

EXTRANEAL- icodextrin, sodium chloride, sodium lactate, calcium chloride, magnesium chloride 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.

EXTRANEAL Solution for Peritoneal Dialysis

Health Care Provider Letter

IMPORTANT PRESCRIBING INFORMATION

DATE: October 22, 2024

Subject: Temporary importation of EXTRANEAL (icodextrin) Peritoneal Dialysis Solution from Ireland for use in Continuous Ambulatory 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. 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 Continuous Ambulatory Peritoneal Dialysis (CAPD) 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	CAPD Fill Volume	Product Code	Bags per Carton	NDC Code
EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis	2000 mL	FPB5268C	5 bags	0941-0717-01 (bag) 0941-0717-05 (carton)
EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis	2500 mL	FPB5270	4 bags	0941-0681-01 (bag) 0941-0681-04 (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 CAPD 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.

- 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 and is fully compatible with peritoneal dialysis sets marketed in the United States. Ireland imported product has a single green frangible near the Y connector which is broken at the same time during flush phase as the corresponding blue frangible in U.S.-manufactured product. The Ireland imported product has solution in the infusion line whereas U.S. manufactured product has a dry line. 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. 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.

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 CAPD therapy
- Table 2: Label images of EXTRANEAL for 2000 mL and 2500 mL CAPD 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 report to:

[Baxter - Product Feedback Portal \(https://productfeedback.baxter.com/\)](https://productfeedback.baxter.com/).

Please refer to the FDA approved prescribing information for EXTRANEAL (icodextrin) Peritoneal Dialysis Solution at [DailyMed \(nih.gov\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/021122Orig1s001.pdf).

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: Ok.
Date: Oct 22, 2024 08:52
CDT

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

Baxter, EXTRANEAL and ULTRABAG (or UltraBag) are registered trademarks of Baxter International Inc.

Attachments:

Product Comparison Tables 1 and 2

Table 1. Key differences of EXTRANEAL for CAPD therapy



	Imported Product from Castlebar, Ireland	US FDA Approved Product
Product name	EXTRANEAL (icodextrin) Solution for Peritoneal Dialysis	EXTRANEAL (icodextrin) Peritoneal Dialysis Solution
Labeled Fill Volume	2000 mL 2500 mL	2000 mL 2500 mL
Container Type	TwinBag (PVC)	UltraBag Container (PVC)
Bags per carton	2000 mL: 5 bags 2500 mL: 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) 0.257 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/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 mOsm/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
Container Closure System		
Container Closure Differences	<ul style="list-style-type: none"> One green frangible in "Y"-junction to be broken in Flush phase Solution in infusion tubing line Purple ring cap 	<ul style="list-style-type: none"> Two frangibles – one blue in "Y"-junction and one green near solution bag Dry tubing lines Purple ring cap

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 Castlebar, Ireland	US FDA Approved Product																
<p>Lot EXP</p> <p>B5268 2000 ml</p> <p>Baxter</p> <p>EXTRANEAL Solution for Peritoneal Dialysis</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Formula 1000 ml</th> <th style="text-align: right;">mmol/l</th> </tr> </thead> <tbody> <tr> <td>Icodextrin</td> <td style="text-align: right;">75 g Na⁺ 133</td> </tr> <tr> <td>Sodium Chloride</td> <td style="text-align: right;">5,4 g Ca⁺⁺ 1,75</td> </tr> <tr> <td>Sodium (S)-lactate</td> <td style="text-align: right;">4,5 g Mg⁺⁺ 0,25</td> </tr> <tr> <td>Calcium Chloride 2H₂O</td> <td style="text-align: right;">0,257 g Cl⁻ 96</td> </tr> <tr> <td>Magnesium Chloride 6H₂O</td> <td style="text-align: right;">0,051 g C₂H₃O₃⁻ 40</td> </tr> <tr> <td>Water for injections</td> <td style="text-align: right;">Osmolarity 284 mOsm/l</td> </tr> <tr> <td>Hydrochloric acid or sodium hydroxide (for pH adjustment)</td> <td style="text-align: right;">pH 5,0 - 6,0</td> </tr> </tbody> </table> <p>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</p> <p>UK: Baxter Healthcare Ltd Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom</p> <p>IE and ME: Baxter Holding B.V. Kobaltweg 49, 3542CE, Utrecht, Netherlands</p> <p>PL 00116/0266 PA 2299/017/001 MA 1277/01101</p> <p>POM</p> <p>Manufactured by Baxter Healthcare S.A. IRL-Castlebar CB-35-04-606</p>	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 ₂ O	0,257 g Cl ⁻ 96	Magnesium Chloride 6H ₂ O	0,051 g C ₂ H ₃ O ₃ ⁻ 40	Water for injections	Osmolarity 284 mOsm/l	Hydrochloric acid or sodium hydroxide (for pH adjustment)	pH 5,0 - 6,0	<p>5B4984 2000 mL <small>NDC 0941-0579-52 (APPROX 80 mL EXCESS)</small></p> <p>Baxter</p> <p>Extraneal (icodextrin) Peritoneal Dialysis Solution</p> <p>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</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> <p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> </div> <p>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</p> <p>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</p> <p>UltraBag CONTAINER PL 146 PLASTIC BAXTER EXTRANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4761237 4573980 4886789 6077836 6248726 B1</p>
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 ₂ O	0,257 g Cl ⁻ 96																
Magnesium Chloride 6H ₂ O	0,051 g C ₂ H ₃ O ₃ ⁻ 40																
Water for injections	Osmolarity 284 mOsm/l																
Hydrochloric acid or sodium hydroxide (for pH adjustment)	pH 5,0 - 6,0																
<p>BAXTER VERSION</p>	<div style="border: 1px solid black; padding: 5px; transform: rotate(90deg); transform-origin: center;"> <p>PD-2 7.5% icodextrin</p> </div>																

Imported Product from Castlebar, Ireland		US FDA Approved Product	
Lot		EXP	
B5268		2000 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 ₂ O	0,257 g	Cl ⁻	96
Magnesium Chloride 6H ₂ O	0,051 g	C ₂ H ₅ O ₂ ⁻	40
Water for injections		Osmolarity	284 mOsm/l
Hydrochloric acid or sodium hydroxide (for pH adjustment)		pH	5,0 – 6,0
<p>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</p> <p>Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom PL 58711/0005</p>			
<p>POM</p> <p style="text-align: right;">GB-35-06-250</p>			
VANTIVE VERSION			

Imported Product from Castlebar, Ireland		US FDA Approved Product	
Lot B5270	EXP 2500 ml	5B4986 NDC 0941-0670-01	2500 mL (APPROX 90 mL EXCESS)
Baxter		Baxter	
EXTRANEAL Solution for Peritoneal Dialysis		Extraneal (Icodextrin) Peritoneal Dialysis Solution	
Formula 1000 ml	mmol/l	EACH 100 mL CONTAINS 7.5 g ICODEXTRIN 535 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 3.56 mg MAGNESIUM CHLORIDE USP WATER FOR INJECTION USP	
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 ₂ O	0,257 g	Cl ⁻	96
Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O ₃ ⁻	40
Water for Injections		Osmolarity	284 mOsm/l
Hydrochloric acid or sodium hydroxide (for pH adjustment)		pH	5,0 - 6,0
<p>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</p> <p>UK: Baxter Healthcare Ltd Coxon Way, Thetford, Norfolk, IP24 3SE, United Kingdom</p> <p>IE and NL: Baxter Holding B.V., Kobaltweg 40, 3542CE, Utrecht, Netherlands</p> <p>PL 00116/0266 PA 2299/017/001 MA 1277/01101</p> <p>PGM</p> <p>Manufactured by Baxter Healthcare S.A. IRL-Castlebar CB-25-04-629</p>		<p>POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER THE DIRECTION OF A PHYSICIAN</p> <p>SEE PACKAGE INSERT FOR DOSAGE INFORMATION USE AS DIRECTED BY PHYSICIAN</p> <p>FOR INTRAPERITONEAL ADMINISTRATION ONLY</p> <p>CAUTIONS SQUEEZE AND INSPECT INNER BAG THAT MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND</p> <p>DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION</p> <p>Rx ONLY</p> <p>STORE IN MOISTURE BARRIER OVERPOUCH IN CARTON UNTIL READY TO USE</p> <p>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</p> <p>UltraBag CONTAINER PL 140 PLASTIC BAXTER EXTRANEAL ULTRABAG AND PL 140 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC</p> <p>BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA US PAT NOS 4761237 4573980 4880789 6077836 6248726 B1</p>	
BAXTER VERSION		PD-2 7.5% icodextrin	

Imported Product from Castlebar, Ireland		US FDA Approved Product	
Lot		EXP	
B5270		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 ₂ O	0,257 g	Cl ⁻	96
Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O ₃ ⁻	40
Water for injections		Osmolarity	284 mOsm/l
Hydrochloric acid or sodium hydroxide (for pH adjustment)		pH	5,0 - 6,0
<p>For intraperitoneal use Not for intravenous use Use as directed by a physician Read the package insert 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</p> <p>Vantive Limited Waverline Technology Park 2 Waverline Boulevard Liverpool, L7 9PE United Kingdom</p> <p>PL 58711/0005</p>			
<p>POM</p> <p style="text-align: right;">CB-35-05-251</p>			
VANTIVE VERSION			

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Lot

EXP

B5268**2000 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 ₂ O	0,257 g	Cl ⁻	96
Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O 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-35-04-608

Lot EXP
 B5268 2000 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	0,257 g	Cl ⁻	96

2H ₂ O			
Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O ₃ ⁻	40
Water for Injections		Osmolarity	284mOsm/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 Symbol

Manufactured by Baxter Healthcare S A IRL-Castlebar CB-35-04-608

EXTRANEAL FPB5268C

2000 ml x 5

Solution for Peritoneal Dialysis

1000 ml:	
Icodextrin	75 g
Sodium Chloride	5,4 g
Sodium (S)-lactate	4,5 g
Calcium Chloride 2H ₂ O	0,257 g
Magnesium Chloride 6H ₂ O	0,051 g
Water for injections to 1000 ml	
Sodium hydroxide or hydrochloric acid (for pH adjustment)	

Do not store below 4°C.



Twin bag with Luer connector

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

POM

For intraperitoneal use
Not for intravenous infusion
Keep out of the sight and reach of children

UK: Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom
IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands

88-46-13-196

Lot:



(01)554 13760423833(17)201200(10)88C88C88B2

FPB5268C
2000 ml x 5



EXTRANEAL

Lot:

EXTRANEAL
FPB5268C
2000 ml x 5

Solution for Peritoneal Dialysis

1000 ml	
Icodextrin	75 g
Sodium Chloride	5,4 g
Sodium (S)-lactate	4,5 g
Calcium Chloride 2H ₂ O	0,257 g
Magnesium Chloride 6H ₂ O	0,051 g
Water for injections to 1000 ml	
Sodium hydroxide or hydrochloric acid (for pH adjustment)	

For intraperitoneal use
Not for intravenous infusion
Keep out of the sight and reach of children

UK: Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom
IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE, Utrecht, Netherlands

88-46-13-196

Lot: EXP

Do not store below 4°C

Twin bag with Luer connector

MA 1277/01101

PA 2299/017/001

PL 00116/0266

POM Symbol

Barcode

(01)554 13760423833(17)201200(10)88C88C88B2

EXTRANEAL

FPB5268C

2000 ml x 5

Lot: EXP

B5268**2000 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 ₂ O	0,257 g	Cl ⁻	96
Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O 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

Vantive Limited
 Wavertree Technology Park
 2 Wavertree Boulevard
 Liverpool, L7 9PE
 United Kingdom
 PL 58711/0005

POM

CB-35-05-250

Lot EXP
 B5268 2000 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 ₂ O	0,257 g	Cl ⁻	96

Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O ₃ ⁻	40
Water for Injections		Osmolarity	284mOsm/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

Wavertree Technology Park

2 Wavertree Boulevard

Liverpool, L7 9PE

United Kingdom

PL 58711/0005

POM Symbol

CB-35-05-250

EXTRANEAL FPB5268C

2000 ml x 5

PR

Solution for Peritoneal Dialysis

1000 ml:	
Icodextrin	75 g
Sodium Chloride	5,4 g
Sodium (S)-lactate	4,5 g
Calcium Chloride 2H ₂ O	0,257 g
Magnesium Chloride 6H ₂ O	0,051 g
Water for injections to 1000 ml	
Sodium hydroxide or hydrochloric acid (for pH adjustment)	

For intraperitoneal use
Not for intravenous infusion
Keep out of the sight and reach of children

Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

88-46-14-007

Lot:



UK Only

Do not store below 4°C.



Twin bag with Luer connector

PL 58711/0005

POM



FPB5268C
2000 ml x 5



EXTRANEAL

Lot:

EXTRANEAL
FPB5268C
2000 ml x 5

Solution for Peritoneal Dialysis

1000 ml	
Icodextrin	75 g
Sodium Chloride	5,4 g
Sodium (S)-lactate	4,5 g
Calcium Chloride 2H ₂ O	0,257 g
Magnesium Chloride 6H ₂ O	0,051 g
Water for injections to 1000 ml	
Sodium hydroxide or hydrochloric acid (for pH adjustment)	

For intraperitoneal use
Not for intravenous infusion
Keep out of the sight and reach of children

Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

88-46-14-007

Lot: EXP

UK Only

Do not store below 4°C

Twin bag with Luer connector

PL 58711/0005

POM Symbol

Barcode

(01)57332414203103 (17)201200(10)88C88C88B2

EXTRANEAL

FPB5268C

2000 ml x 5

Lot: EXP

B5270**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 ₂ O	0,257 g	Cl ⁻	96
Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O 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**

POMManufactured by **Baxter Healthcare S A** IRL-Castlebar CB-35-04-609

Lot EXP
 B5270 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	0,257 g	Cl ⁻	96

2H ₂ O			
Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O ₃ ⁻	40
Water for Injections		Osmolarity	284mOsm/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 Symbol

Manufactured by Baxter Healthcare S A IRL-Castlebar CB-35-04-609

EXTRANEAL FPB5270

2500 ml x 4

Solution for Peritoneal Dialysis

1000 ml:	
Icodextrin	75 g
Sodium Chloride	5,4 g
Sodium (S)-lactate	4,5 g
Calcium Chloride 2H ₂ O	0,257 g
Magnesium Chloride 6H ₂ O	0,051 g
Water for injections to 1000 ml	
Sodium hydroxide or hydrochloric acid (for pH adjustment)	

For intraperitoneal use
Not for intravenous infusion
Keep out of the sight and reach of children

UK: Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom
IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands

88-46-13-197

Lot:



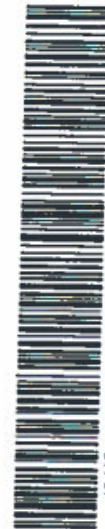
Do not store below 4°C.



Twin bag with Luer connector

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

POM



(01)50085412574412(17)201200(10)88C88C8882

FPB5270
2500 ml x 4



EXTRANEAL

Lot:

EXTRANEAL
FPB5270
2500 ml x 4

Solution for Peritoneal Dialysis

1000 ml	
Icodextrin	75 g
Sodium Chloride	5,4 g
Sodium (S)-lactate	4,5 g
Calcium Chloride 2H ₂ O	0,257 g
Magnesium Chloride 6H ₂ O	0,051 g
Water for injections to 1000 ml	
Sodium hydroxide or hydrochloric acid (for pH adjustment)	

For intraperitoneal use
Not for intravenous infusion
Keep out of the sight and reach of children

UK: Baxter Healthcare Limited Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom
IE and MT: Baxter Holding B.V. Kobaltweg 49, 3542CE, Utrecht, Netherlands

88-46-13-197

Lot: EXP

Do not store below 4°C

Twin bag with Luer connector

MA 1277/01101

PA 2299/017/001

PL 00116/0266

POM Symbol

Barcode

(01)50085412574412(17)201200(10)88C88C88B2

EXTRANEAL

FPB5270

2000 ml x 4

Lot: EXP

Lot

EXP

B5270**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 ₂ O	0,257 g	Cl ⁻	96
Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O 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

Vantive Limited
 Wavertree Technology Park
 2 Wavertree Boulevard
 Liverpool, L7 9PE
 United Kingdom

PL 58711/0005

POM

CB-35-05-251

Lot EXP
 B5270 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 ₂ O	0,257 g	Cl ⁻	96

Magnesium Chloride 6H ₂ O	0,051 g	C ₃ H ₅ O ₃ ⁻	40
Water for Injections		Osmolarity	284mOsm/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


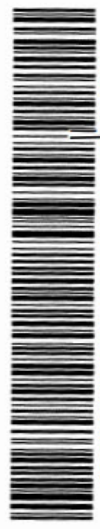

Vantive Limited

Wavertree Technology Park
 2 Wavertree Boulevard
 Liverpool, L7 9PE
 United Kingdom

PL 58711/0005

POM Symbol

CB-35-05-251

EXTRANEAL	FPB5270	2500 ml x 4
Solution for Peritoneal Dialysis		
UK Only		
Do not store below 4°C.		
		
Twin bag with Luer connector		
PL 58711/0005		
POM		
		
(01)57332414202649(17)201200(10)88C85C88B2		
FPB5270		
2500 ml x 4		
 EXP		
EXTRANEAL		
Lot:		

1000 ml:	
Icodextrin	75 g
Sodium Chloride	5.4 g
Sodium (S)-lactate	4,5 g
Calcium Chloride 2H ₂ O	0,257 g
Magnesium Chloride 6H ₂ O	0,051 g
Water for injections to 1000 ml	
Sodium hydroxide or hydrochloric acid (for pH adjustment)	

For intraperitoneal use
 Not for intravenous infusion
 Keep out of the sight and reach of children

Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE United Kingdom

88-46-14-008

Lot:  EXP

EXTRANEAL
FPB5270
2500 ml x 4

Solution for Peritoneal Dialysis

1000 ml	
Icodextrin	75 g
Sodium Chloride	5,4 g
Sodium (S)-lactate	4,5 g
Calcium Chloride 2H ₂ O	0,257 g
Magnesium Chloride 6H ₂ O	0,051 g
Water for injections to 1000 ml	
Sodium hydroxide or hydrochloric acid (for pH adjustment)	

For intraperitoneal use
Not for intravenous infusion
Keep out of the sight and reach of children

Vantive Limited Wavertree Technology Park 2 Wavertree Boulevard Liverpool, L7 9PE
United Kingdom

88-46-14-008

Lot: EXP

UK Only

Do not store below 4°C

Twin bag with Luer connector

PL 58711/0005

POM Symbol

Barcode
(01)57332414202649 (17)201200(10)88C88C88B2

EXTRANEAL
FPB5270

2500 ml x 4

Lot: EXP

EXTRANEAL

icodextrin, sodium chloride, sodium lactate, calcium chloride, magnesium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0941-0681
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ICODEXTRIN (UNII: 2NX48Z0A9G) (ICODEXTRIN - UNII:2NX48Z0A9G)	ICODEXTRIN	7.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	540 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	SODIUM LACTATE	450 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	25.7 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.1 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0681-04	4 in 1 CARTON	10/21/2024	
1	NDC:0941-0681-01	2500 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		10/21/2024	

EXTRANEAL

icodextrin, sodium chloride, sodium lactate, calcium chloride, magnesium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0941-0717
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ICODEXTRIN (UNII: 2NX48Z0A9G) (ICODEXTRIN - UNII:2NX48Z0A9G)	ICODEXTRIN	7.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	540 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	SODIUM LACTATE	450 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	25.7 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.1 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0941-0717-05	5 in 1 CARTON	10/21/2024	
1	NDC:0941-0717-01	2000 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		10/21/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare S.A.		988899845	analysis(0941-0681, 0941-0717) , api manufacture(0941-0681, 0941-0717) , label(0941-0681, 0941-0717) , manufacture(0941-0681, 0941-0717) , pack(0941-0681, 0941-0717) , sterilize(0941-0681, 0941-0717)

Revised: 11/2024

Baxter Healthcare Corporation