IMPORTANT PRESCRIBING INFORMATION

DATE: October 21, 2024

Subject: Temporary importation of DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose (2000 mL) and DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose (2000 mL) from Guangzhou, China for use in Automated Peritoneal Dialysis to address drug shortages

Dear Healthcare Professional,

Due to the current critical shortage of DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution in the United States (US) market, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose and Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose (2000 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 PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose and Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose (2000 mL) for use in Ambulatory 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 PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose and Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose (2000 mL) 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 Solution Volume	Product Code	Bags per Carton	NDC Code
DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose	2000 mL	6AB5177E	6 bags	NDC 0941-0698-01 (bag) NDC 0941-0698-06 (carton)
DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	2000 mL	6AB9747E	6 bags	NDC 0941-0696-01 (bag) NDC 0941-0696-06 (carton)

It is important to note the following:

- DIANEAL PD-2 with 2.5% Dextrose and DIANEAL Low Calcium (2.5mEq/L) PD Solution with 4.25% Dextrose imported from China will only be available in 2000 mL volume for APD, so there will need to be adaptation to the PD prescription for some patients.
- **DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose contains 2.5 mEq/L of calcium compared to DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose which contains 3.5 mEq/L of calcium.** Patients receiving China-imported DIANEAL Low Calcium (2.5mEq/L) PD Solution solution with 4.25% dextrose should have their serum calcium levels monitored for the development of hypocalcemia.
- There are no other clinically relevant differences in the DIANEAL drug composition between the U.S.-manufactured and China-manufactured product (see Table 1, below). As such, clinical practice for usage, administration, and dosage for the China imported product is the same as with DIANEAL PD-2 and DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution manufactured in the US. Please refer to the FDA-approved Dianeal Peritoneal Dialysis Solution Prescribing Information for reference.
- 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 U.S. 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 imported product but blue in U.S. 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 may include barcodes on the shipping carton; however, the **barcodes may not register accurately in the U.S. scanning systems**. There are no barcodes on the solution containers of the China 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. Please note that the imported solutions bags do not have barcodes.

Before prescribing, healthcare providers should be aware of some key differences in the container packaging and labeling between the China imported products and the FDA-approved products 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: Label images of DIANEAL 2000 mL APD product presentations

Reporting Adverse Events

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

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

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

Please refer to the FDA approved full prescribing information for Dianeal Peritoneal Dialysis Solution at DailyMed (nih.gov)

If you have any questions about the information contained in this letter or the use of imported DIANEAL PD-2 with 2.5% Dextrose and DIANEAL Low Calcium (2.5mEq/L) PD Solution with 4.25% Dextrose (2000 mL), please contact Baxter's Medical Information Service at 1-888-736-2543.

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

Sincerely,

Geovana Basso

Electronically signed by:
Geovana Basso
Reason: Ok.
Date: Oct 21, 2024 14:22 CDT

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

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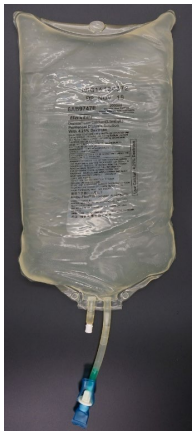
Attachments:
Product Comparison Tables 1 and 2

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

	Imported Product (Guangzhou, China) DIANEAL Low Calcium 4.25% Dextrose	Imported Product (Guangzhou, China) DIANEAL PD-2 2.5% Dextrose	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD2
Product name	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose	DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	DIANEAL PD2 Peritoneal Dialysis Solution with 2.5% Dextrose DIANEAL PD2 Peritoneal Dialysis Solution with 4.25% Dextrose
Labeled Fill Volume	2000 mL	2000 mL	2000 mL and 3000 mL solution fill volumes available	1000, 2000 mL and 3000 mL solution fill volumes available
Container Type	Ambu-Flex (PVC) container with luer-lock and blue tip connector cap	Ambu-Flex (PVC) container with luer-lock and blue tip connector cap	AMBU-FLEX II (PVC) container with luer-lock connector and colored pull ring caps	AMBU-FLEX II (PVC) container with luer-lock connector and colored pull ring caps
Bags per Carton	6 bags	6 bags	2000 mL: 6 bags 3000 mL: 4 bags	1000 mL: 12 bags 2000 mL: 6 bags 3000 mL: 4 bags
Indications	DIANEAL Low Calcium peritoneal dialysis solutions is indicated for use in chronic renal failure patients being maintained on peritoneal dialysis	Peritoneal dialysis is indicated for patients in acute or chronic renal failure when nondialytic medical therapy is judged to be inadequate (Vaamonde and Perez 1977). It may also be indicated in the treatment of certain fluid and electrolyte disturbances, and for patients intoxicated with certain poisons and drugs (Knepshield et al. 1977). However, for many substances other methods of detoxification have been reported to be more effective than peritoneal dialysis (Vaamonde and Perez; Chang 1977)	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)	Dextrose Hydrous, USP 4.25g / 100mL	Dextrose Hydrous, USP 2.5g / 100mL	**1.5% Dextrose**: Dextrose Hydrous, USP 1.5g / 100mL **2.5% Dextrose**: Dextrose Hydrous, USP 2.5g / 100mL **4.25% Dextrose**: Dextrose Hydrous, USP 4.25g / 100mL	**1.5% Dextrose**: Dextrose Hydrous, USP 1.5g / 100mL **2.5% Dextrose**: Dextrose Hydrous, USP 2.5g / 100mL **4.25% Dextrose**: Dextrose Hydrous, USP 4.25g / 100mL
Active Ingredients - Electrolytes	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	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

	Imported Product (Guangzhou, China) DIANEAL Low Calcium 4.25% Dextrose	Imported Product (Guangzhou, China) DIANEAL PD-2 2.5% Dextrose	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD2
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 3.5 mEq/L Magnesium 0.5 mEq/L Chloride 96 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 (4.5 to 6.5)	5.2 (4.0 to 6.5)	5.2 (4.0 to 6.5)
Additional Information	**4.25% Dextrose:** Osmolarity 483 mOsmol/L (Calc)	**2.5% Dextrose**: Osmolarity 396 mOsmol/L (Calc)	**2.5% Dextrose**: Osmolarity 395 mOsmol/L (Calc) **4.25% Dextrose** Osmolarity 483 mOsmol/L (Calc)	**2.5% Dextrose**: Osmolarity 396 mOsmol/L (Calc) **4.25% Dextrose**: Osmolarity 485 mOsmol/L (Calc)
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 (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	1000 mL: 18 months 2000 mL: 24 months 3000 mL: 24 months
Container Closure System				

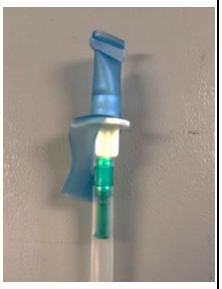
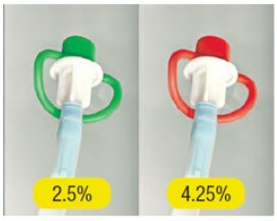
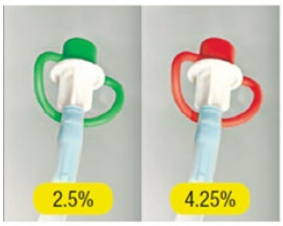
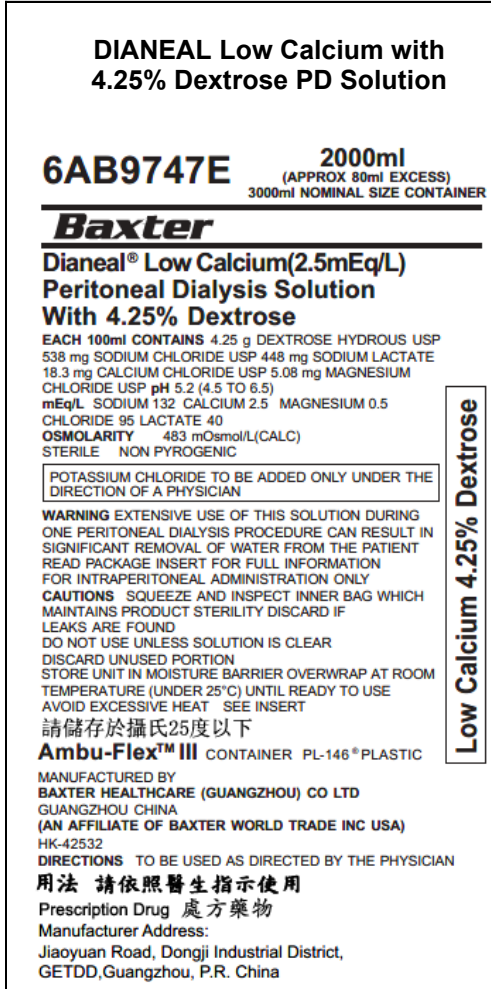
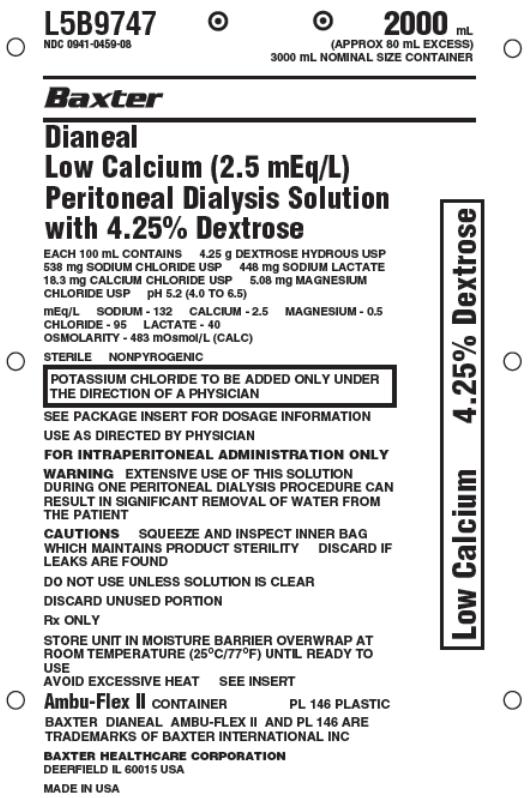
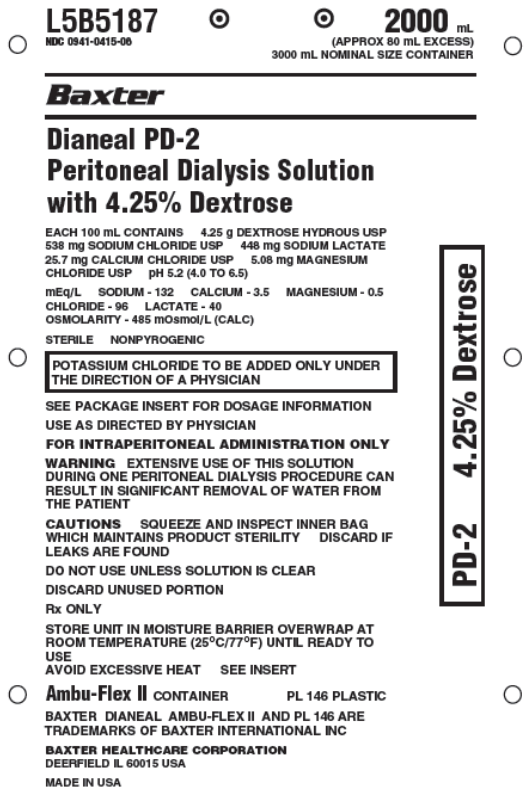
	Imported Product (Guangzhou, China) DIANEAL Low Calcium 4.25% Dextrose	Imported Product (Guangzhou, China) DIANEAL PD-2 2.5% Dextrose	U.S. FDA Approved Product DIANEAL Low Calcium	U.S. FDA Approved Product DIANEAL PD2
Container Closure				
Container Closure Differences	• One green frangible at luer connector • Blue protective tip protector	• One green frangible at luer connector • Blue protective tip protector	• One blue frangible at luer connector • Pull ring cap color-coded to solution dextrose concentration: ▪ Green = 2.5% dextrose ▪ Red = 4.25% dextrose	• One blue frangible at luer connector • Pull ring cap color-coded to solution dextrose concentration: ▪ Green = 2.5% dextrose ▪ Red = 4.25% dextrose

Table 2. Label images of DIANEAL 2000 mL APD product presentations

Comparative container labels are presented below for DIANEAL Peritoneal Dialysis Solution in the 2000 mL fill volume. Labels for other US approved solution fill volumes differ only by product code / NDC / Fill Volume / Barcode. There are no differences in composition or other safety-related information.

Imported Product (Guangzhou, China) 2000mL DIANEAL PD Solution	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2
		

Baxter

Imported Product (Guangzhou, China) 2000mL DIANEAL PD Solution	US FDA Approved Product DIANEAL Low Calcium PD Solution	US FDA Approved Product DIANEAL PD-2

DIANEAL PD-2 with
2.5% Dextrose PD Solution

6AB5177E **2000ml**
(APPROX 80ml EXCESS)
3000ml NOMINAL SIZE CONTAINER

Baxter

Dianeal® PD-2
Peritoneal Dialysis Solution
With 2.5% Dextrose

EACH 100ml CONTAINS 2.5 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 (4.5 TO 6.5)
mEq/L SODIUM 132 CALCIUM 3.5 MAGNESIUM 0.5 CHLORIDE 96 LACTATE 40 **OSMOLARITY** 396 mOsmol/L(CALC)
STERILE NON PYROGENIC

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

READ PACKAGE INSERT FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY
CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
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
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-42533
DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN
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

L5B9727 **2000** mL
NDC 0941-0457-08
(APPROX 80 mL EXCESS)
3000 mL NOMINAL SIZE CONTAINER

Baxter

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

(01)00309410457085

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)

mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 395 mOsmol/L (CALC)

STERILE NONPYROGENIC

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SEE PACKAGE INSERT FOR DOSAGE INFORMATION
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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
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

Low Calcium 2.5% Dextrose

L5B5177 **2000** mL
NDC 0941-0413-06
(APPROX 80 mL EXCESS)
3000 mL NOMINAL SIZE CONTAINER

Baxter

Dianeal PD-2
Peritoneal Dialysis Solution
with 2.5% Dextrose

EACH 100 mL CONTAINS 2.5 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 - 396 mOsmol/L (CALC)

STERILE NONPYROGENIC

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

SEE PACKAGE INSERT FOR DOSAGE INFORMATION
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DO NOT USE UNLESS SOLUTION IS CLEAR
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STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT
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

PD-2 2.5% Dextrose