Baxter

IMPORTANT PRESCRIBING INFORMATION

DATE: October 22, 2024

Subject: Temporary importation of EXTRANEAL 7.5% (icodextrin) (2500 mL) Peritoneal Dialysis Solution from Canada for use in Automated Peritoneal Dialysis (APD) 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 7.5% (icodextrin) Peritoneal Dialysis Solution (2500 mL) from Baxter's manufacturing facility in Alliston, Canada. FDA has not approved this product manufactured by Baxter's Alliston, Canada 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 7.5% w/v 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 Alliston, Canada and is marketed in Canada. At this time, importation or distribution of this EXTRANEAL 7.5% w/v 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 Alliston, Canada:

Product Name and Description	APD Fill Volume	Product Code	Bags per Carton	NDC Code
EXTRANEAL 7.5% w/v Icodextrin Peritoneal Dialysis Solution	2500 mL	JB9923L	5 bags	NDC 0941-0709-01 (Bag) NDC 0941-0709-05 (Carton)

It is important to note the following:

- There are no clinically relevant differences in the EXTRANEAL drug composition between the Canadian-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 Canada) 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 7.5% w/v Icodextrin Peritoneal Dialysis Solution imported from Canada will only be available in 2500 mL fill volume for APD, so there will be a need to adapt the PD prescription for some patients.
- Electrolyte concentrations are identical in EXTRANEAL manufactured in the Canada and US but appear different as they are expressed in mmol/L (Canada) and in mEq/L (US).

- The Luer-lock connector on the Canada imported product functions the same and is fully compatible with peritoneal dialysis sets marketed in the United States. Additionally, the Canada imported product has the same purple pull ring cap as the US-manufactured product. See Table 1 for more details of product differences.
- EXTRANEAL 7.5% w/v Icodextrin Peritoneal Dialysis Solution imported product solution container and carton labeling include barcodes; however, **the barcodes may not register accurately in the US scanning systems.** 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 manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned.
- EXTRANEAL 7.5% Icodextrin Peritoneal Dialysis Solution is available only by prescription in the U.S. 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 7.5% w/v Icodextrin Peritoneal Dialysis Solution products (manufactured in Canada) and EXTRANEAL (icodextrin) Peritoneal Dialysis Solution (manufactured in US).

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 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 7.5% w/v 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: Oct 22, 2024 20:14 CDT

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

Table 1. Key differences of EXTRANEAL for APD therapy

	Imported Product from Canada	US FDA Approved Product
Product name	EXTRANEAL 7.5% w/v Icodextrin Peritoneal Dialysis Solution	EXTRANEAL (icodextrin) Peritoneal Dialysis Solution
Labeled Fill Volume	2500 mL	2000 mL 2500 mL
Container Type	Viaflex PVC Container	Ambu-Flex Container (PVC)
Bags per carton	5 bags	2000 mL: 6 bags 2500 mL: 5 bags
Indications	EXTRANEAL (icodextrin, sodium chloride, sodium lactate, calcium chloride, magnesium chloride) is indicated for use as an osmotic agent for long dwell, up to 12 hours, in continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD), where it can be used for 14 and up to 16 hours.	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) 5.35 g/L Sodium Chloride (535 mg/100 mL) 4.48 g/L Sodium Lactate (448 mg/100 mL) 0.257 g/L Calcium Chloride (25.7 mg/100 mL) 0.051 g/L Magnesium Chloride (5.1 mg/100 mL)	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 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	Store at 15–25°C. Do not freeze	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	12 months	18 months

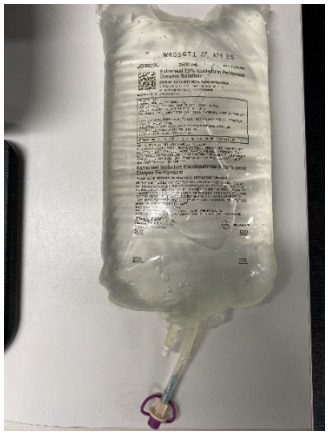
	Imported Product from Canada	US FDA Approved Product
Container Closure System		
Container Closure	 • One blue frangible at luer-lock connector • Purple pull ring cap closure	 • One blue frangible at luer-lock connector • Purple pull ring cap closure

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

Imported Product from Canada	US FDA approved Product