Baxter

IMPORTANT PRESCRIBING INFORMATION

DATE: October 18, 2024

Subject: Temporary importation of EXTRANEAL (icodextrin) Peritoneal Dialysis Solution from Ireland 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 Castlebar, Ireland. You may be provided with additional letters for other imported peritoneal dialysis solutions you receive. FDA has not approved this product manufactured by Baxter's Castlebar, Ireland 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 Castlebar, Ireland and is marketed in the United Kingdom and other countries within the European Union (EU). At this time, importation or distribution of 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 Castlebar, Ireland:

Product Name and Description	APD Fill Volume	Product Code	Bags per Carton	NDC Code
EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis	2500 mL	FPB4945R	4 bags	0941-0681-02 (bag) 0941-0681-08 (carton)

It is important to note the following:

- There are no clinically relevant differences in the EXTRANEAL drug composition between the European-manufactured and U.S.-manufactured APD product (see Table 1). As such, clinical practice for usage, administration, and dosage for Extraneal with 7.5% icodextrin (manufactured in EU) products is the same as with the Extraneal with 7.5% icodextrin (manufactured in U.S.). Please refer to the FDA-approved EXTRANEAL (icodextrin) Peritoneal Dialysis Solution Prescribing Information for reference.
- EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis imported from the EU will only be available in 2500 mL fill volume for APD.
- Calcium and Magnesium electrolyte concentrations are identical in EXTRANEAL manufactured in the EU and U.S. but appear different as they are expressed in mmol/L (EU) and in mEq/L (U.S.).

- The Luer-lock connector on the Ireland 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 a purple pull ring covering the luer to identify the solution, while the Ireland imported product has a blue protective tip protector. The frangible is green in the Ireland 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 (icodextrin) solution for peritoneal dialysis imported carton labeling includes barcodes; however, **the barcodes may not register accurately in the U.S. scanning systems**. There are no barcodes on the solution containers of the Ireland imported product. Institutions should manually input the product into their systems to 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 in all systems and processes and administered to individual patients.

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 EU) and EXTRANEAL (icodextrin) Peritoneal Dialysis Solution (manufactured in U.S.).

Key differences are highlighted in the following Product Comparison Tables:

- Table 1: Key differences of EXTRANEAL for APD therapy
- Table 2: Label images of EXTRANEAL for 2500 mL APD product presentations

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 **Online**: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax:** Download form http://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 contact Baxter Product Surveillance at 1-800-437-5176.

Please refer to the FDA approved 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) 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,

Geovana Basso

Electronically signed by:
Geovana Basso
Reason: .
Date: Oct 18, 2024 16:46 CDT

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

Attachments:

Product Comparison Tables 1 and 2

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Table 1. Key differences of EXTRANEAL for APD therapy

	Imported Product from Ireland	U.S. FDA Approved Product
Product name	EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis	EXTRANEAL (icodextrin) Peritoneal Dialysis Solution
Labeled Fill Volume	2500 mL	2000 mL 2500 mL
Container Type	PVC Container	Ambu-Flex Container (PVC)
Bags per carton	4 bags	2000 mL: 6 bags 2500 mL: 5 bags
Indications	Extraneal is recommended as a once daily replacement for a single glucose exchange as part of a continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for patients who have lost ultrafiltration on glucose 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	75 g/L Icodextrin (7.5 g/100 mL) 5.4 g/L Sodium Chloride (540 mg/100 mL) 4.5 g/L Sodium Lactate (450 mg/100 mL) 0.257g/L Calcium Chloride (25.7 mg/100 mL) 0.051g/L Magnesium Chloride (5.10 mg/100 mL)	7.5 g/100 mL Icodextrin *535 mg/100 mL Sodium Chloride, USP** *448 mg/100 mL Sodium Lactate** *25.7 mg/100 mL Calcium Chloride, USP** *5.08 mg/100 mL Magnesium Chloride, USP** ** considered excipients in US drug registration*
Electrolyte Content per Liter	Sodium 133 mmol/L (equivalent to 133 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 5.0 – 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 mOsm/L	Osmolarity (Calc) 282 – 286 mOsmol/L
Storage Conditions	Do not store below 4°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 Ireland	U.S. FDA Approved Product
Container Closure System		
Container Closure		
Container Closure System Differences	• One green frangible at luer-lock connector • Blue protective tip protector	• One blue frangible at luer-lock connector • Purple pull ring cap closure

Table 2. Comparison of EXTRANEAL (icodextrin) PD Solution Container Labels

A comparison of labels is provided below. Note, both Baxter and Vantive-branded labels are presented, which represent all imported lot labeling scenarios during this transition.

Imported Product from Ireland	US FDA approved Product

Lot B4945R EXP 2500 ml

Baxter

EXTRANEAL Solution for Peritoneal Dialysis

Formula 1000 ml			mmol/l
Icodextrin	75 g	Na^+	133
Sodium Chloride	5,4 g	Ca^{++}	1,75
Sodium (S)-lactate	4,5 g	Mg^{++}	0,25
Calcium Chloride $2H_2O$	0,257 g	Cl^-	96
Magnesium Chloride $6H_2O$	0,051 g	$C_3H_5O_3^-$	40
Water for Injections		Osmolarity	284 mOsm/l
Hydrochloric acid or sodium hydroxide (for pH adjustment)		pH	5,0 – 6,0

For intraperitoneal use
Not for intravenous use
Use as directed by a physician
Read the package leaflet before use
Keep out of the sight and reach of children
Nonpyrogenic
Do not store below 4°C
Do not use unless solution is clear and container undamaged
For single use only
Once removed from the overpouch use immediately
Discard unused solution

UK:
Baxter Healthcare Ltd
Caxton Way, Thetford, Norfolk, IP24 3SE,
United Kingdom

IE and MT:
Baxter Holding B.V.,
Kobaltweg 49, 3542CE, Utrecht,
Netherlands

PL 00116/0266
PA 2299/017/001
MA 1277/01101
POM

Manufactured by Baxter Healthcare S A IRL-Castlebar CB-35-04-606

BAXTER VERSION

L5B4976 2500 mL
NDC 0941-0679-05 (APPROX 90 mL EXCESS)

Baxter

Extraneal (icodextrin)
Peritoneal Dialysis Solution

(01)00309410679050

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

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

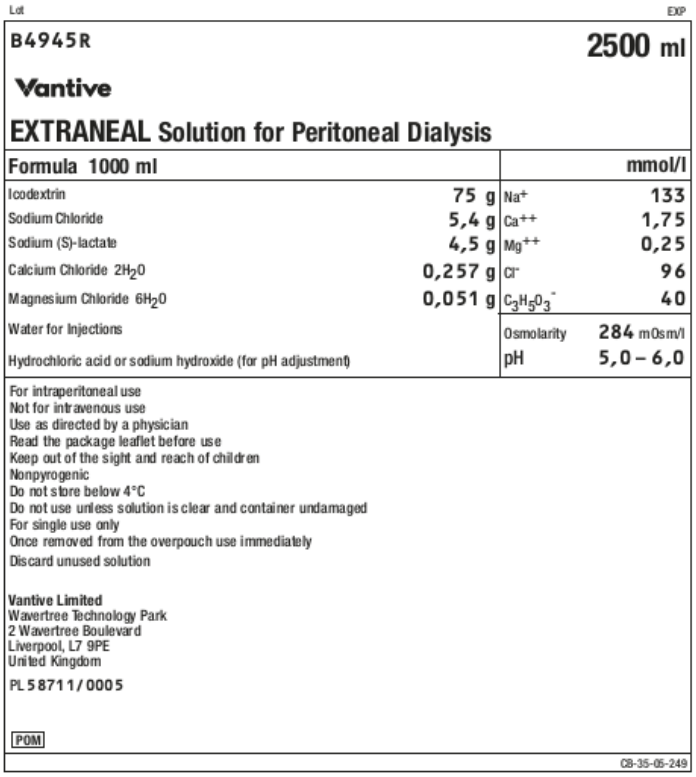
BAXTER EXTRANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA

US PAT NOS 4761237 4886799 6077836 6248726 B1

PD-2 7.5% icodextrin

Imported Product from Ireland	US FDA approved Product
	

Lot B4945R

EXP 2500 ml

Vantive

EXTRANEAL Solution for Peritoneal Dialysis

Formula 1000 ml			mmol/l
Icodextrin	75 g	Na^+	133
Sodium Chloride	5,4 g	Ca^{++}	1,75
Sodium (S)-lactate	4,5 g	Mg^{++}	0,25
Calcium Chloride $2H_2O$	0,257 g	Cl^-	96
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Water for Injections		Osmolarity	284 mOsm/l
Hydrochloric acid or sodium hydroxide (for pH adjustment)		pH	5,0 – 6,0

For intraperitoneal use
Not for intravenous use
Use as directed by a physician
Read the package leaflet before use
Keep out of the sight and reach of children
Nonpyrogenic
Do not store below 4°C
Do not use unless solution is clear and container undamaged
For single use only
Once removed from the overpouch use immediately
Discard unused solution

Vantive Limited
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2 Wavertree Boulevard
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PL 58711/0005

POM

CB-35-05-249

VANTIVE VERSION