Baxter

IMPORTANT PRESCRIBING INFORMATION

DATE: November 15, 2024

Subject: Temporary importation of EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin from Singapore for use in Automated Peritoneal Dialysis to address drug shortages

Dear Healthcare Professional,

Due to the current critical shortage of EXTRANEAL (icodextrin) 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 EXTRANEAL from Baxter's manufacturing facility in Woodlands, Singapore. FDA has not approved this product manufactured by Baxter's Woodlands, Singapore facility.

You may be provided with additional letters for other 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 EXTRANEAL (icodextrin) Peritoneal Dialysis Solution for use in Automated Peritoneal Dialysis (APD) therapy as described in the table below. This product is manufactured by Baxter's manufacturing facility in Woodlands, Singapore and is marketed in Singapore. At this time, importation or distribution of this EXTRANEAL (icodextrin) 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 Woodlands, Singapore:

Product Name and Description	CAPD Fill Volume	Product Code	Bags per Carton	NDC Code
EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin	2000 mL	FNB4974SG	6	NDC 0941-0707-03 (Bag) NDC 0941-0707-08 (Carton)

It is important to note the following:

- There are no clinically relevant differences in the EXTRANEAL drug composition between the Singapore-manufactured and US-manufactured APD product (see Table 1). As such, clinical practice for usage, administration, and dosage for Extraneal with 7.5% icodextrin (manufactured in Singapore) product is the same as with the Extraneal with 7.5% icodextrin (manufactured in US). Please refer to the FDA-approved EXTRANEAL (icodextrin) Peritoneal Dialysis Solution Prescribing Information for reference.
- EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis imported from Singapore will only be available in 2000 mL fill volume for APD.

- Calcium and Magnesium electrolyte concentrations are identical in EXTRANEAL manufactured in Singapore and the US but appear different as they are expressed in mmol/L (Singapore) and in mEq/L (US).
- The Luer-lock connector functions the same and is fully compatible with peritoneal dialysis sets marketed in the United States. However, the U.S. product has a purple pull ring covering the luer to identify the solution, while the Singapore imported product has a blue protective tip protector. The frangible is green in the Singapore imported product, but blue in U.S. product. Users of the imported product should check the product label to ensure that they are using the correct APD solution. See Table 1 for more details of product differences.
- EXTRANEAL Solution for Peritoneal Dialysis with 7.5% icodextrin imported from Singapore 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.
- EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis is available only by prescription in the US. However, the imported product does 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 EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis products (manufactured in Singapore) and EXTRANEAL (icodextrin) Peritoneal Dialysis Solution (manufactured in US).

Key differences are highlighted in the following Product Comparison Tables:

- Table 1: Key differences between imported and FDA-approved EXTRANEAL for APD therapy
- Table 2: Label images of imported and FDA-approved EXTRANEAL for APD therapy

Reporting Adverse Events

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

- Complete and submit the report **On-line**: www.fda.gov/medwatch/report.htm
- **Regular Mail / 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 EXTRANEAL (icodextrin) Peritoneal Dialysis Solution at DailyMed (nih.gov).

If you have any questions about the information contained in this letter or the use of imported EXTRANEAL (icodextrin) Peritoneal Dialysis Solution, 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: Nov 15, 2024 13:57 CST

Geovana Basso, M.D.
Director of Americas Medical Affairs
Baxter Healthcare Corporation
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Attachments:
Product Comparison Tables 1 and 2

Table 1. Key differences between Imported and FDA-approved EXTRANEAL for APD therapy

	Imported Product from Singapore	US FDA Approved Product
Product name	EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin	EXTRANEAL (icodextrin) Peritoneal Dialysis Solution
Labeled Fill Volume	2000 mL	2000 mL 2500 mL
Container Type	Ambu-Flex Container (PVC)	Ambu-Flex Container (PVC)
Bags per carton	6 bags	2000 mL: 6 bags 2500 mL: 5 bags
Indications	EXTRANEAL is recommended as a once daily replacement for a single Dextrose exchange as part of a CAPD or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for some categories of patients who have lost ultrafiltration on Dextrose solutions, because it can extend time on CAPD therapy in such patients.	EXTRANEAL (icodextrin) is indicated for a single daily exchange for the long (8- to 16- hour) dwell during continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) for the management of kidney failure in patients requiring long-term kidney replacement therapy. EXTRANEAL is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high average or greater transport characteristics, as defined using the peritoneal equilibration test (PET).
Active Ingredients	7.5 g/100mL Icodextrin 538 mg/100mL Sodium Chloride, USP 448mg/ 100mL Sodium Lactate 25.7 mg/100mL Calcium Chloride, USP 5.08 mg/100mL Magnesium Chloride, USP	7.5 g/100 mL Icodextrin *535 mg/100 mL Sodium Chloride, USP** *448 mg/100mL Sodium Lactate** *25.7 mg/100mL Calcium Chloride, USP** *5.08 mg/100 mL Magnesium Chloride, USP** ** considered excipients in US drug registration*
Electrolyte Content per Liter	Sodium 132 mmol/L (equivalent to 132 mEq/L) Calcium 1.75 mmol/L (equivalent to 3.5 mEq/L) Magnesium 0.25 mmol/L (equivalent to 0.5 mEq/L) Chloride 96 mmol/L (equivalent to 96 mEq/L) Lactate 40 mmol/L (equivalent to 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	pH 5.2 (5.0 – 6.0) HCl / NaOH may have been used to adjust pH	pH 5.0 – 6.0 HCl / NaOH may have been used to adjust pH
Additional Information	Osmolarity 284 mOsmol/L	Osmolarity (Calc) 282 – 286 mOsmol/L
Storage Conditions	Store below 30°C	Store at 20–25°C (68–77°F). Excursions permitted to 15–30°C (59–86°F) [See USP Controlled Room Temperature]. Protect from freezing.
Expiration Dating	24 months	18 months

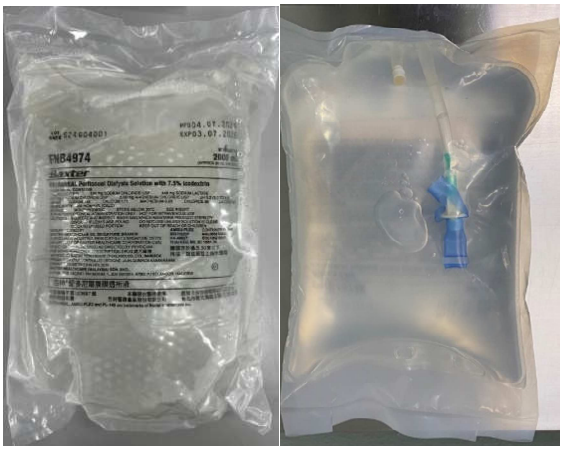
	Imported Product from Singapore	US FDA Approved Product
Container Closure System		
Container Closure Differences	• One green frangible at luer-lock connector • Blue protective tip connector	• One blue frangible at luer-lock connector • Purple pull ring cap closure

Table 2. Comparison of Imported and FDA-approved EXTRANEAL (icodextrin) PD Solution Container Labels

Imported Product from Singapore	US FDA approved Product
FNB4974 ยาสิ้นอายุ **2000 mL** (APPROX 80 mL EXCESS) **Baxter** **EXTRANEAL Peritoneal Dialysis Solution with 7.5% Icodextrin** **EACH 100 mL CONTAINS** 7.5 g ICODEXTRIN 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (5.0 TO 6.0) **mmol/L** SODIUM 132 CALCIUM 1.75 MAGNESIUM 0.25 CHLORIDE 96 LACTATE 40 **OSMOLARITY** 284 mOsmol/L (CALC) STERILE NONPYROGENIC STORE BELOW 30°C SEE INSERT FOR INTRAPERITONEAL ADMINISTRATION ONLY NOT FOR INTRAVENOUS USE 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 KEEP OUT OF REACH OF CHILDREN MANUFACTURED BY **AMBU-FLEX** CONTAINER PL-146 **BAXTER HEALTHCARE SA, SINGAPORE BRANCH** **SIN11220P** **MAL05021264AZ** 2 WOODLANDS INDUSTRIAL PARK D STREET 2 SINGAPORE 737778 **HK-46627** **BRU13021011P** (AN AFFILIATE OF BAXTER HEALTHCARE CORPORATION USA) **THAI REG. NO. 2C 16/51 (N)** DIRECTION TO BE USED AS DIRECTED BY PHYSICIAN 請儲存於攝氏30度以下 FOR HONG KONG ONLY: PRESCRIPTION DRUG 處方藥物 用法：請依照醫生指示使用 IMPORTED BY **BAXTER HEALTHCARE (THAILAND) CO., LTD., BANGKOK** FOR MALAYSIA ONLY: CONTROLLED MEDICINE. JAUHI DARIPADA KANAK-KANAK PRODUCT REGISTRATION HOLDER: **BAXTER HEALTHCARE (MALAYSIA) SDN. BHD.,** B-21-3A, THE ASCENT, PARADIGM, 1, JLN SS7/26A, 47301 PJ SELANGOR, MALAYSIA "百特"愛多尼爾腹膜透析液 衛署藥輸字第023687號 本藥限由醫師使用 批號及保存期限詳如包裝所示 請詳閱說明書 百特醫療產品股份有限公司 台北市敦化南路2段95號28樓 **EXTRANEAL, AMBU-FLEX and PL-146** are trademarks of Baxter International Inc.	**L5B4974** **2000** mL NDC 0941-0679-06 (APPROX 80 mL EXCESS) **Baxter** **Extraneal (icodextrin)** **Peritoneal Dialysis Solution** **EACH 100 mL CONTAINS** 7.5 g ICODEXTRIN 535 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP WATER FOR INJECTION USP mEq/L SODIUM 132 CALCIUM 3.5 MAGNESIUM 0.5 CHLORIDE 96 LACTATE 40 pH 5.0 - 6.0 pH MAY HAVE BEEN ADJUSTED WITH HYDROCHLORIC ACID OR SODIUM HYDROXIDE (01) 00300941067067 EXTRANEAL SOLUTION CONTAINS NO BACTERIOSTATIC OR ANTIMICROBIAL AGENTS OSMOLARITY (CALC) 282 - 286 mOsmol/L 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** **CAUTIONS** SQUEEZE AND INSPECT INNER BAG THAT MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION **Rx ONLY** STORE IN MOISTURE BARRIER OVERPOUCH IN CARTON UNTIL READY TO USE STORE AT 20-25°C (68-77°F) EXCURSIONS PERMITTED TO 15-30°C (59-86°F) [SEE USP CONTROLLED ROOM TEMPERATURE] PROTECT FROM FREEZING **Ambu-Flex II** CONTAINER PL 146 PLASTIC BAXTER EXTRANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC **BAXTER HEALTHCARE CORPORATION** DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4761237 4886789 6077836 6248726 B1 **PD-2 7.5% icodextrin**