

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: 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





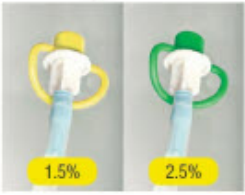

Baxter and DIANEAL are registered trademarks of Baxter International Inc.

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, 535 mg SODIUM CHLORIDE USP, 449 mg SODIUM LACTATE, 58.3 mg CALCIUM CHLORIDE USP, 5.06 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 49</p> <p>OSMOLALITY 344 (OSMOL/L/CALC)</p> <p>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 30°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) 19C-42530</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</p> <p>Manufacturer Address: Jiayuan Road, Dongji Industrial District, GETDD, Guangzhou, P.R. China</p>	<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, 535 mg SODIUM CHLORIDE USP, 449 mg SODIUM LACTATE, 58.3 mg CALCIUM CHLORIDE USP, 5.06 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 - 49</p> <p>OSMOLALITY - 344 (OSMOL/L/CALC)</p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION</p> <p>USE AS DIRECTED BY PHYSICIAN</p> <p>FOR INTRAPERITONEAL ADMINISTRATION ONLY</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>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, 535 mg SODIUM CHLORIDE USP, 449 mg SODIUM LACTATE, 26.7 mg CALCIUM CHLORIDE USP, 5.06 mg MAGNESIUM CHLORIDE USP, pH 5.2 (4.5 TO 6.5)</p> <p>MEQ/L: SODIUM - 132, CALCIUM - 3.5, MAGNESIUM - 0.5, CHLORIDE - 95, LACTATE - 49</p> <p>OSMOLALITY - 346 (OSMOL/L/CALC)</p> <p>STERILE NONPYROGENIC</p> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION</p> <p>USE AS DIRECTED BY PHYSICIAN</p> <p>FOR INTRAPERITONEAL ADMINISTRATION ONLY</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>

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 5.00 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.5 TO 6.5) mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5 CHLORIDE 95 LACTATE 40 OSMOLARITY - 395 mOsm/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 (JAN AFFILIATE OF BAXTER WORLD TRADE INC USA) FR-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</p> <p>Manufacturer Address: Jiaoyuan Road, Dongi 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 5.00 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.5 TO 6.5) mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 395 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</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 (20°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 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 549 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.00 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5) mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 95 LACTATE - 40 OSMOLARITY - 395 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</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 (20°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 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>

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

6AB9770E

6000ml
(APPROX 225ml EXCESS)

Baxter

**Dianeal® Low Calcium(2.5mEq/L)
Peritoneal Dialysis Solution
With 1.5% Dextrose**

EACH 100ml CONTAINS 1.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.5 TO 6.5)
mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5
CHLORIDE 95 LACTATE 40
OSMOLARITY 344 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-42530
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

Low Calcium 1.5% Dextrose

6AB9770E 6000ml
(APPROX 225ml EXCESS)

BaxterLogo

Dianeal® Low Calcium(2.5mEq/L)
Peritoneal Dialysis Solution
With 1.5% Dextrose

EACH 100ml CONTAINS1.5 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)
mEq/LSODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5
CHLORIDE 95 LACTATE 40
OSMOLARITY344 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

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

Prescription Drug

Manufacturer Address:

Jiaoyuan Road, Dongji Industrial District,
GETDD, Guangzhou, P.R. China

Low Calcium 1.5% Dextrose

1.5 LOW CALCIUM WITH 1.5% DEXTROSE 6000mlX2
1.5 LOT G00000000 EXP JAN 00 **6AB9770E** S/N 0000

1.5 LOW CALCIUM WITH 1.5% DEXTROSE 6000mlX2
LOT G00000000 EXP JAN 00 6AB9770E S/N 0000

6AB9771E

6000ml
(APPROX 225ml EXCESS)

Baxter

**Dianeal® Low Calcium(2.5mEq/L)
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
18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.5 TO 6.5)
mEq/L SODIUM 132 CALCIUM 2.5 MAGNESIUM 0.5
CHLORIDE 95 LACTATE 40
OSMOLARITY 395 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-42531

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

Low Calcium 2.5% Dextrose

6AB9771E 6000ml
(APPROX 225ml EXCESS)

BaxterLogo

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

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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

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DIRECTIONS TO BE USED AS DIRECTED BY THE PHYSICIAN

Prescription Drug
Manufacturer Address:
Jiaoyuan Road, Dongji Industrial District,
GETDD, Guangzhou, P.R. China

Low Calcium 1.5% Dextrose

2.5 LOW CALCIUM WITH 2.5% DEXTROSE 6000mlX2
LOT G00000000 EXP JAN 00 6AB9771E S/N 0000

2.5 LOW CALCIUM WITH 2.5% DEXTROSE 6000mlX2
LOT G00000000 EXP JAN 00 6AB9771E S/N 0000

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:0941-0701
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7ROOK)	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	18.3 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.08 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0701-02	2 in 1 CARTON	11/07/2024	
1	NDC:0941-0701-01	6000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		11/07/2024	

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:0941-0703
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7ROOK)	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	18.3 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.08 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0703-02	2 in 1 CARTON	11/07/2024	
1	NDC:0941-0703-01	6000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		11/07/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare (Guangzhou) Co., Ltd		421040114	analysis(0941-0701, 0941-0703) , label(0941-0701, 0941-0703) , manufacture(0941-0701, 0941-0703) , pack(0941-0701, 0941-0703) , sterilize(0941-0701, 0941-0703)

Revised: 11/2024

Baxter Healthcare Corporation