

IMPORTANT PRESCRIBING INFORMATION

DATE: October 22, 2024

Subject: Temporary importation of DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solutions with 1.5% and 2.5% Dextrose (6000 mL) from Guangzhou, China for use in Automated Peritoneal Dialysis to address drug shortages

Dear Healthcare Professional,

Due to a potential shortage of DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution in the United States (US) market, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solutions with 1.5% and 2.5% Dextrose (6000 mL) from Baxter's manufacturing facility in Guangzhou, China. FDA has not approved this product manufactured by Baxter's Guangzhou, China facility.

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

Baxter has initiated temporary importation of DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 1.5% and 2.5% Dextrose (6000 mL) for use in Automated Peritoneal Dialysis (APD) therapy as described in the table below. This product is manufactured by Baxter's manufacturing facility in Guangzhou, China and is marketed in Hong Kong. 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 Guangzhou, China:

China Imported Product Name and Description	APD Container Volume	Product Code	Bags per Carton	NDC Code
DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose	6000 mL	6AB9770E	2 bags	0941-0701-01 (bag) 0941-0701-02 (carton)
DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose	6000 mL	6AB9771E	2 bags	0941-0703-01 (bag) 0941-0703-02 (carton)

It is important to note the following:

- **DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with Dextrose 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 China-imported DIANEAL solution should have their serum calcium levels monitored for the development of hypocalcemia.
- There are no other clinically relevant differences in the drug composition between the US-manufactured and China-manufactured DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with Dextrose product (see Table 1, below). As such, clinical practice for usage, administration, and dosage is the same as with DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution manufactured in US. Please refer to the FDA-approved Dianeal Peritoneal Dialysis Solution with Dextrose Full Prescribing Information for reference.
- DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 1.5% and 2.5% Dextrose imported from China will only be available in 6000 mL volume for APD, so there will need to be adaptation to the PD prescription for some patients.
- The Luer-lock connector on the China imported product functions the same as and is fully compatible with peritoneal dialysis sets marketed in the United States. However, the US product has color-coded pull rings covering the luer to identify the dextrose concentration, while the China imported product has a blue protective tip protector which is the same for all dextrose concentrations. The frangible is green in the China imported product but blue in US product. Users of the China-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.
- The China imported product includes barcodes on the shipping carton however, **the barcodes may not register accurately in the US scanning systems.** There are no barcodes on the solution containers of the imported product. Alternative procedures should be followed to assure that the correct drug product is being used in all systems and processes and administered to individual patients. For example, institutions should consider manually inputting the product into their systems and confirm that barcode systems do not provide incorrect information when the product is scanned.
- DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solutions with 1.5% and 2.5% Dextrose (6000 mL) are available only by prescription in the U.S. However, the imported products do not have the statement “Rx only” on the labeling.

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

- Table 1: Key differences of DIANEAL Peritoneal Dialysis Solution for APD therapy
- Table 2: Comparison of 6000 mL DIANEAL PD Solution Container Labeling

Reporting Adverse Events

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

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)


To report product quality issues, please report to:
[Baxter - Product Feedback Portal \(https://productfeedback.baxter.com/\)](https://productfeedback.baxter.com/).

Please refer to the FDA approved [full prescribing information](#) for DIANEAL Peritoneal Dialysis Solution.

If you have any questions about the information contained in this letter or the use of imported DIANEAL 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: Oct 22, 2024 19:07
CDT*

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







Baxter and DIANEAL are registered trademarks of Baxter International Inc.

Attachments:

Product Comparison Tables 1 and 2

Table 1. Key differences of DIANEAL Peritoneal Dialysis Solutions for APD therapy

	Imported Product (Guangzhou, China) DIANEAL Low Calcium (2.5 mEq/L)	US FDA-Approved Product DIANEAL Low Calcium (2.5 mEq/L)	US FDA-Approved Product DIANEAL PD2
Product name	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 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 PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose
Labeled Fill Volume	6000 mL	5000 mL 6000 mL	5000 mL 6000 mL
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	2	2
Indications	DIANEAL Low Calcium Peritoneal dialysis solution is indicated for use in chronic renal failure patients being maintained on peritoneal dialysis.	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)	1.5% Dextrose: Dextrose Hydrus, USP 1.5g / 100mL 2.5% Dextrose : Dextrose Hydrus, USP 2.5g / 100mL	1.5% Dextrose: Dextrose Hydrus, USP 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrus, USP 2.5 g / 100 mL	1.5% Dextrose: Dextrose Hydrus, USP 1.5 g / 100 mL 2.5% Dextrose: Dextrose Hydrus, USP 2.5 g / 100 mL
Active Ingredients - Electrolytes	Sodium Chloride, USP 538 mg/ 100 mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 18.3 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL	Sodium Chloride, USP 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 18.3 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL	Sodium Chloride, USP 538 mg / 100mL Sodium Lactate 448 mg / 100 mL Calcium Chloride, USP 25.7 mg / 100 mL Magnesium Chloride, USP 5.08 mg / 100 mL
Electrolyte Content per Liter	Sodium 132 mEq/L Calcium 2.5 mEq/L Magnesium 0.5 mEq/L Chloride 95 mEq/L Lactate 40 mEq/L	Sodium 132 mEq/L Calcium 2.5 mEq/L Magnesium 0.5 mEq/L Chloride 95 mEq/L Lactate 40 mEq/L	Sodium 132 mEq/L Calcium 3.5 mEq/L Magnesium 0.5 mEq/L Chloride 96 mEq/L Lactate 40 mEq/L
pH	5.2 (4.5 to 6.5)	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
Additional Information	1.5% Dextrose: Osmolarity 344 mOsmol/L (Calc) 2.5% Dextrose: 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)

	Imported Product (Guangzhou, China) DIANEAL Low Calcium (2.5 mEq/L)	US FDA-Approved Product DIANEAL Low Calcium (2.5 mEq/L)	US FDA-Approved Product DIANEAL PD2
Storage Conditions	Store at room temperature (25°C / 77°F) Brief exposure up to 40°C (104°F) 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	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
Container Closure System			
Container Closure			

	Imported Product (Guangzhou, China) DIANEAL Low Calcium (2.5 mEq/L)	US FDA-Approved Product DIANEAL Low Calcium (2.5 mEq/L)	US FDA-Approved Product DIANEAL PD2
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 	<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 6000 mL DIANEAL PD Solution Container Labels for APD

Comparative container labels are presented below for the 6000 mL fill volume. Labels for the US approved 5000 mL solution fill volume differ only by product code / NDC / Fill Volume / Barcode. There are no differences in composition or other safety-related information.

Imported Product (Guangzhou, China) 6000 mL DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution
<p>6AB9770E 6000ml (APPROX 225ml EXCESS)</p> <p>Baxter</p> <p>Dianeal® Low Calcium(2.5mEq/L) Peritoneal Dialysis Solution With 1.5% Dextrose</p> <p>EACH 100ml CONTAINS 1.5 g DEXTROSE HYDROUS USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE USP 5.06 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.5 TO 6.5) mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 96 LACTATE 40 OSMOLARITY 344 mOsmol/L(CALC) STERILE NON PYROGENIC</p> <div style="border: 1px solid black; padding: 2px; width: fit-content;"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY. CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (UNDER 25°C) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT 請儲存於攝氏25度以下</p> <p>Ambu-Flex™ III CONTAINER PL-146® PLASTIC MANUFACTURED BY BAXTER HEALTHCARE (GUANGZHOU) CO LTD GUANGZHOU CHINA (AN AFFILIATE OF BAXTER WORLD TRADE INC USA) HK-42530 DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN</p> <p>用法 請依照醫生指示使用 Prescription Drug 處方藥物 Manufacturer Address: Jiaoyuan Road, Dongji Industrial District, GETDD, Guangzhou, P.R. China</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; position: absolute; right: 0; top: 50%; transform: translateY(-50%);"> <p>Low Calcium 1.5% Dextrose</p> </div>	<p>L5B9770 6000 mL (APPROX 225 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 5.06 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5) mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 LACTATE - 40 OSMOLARITY - 344 mOsmol/L (CALC) STERILE NONPYROGENIC</p> <div style="border: 1px solid black; padding: 2px; width: fit-content;"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <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 (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> <div style="border: 1px solid black; padding: 2px; width: fit-content; position: absolute; right: 0; top: 50%; transform: translateY(-50%);"> <p>Low Calcium 1.5% Dextrose</p> </div>	<p>L5B9710 6000 mL (APPROX 225 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 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5) mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 346 mOsmol/L (CALC) STERILE NONPYROGENIC</p> <div style="border: 1px solid black; padding: 2px; width: fit-content;"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <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 (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> <div style="border: 1px solid black; padding: 2px; width: fit-content; position: absolute; right: 0; top: 50%; transform: translateY(-50%);"> <p>PD-2 1.5% Dextrose</p> </div>

Imported Product (Guangzhou, China) 6000 mL DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2 PD Solution
<p>6AB9771E 6000ml (APPROX 225ml EXCESS)</p> <p>Baxter</p> <p>Dianeal® Low Calcium(2.5mEq/L) Peritoneal Dialysis Solution With 2.5% Dextrose</p> <p>EACH 100ml 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 (4.5 TO 6.5)</p> <p>mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40 OSMOLARITY 395 mOsmol/L(CALC) STERILE NON PYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>READ PACKAGE INSERT FOR FULL INFORMATION FOR INTRAPERITONEAL ADMINISTRATION ONLY</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR</p> <p>DISCARD UNUSED PORTION</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (UNDER 25°C) UNTIL READY TO USE</p> <p>AVOID EXCESSIVE HEAT SEE INSERT</p> <p>請儲存於攝氏25度以下</p> <p>Ambu-Flex™ III CONTAINER PL-146* PLASTIC</p> <p>MANUFACTURED BY BAXTER HEALTHCARE (GUANGZHOU) CO LTD GUANGZHOU CHINA (AN AFFILIATE OF BAXTER WORLD TRADE INC USA) HK-42531</p> <p>DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN</p> <p>用法 請依照醫生指示使用</p> <p>Prescription Drug 處方藥物 Manufacturer Address: Jiaoyuan Road, Dongji Industrial District, GETDD, Guangzhou, P.R. China</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 2.5% Dextrose</p>	<p>L5B9771 6000 mL (APPROX 225 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 - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 395 mOsmol/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</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR</p> <p>DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE</p> <p>AVOID EXCESSIVE HEAT SEE INSERT</p> <p>Ambu-Flex II CONTAINER PL 146 PLASTIC</p> <p>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> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Low Calcium 2.5% Dextrose</p>	<p>L5B9711 6000 mL (APPROX 225 mL EXCESS)</p> <p>Baxter</p> <p>Dianeal PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</p> <p>EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 28.7 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 - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40 OSMOLARITY - 396 mOsmol/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</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR</p> <p>DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE</p> <p>AVOID EXCESSIVE HEAT SEE INSERT</p> <p>Ambu-Flex II CONTAINER PL 146 PLASTIC</p> <p>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> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">PD-2 2.5% Dextrose</p>