium / Natriumlactat	$C_3H_5NaO_3$ 4,48 g	Ca ⁺⁺ 1,25	Calcii Chloridum / Calcium Chloride / Chlorure de Calcium dihydrate / Calciumchlorid + 2H ₂ O / Calcium Chlorid 2H ₂ O / Calciumchloridhydrate	$CaCl_2 \cdot 2H_2O$ 0,184 g	Mg ⁺⁺ 0,25	Magnesi Chloridum / Magnesium Chloride / Chlorure de Magnesium hexahydrat / Magnesiumchlorid + 6H ₂ O / Chlorure Magnésium 6H ₂ O / Magnesiumchloridhexahydrat	$MgCl_2 \cdot 6H_2O$ 0,051 g	Cl ⁻ 95	Aqua ad injectabilia / Water for injections ad / eau pour préparations injectables epu 1000 ml / to 1000 ml / Agua para inyección en / to 1000 ml / Wasser für Injektionszwecke ad 1000 ml / Water voor injecties ad 1000 ml	C_2H_5O 40		<p> </p> <p>L5B5202 5000 mL (APPROX 150 mL EXCESS)</p> <p>Baxter</p> <p>Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)</p> <p>mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.6 CHLORIDE - 95 LACTATE - 40 OSMOLALITY - 395 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</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (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</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>
Formula / Formule / 1000 ml enthält / Sammenstilling per 1000 ml / Composición por 1000 ml / Lijvening op 1000 ml	g/l	Osmolality / Osmolarité / Osmolaliteit / Osmolaridade / Osmolarität / Osmolariteit / Osmolaridad / Osmolariteit																				
Dextrosium (Glucosum) Anhydriyum / Anhydrius Glucose / Glucose anhydri / Glucose anhidra / Glucose wasserfrei / Waterrijge glucose	$C_6H_{12}O_6$ 22,7 g	395 mOsmol/l																				
Natrii Chloridum / Sodium Chloride / Chlorure de Sodium / Natriumchlorid / Chlorure Sodium / Natriumchlorid	NaCl 5,38 g	132 mmol/l																				
Natrii Lactas / Sodium Lactate / Lactate de Sodium / Natrium L (+) Lactat / Lactato Sodium / Natriumlactat	$C_3H_5NaO_3$ 4,48 g	Ca ⁺⁺ 1,25																				
Calcii Chloridum / Calcium Chloride / Chlorure de Calcium dihydrate / Calciumchlorid + 2H ₂ O / Calcium Chlorid 2H ₂ O / Calciumchloridhydrate	$CaCl_2 \cdot 2H_2O$ 0,184 g	Mg ⁺⁺ 0,25																				
Magnesi Chloridum / Magnesium Chloride / Chlorure de Magnesium hexahydrat / Magnesiumchlorid + 6H ₂ O / Chlorure Magnésium 6H ₂ O / Magnesiumchloridhexahydrat	$MgCl_2 \cdot 6H_2O$ 0,051 g	Cl ⁻ 95																				
Aqua ad injectabilia / Water for injections ad / eau pour préparations injectables epu 1000 ml / to 1000 ml / Agua para inyección en / to 1000 ml / Wasser für Injektionszwecke ad 1000 ml / Water voor injecties ad 1000 ml	C_2H_5O 40																					

Product manufactured in EU – 5000 mL

Product manufactured in US – 5000 mL

Lot / Ch B / Παρτίδα Exp / Προσφ / Κατάσθ / Val / Utl dal / Ισχύει μέχρι / Verw bij / Bijz

Baxter **B5235R** **STERILE** **5000 ml**

DIANEAL PD4 Glucose **3,86% w/v / 38,6 mg/ml**
 Glucosa

Solúcio ad dialysis peritoneales usum preparata Peritonealdialyseslösung Peritonealdialysylaineste
 Solution for Peritoneal Dialysis Peritonealdialysylratka Solución para Diálisis Peritoneal
 Solution pour dialyse péritonéale en poche Peritonealdialyseszesko, opletning Σελυγία ήρ προτοναϊκής διαλύσεως (Καθαρής)

Formula / Formula / 1000 ml enthalten / Sammensetning per 1000 ml /
 Composition per 1000 ml / Élévelem az 1000 ml

	g/l	mmol/l
Dextrosam (Glucose) / Melyhidram / Anhydrous Glucose / Glucose anhydrous / Glucose anhidra / Glucose ananhydrous / Waferrnne glucose	$C_6H_{12}O_6$ 38,6 g	483 mEq/l
Natrii Chloridum / Sodium Chloride / Chlorure de Sodium / Natriumchlorid / Chloruro Sodico / Natriumchlorid	NaCl 5,38 g	Na ⁺ 132
Natrii Lactas / Sodium Lactate / Lactate de Sodium / Natrium L (-) Lactat / Lactato Sodico / Natriumlactat	$C_3H_5NaO_3$ 4,48 g	Ca ⁺⁺ 1,25
Calcii Chloridum / Calcium Chloride / Chlorure de Calcium dihydrate / Calciumchlorid • 2H ₂ O / Chloruro Calcico 2H ₂ O / Calciumchlorid-dihydrat	$CaCl_2 \cdot 2H_2O$ 0,184 g	Mg ⁺⁺ 0,25
Magnesi Chloridum / Magnesium Chloride / Chlorure de Magnesium hexahydrate / Magnesiumchlorid • 6H ₂ O / Chloruro Magneseo 6H ₂ O / Magnesiumchloridhexahydrat	$MgCl_2 \cdot 6H_2O$ 0,051 g	Cl ⁻ 95
Aqua ad injectabilia / Water for injection ad / eau pour préparations injectables - qte 1000 ml / to 1000 ml / Aqua para inyección ca / Az ad injezt ad 1000 ml / Water for hypodermocentesis ad 1000 ml / Water voor injecties ad 1000 ml	$C_2H_4O_2$ 40	

Free from Bacterias Endotoxins. Do not use saline solution in dialysis.
 Do not store above 25°C. For immediate use. Discard any unused
 solution. Not for intravenous infusion. For intraperitoneal infusion
 keep out of reach and sight of children.

Baxter Healthcare Ltd POB 167/84/21
 Baxter Healthcare Ltd POB 167/84/21
 Baxter Healthcare Ltd POB 167/84/21

Pyrogenfrei. Nur klare Lösungen in sterisierter Behälterpackung verwenden.
 Rostungen vermeiden. Nicht zur intravenösen Infusion. Zur intraperitonealen Infusion.
 Gebrauchsanweisungen beachten. Nicht über 25°C lagern.
 Für Kinder ungeeignet aufbewahren. Nicht anfeuchten. Nur zum Einmalgebrauch.
 Zuluftungsöffnungen in Behälter.
 Baxter SA B-7860 Lössen. Rezeptpflichtig. 3951S134F12
 Baxter BV NL-5542 CE Lössen. UR
 Baxter SA B-7860 Lössen. Op medisch voorschrijft. 3951S134F12

Pyrogenfrei. Achtung! Dieses Arzneimittel kann die Reaktionsfähigkeit und
 Verkehrsfähigkeit beeinträchtigen. Nur klare Lösungen in sterisierter
 Behälterpackung verwenden. Rostungen vermeiden. Nicht zur intravenösen Infusion.
 Zur intraperitonealen Anwendung. Arzneimittel für Kinder ungeeignet aufbewahren.
 Packungsbeilage beachten. Rezept- und apothekenpflichtig. Nicht über 25°C lagern.
 In der Originalverpackung aufbewahren. Einpackung mit Luft-Kennzeichen.
 Pharmazeutisches Unternehmen: Baxter Healthcare GmbH, 10223 Wien. Z Nr 1-21584

Pyrogenfrei. Användas bara i sterilt förpackat eller klar. Åter användning av lösningen är förbjuden.
 Åter användning av lösningen är förbjuden. Till intravenös bruk. Omedelbart utsläppningsfärdigt för bruk.
 Baxter A/S DK-3450 Allerslev. MTr 14647 DK

Pyrogenfrei. Användas endast i sterilt förpackat eller klar.
 Omgående vidta åtgärder. Ej för intravenös bruk.
 För intraperitonealt bruk. Förvaras oöppnat för bruk.
 Baxter Medical AB. SE-164 94 Kista. MTr 11440 SE

TRK500204 B
 CB-35-03-353

L5B5203 **5000 ml**
 NDC 0641-8456-05 (APPROX 150 mL EXCESS)

Baxter

Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 4.25% Dextrose

EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP
 526 mg SODIUM CHLORIDE USP 436 mg SODIUM LACTATE
 18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
 CHLORIDE USP pH 5.2 (4.0 TO 6.5)
 mEq/L SODIUM - 132 CALCIUM - 2.6 MAGNESIUM - 0.25
 CHLORIDE - 95 LACTATE - 46
 OSMOLALITY - 483 mOsm/L (CALC)

STERILE NONPYROGENIC

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

SEE PACKAGE INSERT FOR DOSAGE INFORMATION
 USE AS DIRECTED BY PHYSICIAN

FOR INTRAPERITONEAL ADMINISTRATION ONLY
WARNING EXTENSIVE USE OF THIS SOLUTION
 DURING ONE PERITONEAL DIALYSIS PROCEDURE CAN
 RESULT IN SIGNIFICANT REMOVAL OF WATER FROM
 THE PATIENT

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

Ambii-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

Low Calcium 4.25% Dextrose

COMPARISON GUIDE



Temporary supply of Baxter-manufactured DIANEAL PD4 PD solution from Europe

“Why do the Baxter bags look different?”

Baxter Healthcare will be shipping DIANEAL PD4 with Glucose Solution for PD, manufactured in Europe (“DIANEAL PD4”), as a temporary supply for Dianeal Low Calcium (2.5% mEq/L) PD Solution, manufactured in US (“Dianeal Low Calcium”). The US-manufactured Dianeal Low Calcium is the PD solution used for APD therapy.

- DIANEAL PD4 (manufactured in EU) solutions and bags are made to the same high-quality standards as Dianeal Low Calcium (manufactured in US) solutions and bags. The DIANEAL solutions inside are comparable.
- The method of connection is exactly the same—there is no need to use adapters or change the bag connection process.
- DIANEAL PD4 (manufactured in EU) bags—and their shipping cartons—have a slightly different appearance compared to Dianeal Low Calcium (manufactured in US) bags and shipping cartons.
- Dianeal Low Calcium (manufactured in US) bags come in a variety of bag sizes. DIANEAL PD4 (manufactured in EU) bags will be 5000 mL bag size only. This might require modification of the number of solution bags per treatment.

If you have questions, please do not hesitate to call Baxter HomeCare Services at 1-800-284-4060.

Differences in the shipping cartons

What do the new shipping cartons look like?



Made in United States



Made in Europe



Differences in glucose/dextrose concentration and shipping carton color-coding

Glucose/dextrose concentrations are written differently, but the amount is exactly the same.

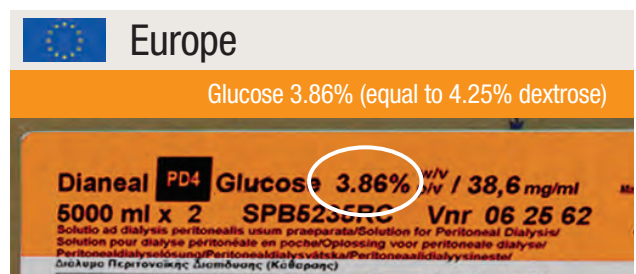
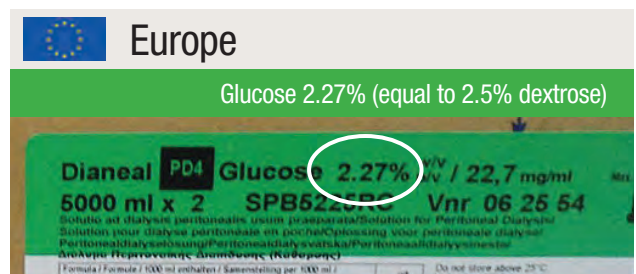
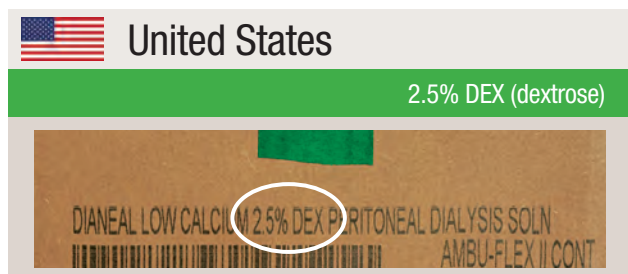
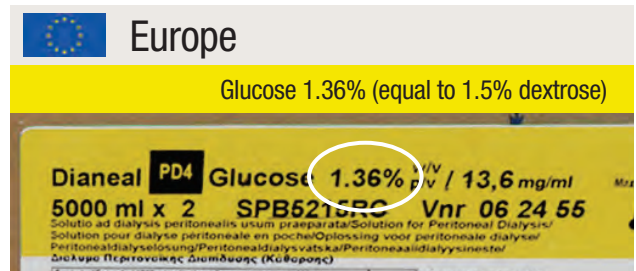
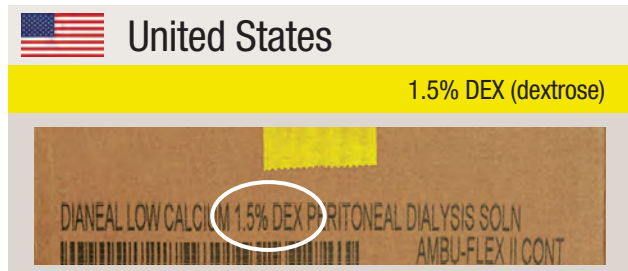
The US PD solutions are labeled as dextrose with concentrations that are different than the EU PD solutions as they are made with a different form of glucose; however, the actual concentrations of glucose in both PD solutions are identical.

- Color coding is the same for “yellow” and “green” concentrations, but the “red” concentration is color-coded “orange” on the DIANEAL PD4 (manufactured in EU) shipping cartons.

 US bag	Shipping carton <u>tape</u> color		 Europe bag	Shipping carton <u>label</u> color
1.5% DEX	Yellow	equals	Glucose 1,36%	Yellow
2.5% DEX	Green	equals	Glucose 2,27%	Green
4.25% DEX	Red	equals	Glucose 3,86%	Orange

The type and location of the color-coding on the shipping cartons are also different.

- Dianeal Low Calcium (manufactured in US) shipping cartons (below, on left) use a color-coded sealing tape across the shipping carton top.
- DIANEAL PD4 (manufactured in EU) shipping cartons (below, on right) have color-coded paper labels attached to the side of the shipping carton.



Differences in the bags clinics and patients receive

What do the DIANEAL PD4 (made in EU) solution bags look like?

Bag Labeling



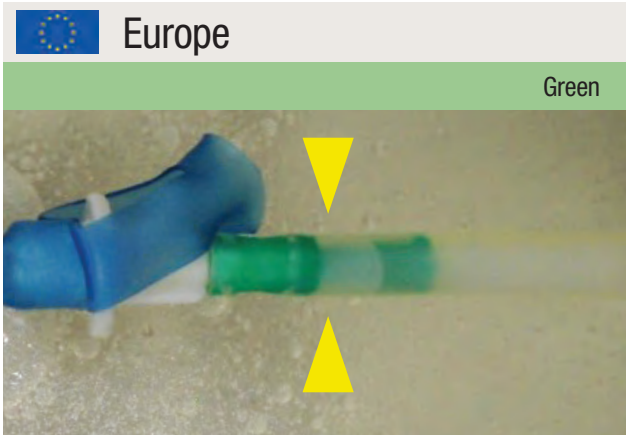
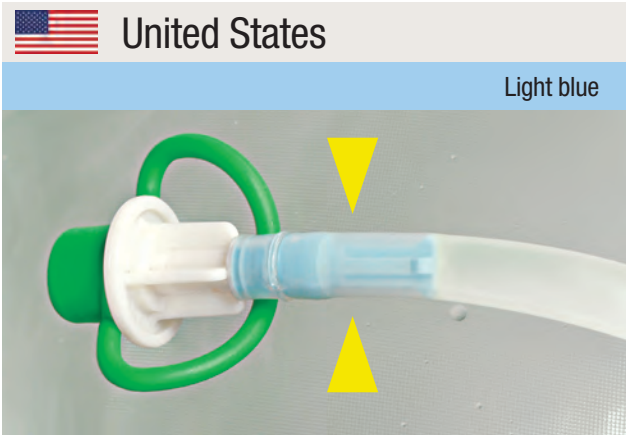
Made in United States



Made in Europe



Frangible (different colors, but function exactly the same)

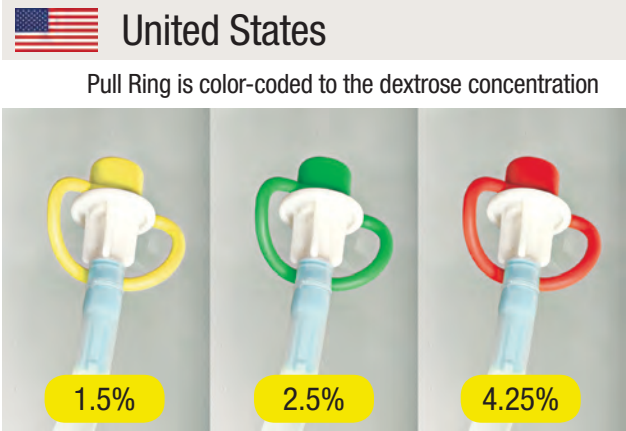


Medication Ports / Injection Sites (different, but function exactly the same)



Connection Caps (different, but connection method is exactly the same)

- Do not use if Pull Ring or Blue Pull Tip is not attached to the connector.



Using DIANEAL PD4 (manufactured in EU)

The connection technique is exactly the same.

Always follow the instructions in the HomeChoice and HomeChoice PRO APD Patient At-Home Guide or HomeChoice Automated PD System Procedure Guide (flipchart) for the set up of the cyclor machine.

As usual, it is important to check the bags carefully before using them:

- % **STRENGTH** of the glucose/dextrose solution in the bag—1,36%, 2,27%, 3,86%
- **EXPIRATION** date
- **AMOUNT** of solution or size of the bag
- Make sure there are **NO LEAKS** and that the fluid is **CLEAR**

Important reminder:

Dianeal Low Calcium (manufactured in US) bags come in a variety of bag sizes. DIANEAL PD4 (manufactured in EU) bags will be 5000 mL bag size only. This might require modification of the number of solution bags per treatment.

Baxter and DIANEAL are registered trademarks of Baxter International Inc.

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

USMP/76/14-0013 10/2014