

Vantive

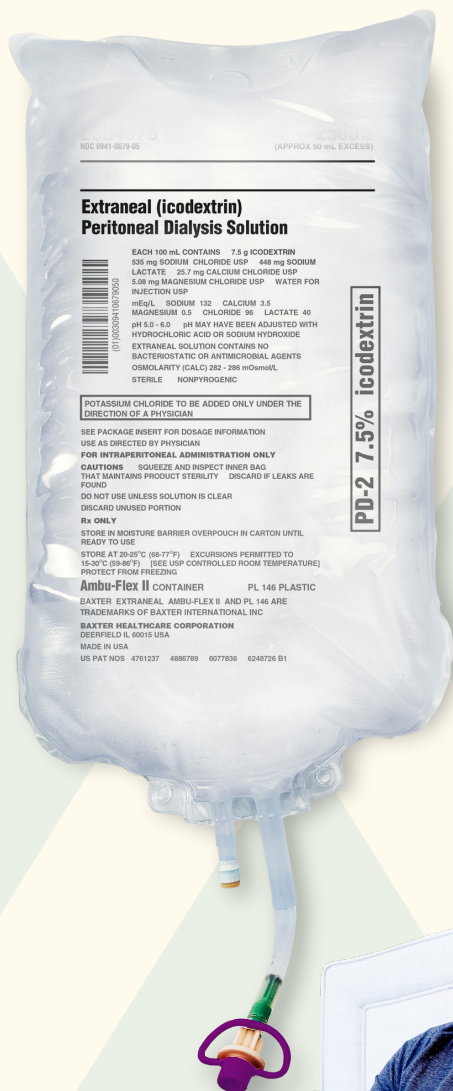
Extraneal

(ICODEXTRIN) PERITONEAL DIALYSIS SOLUTION

VANTIVE KIDNEY CARE

PD | HD | HDx | CRRT | EDUCATION | SUPPORT

START WITH EXTRANEAL



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
EXTRANEAL SOLUTION CONTAINS NO
BACTERIOSTATIC OR ANTIMICROBIAL AGENTS
OSMOLARITY (CALC) 282 - 286 mOsm/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



INDICATIONS:

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).

LET'S START AT THE BEGINNING:

Compared to dextrose PD solutions, prescribing one bag a day of icodextrin-based **EXTRANEAL** (icodextrin) Peritoneal Dialysis Solution, **from the start of Peritoneal Dialysis (PD) therapy** has the following benefits:

- Reduces glucose exposure over time and its associated complications¹⁻⁷
- May result in improved fluid balance^{3,8-16}
- Longer sustained PD success^{2,16,17}

Deliver an optimal PD experience from the start by prescribing **EXTRANEAL** Solution. Because less glucose exposure and its associated complications over time¹⁻⁷ can mean everything, including a chance to protect your patient's choice for PD.

YOU AND YOUR PATIENTS DESERVE NOTHING LESS.

WHAT IS EXTRANEAL?

EXTRANEAL Solution is a **non-glucose, 7.5% icodextrin solution** for the long dwell, widely used by nephrologists for 20+ years.

EXTRANEAL Solution is available for both CAPD and APD patients in the following containers and fill volumes:

THERAPY TYPE	FILL VOLUME	PRODUCT CODE
CAPD	2.0 L	5B4984
	2.5 L	5B4986
APD	2.0 L	L5B4974
	2.5 L	L5B4976

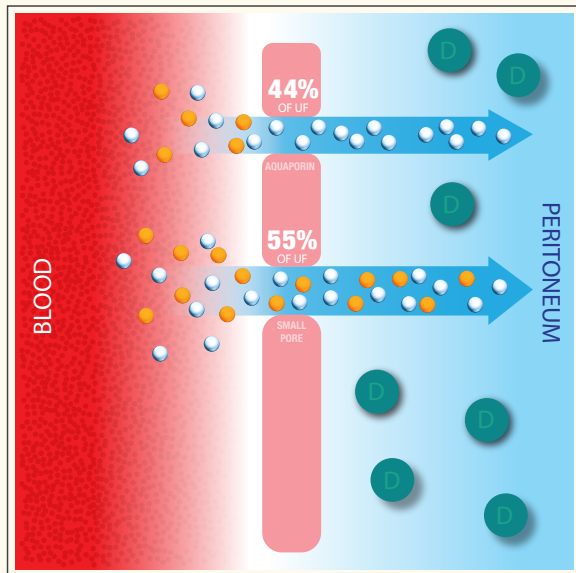
THE LONG DWELL

The dwell time is the prescribed period of time the dialysis fluid stays in the patient's abdomen. A short dwell is typically below 4 to 6 hours, while the long dwell is 8 to 16 hours. The challenge over the long dwell is that glucose will be absorbed over time leading to gradual fluid resorption from the peritoneal cavity.¹⁵

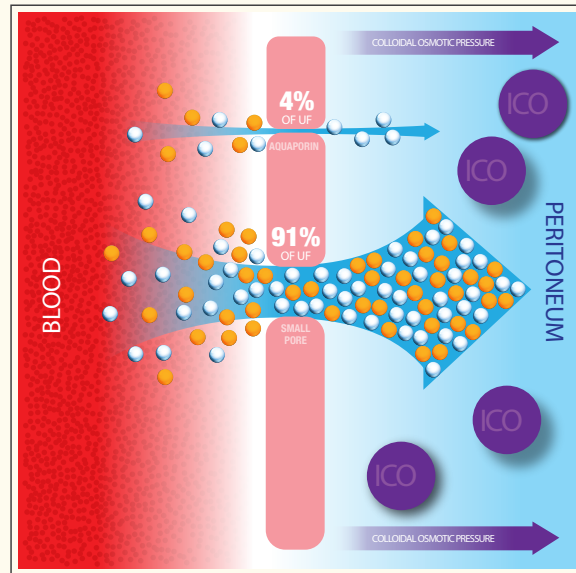
Please see important risk information to follow.

HOW DOES EXTRANEAL (ICODEXTRIN) WORK?

DEXTROSE



ICODEXTRIN

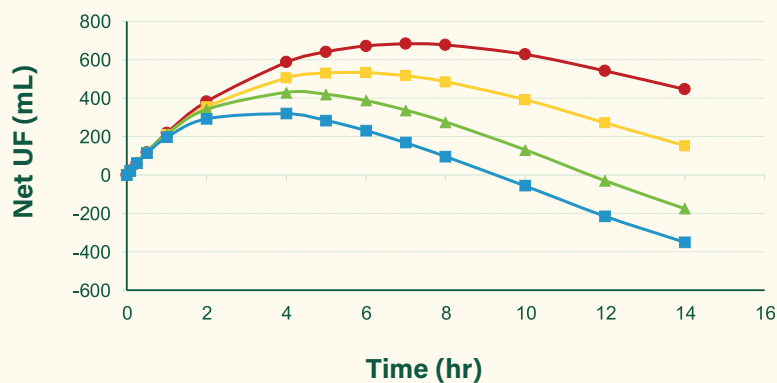


Adapted from Devuyst O, Rippe B. *Kidney Int.* 2014;85(4):750-758¹⁸

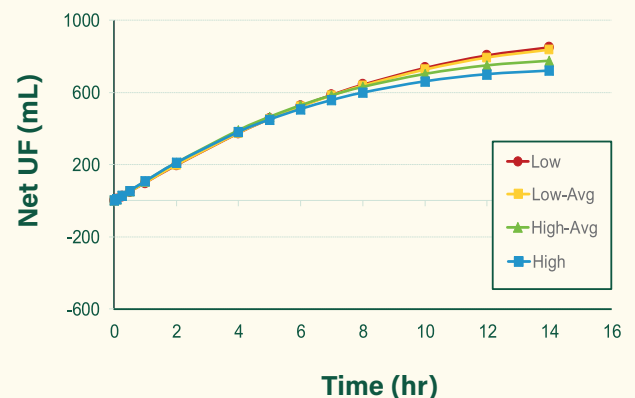
Extraneal (icodextrin) Functions Irrespective of Transport Type¹⁹

TEMPORAL PROFILE OF NET ULTRAFILTRATION IN THE FOUR STANDARD TRANSPORT CATEGORIES WITH THE USE OF 2.5% DEXTROSE SOLUTION AND 7.5% ICODEXTRIN SOLUTION¹⁹

2.5% DEXTROSE¹⁹



EXTRANEAL (ICODEXTRIN)¹⁹



Computer-generated model. Adapted from Mujais S, et al. *Kidney Int Suppl.* 2002;(81):S17-S22.

Please see important risk information to follow.

ONE DAILY BAG. MULTIPLE BENEFITS.

Prescribing one bag **EXTRANEAL** (icodextrin) Peritoneal Dialysis Solution **FROM THE START** of PD therapy may bring the following benefits to patient outcomes:



1. LESS GLUCOSE FROM THE START

Prescribing PD patients with icodextrin solution, such as **EXTRANEAL** (icodextrin 7.5%) Solution for Peritoneal Dialysis from the start, limits glucose exposure during PD therapy, potentially minimizing changes to the peritoneal membrane and cardiovascular (CV) metabolic risk.¹⁻⁷



2. LESS TREATMENT COMPLICATIONS

Icodextrin solution, such as **EXTRANEAL** (icodextrin 7.5%) Solution for Peritoneal Dialysis may improve clinical outcomes by increasing ultrafiltration and maintaining fluid balance.^{3,8-16} Achieving fluid balance throughout the time on PD therapy is critical in the success of therapy, as fluid overload may result in transfer to HD and increased risk of cardiac events and mortality.^{8,10,13,16,17,20,21}

Selected Risk Information:

Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.



3. LESS POTENTIAL RISK FOR PD DROPOUT

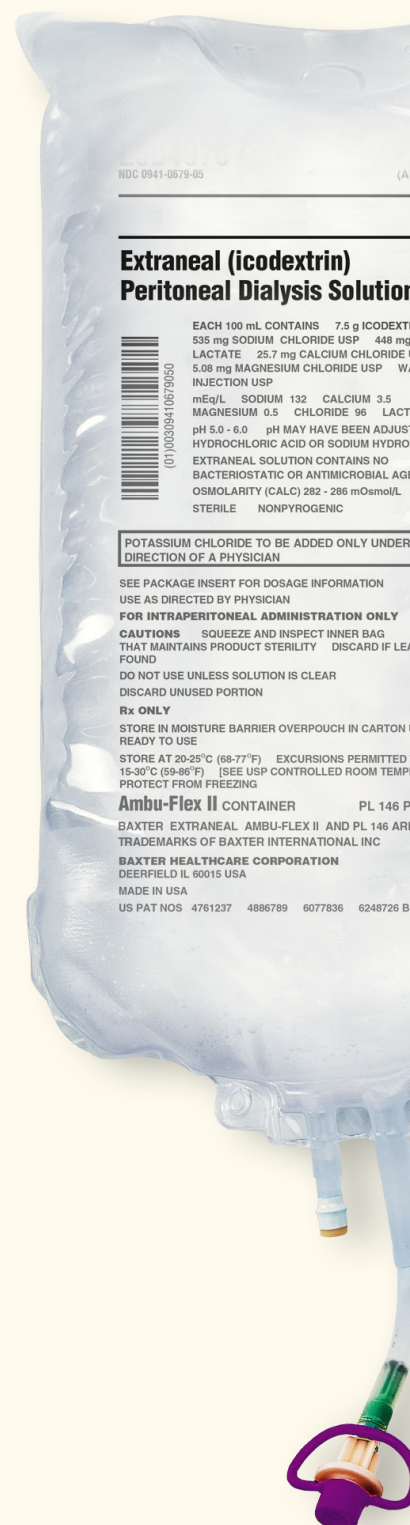
When prescribed from the onset of PD, one daily bag of icodextrin solution, such as **EXTRANEAL** (icodextrin 7.5%) Solution for Peritoneal Dialysis for the long dwell may increase patient time on therapy.^{2,16,17} Extended time on therapy supports key patient and clinician priorities, including staying on the patients' modality of choice, preserving residual kidney function (RKF) and remaining active in society.^{2,17,22}



ISPD GUIDELINES RECOMMENDS THE USE OF ICODEXTRIN

The International Society for Peritoneal Dialysis (ISPD) guidelines recommend "high-quality goal-directed peritoneal dialysis."²³

Individualization of the prescription is a key component of this high quality dialysis therapy, and can be achieved through a combination of Icodextrin and glucose based solutions.²³ This is contrary to the prevalent notion that only glucose solutions should be used at the beginning of PD therapy.



NOTHING LESS THAN EVERYTHING.

Please see important risk information to follow.

EXTRANEAL (ICODEXTRIN) PERITONEAL DIALYSIS SOLUTION

INDICATIONS AND IMPORTANT RISK INFORMATION (IRI)

INDICATIONS:

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).

IMPORTANT RISK INFORMATION:

- EXTRANEAL is contraindicated in patients with a known hypersensitivity to icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with severe lactic acidosis.
- When measuring blood glucose levels in patients using EXTRANEAL, do not use blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ)-, glucose-dye-oxidoreductase (GDO)-, and some glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods because these systems may result in falsely elevated glucose readings (due to the presence of maltose). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately leading to unrecognized hypoglycemia. Falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL therapy when GDH-PQQ, GDO, and GDHFAD-based blood glucose monitors and test strips are used. Additionally, other glucose-measuring technologies, such as continuous glucose monitoring systems, may or may not be compatible with EXTRANEAL. Always contact the device manufacturer for current information regarding compatibility and intended use of the device in the dialysis patient population.
- EXTRANEAL is intended for intraperitoneal administration only. Not for intravenous or intra-arterial administration. Aseptic technique should be used throughout the peritoneal dialysis procedure.
- Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using EXTRANEAL.
- Serious hypersensitivity reactions to EXTRANEAL have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. If a serious reaction is suspected, discontinue EXTRANEAL immediately and institute appropriate therapeutic countermeasures.
- Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat overinfusion.
- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with EXTRANEAL. Monitor blood glucose and adjust insulin, if needed.
- Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.
- In clinical trials, the most frequently reported adverse events occurring in $\geq 10\%$ of patients and more common in EXTRANEAL PD solution patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse reaction for EXTRANEAL PD solution patients was skin rash.

Please see accompanying full Prescribing Information for Extraneal PD Solution.

START WITH EXTRANEAL AND HELP PROTECT YOUR PATIENTS' CHOICE OF PD.

TALK TO YOUR VANTIVE SALES REPRESENTATIVE FOR MORE INFORMATION ON EXTRANEAL PD SOLUTION.



Scan the QR code for additional information on the benefits of Extraneal.

<https://pro.vantive.com/extraneal-icodextrin-pd-solution>



Scan the QR code to read the ISPD Guidelines.

<https://journals.sagepub.com/doi/pdf/10.1177/0896860820982218>

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