DIANEAL Peritoneal Dialysis Solution

For intraperitoneal administration only

DIANEAL PD-2 Peritoneal Dialysis Solution With 1.5% Dextrose	DIANEAL PD-2 Peritoneal Dialysis Solution With 2.5% Dextrose	DIANEAL PD-2 Peritoneal Dialysis Solution With 4.25% Dextrose	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution With 1.5% Dextrose	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution With 2.5% Dextrose	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution With 4.25% Dextrose

DESCRIPTION

DIANEAL Peritoneal Dialysis Solutions are sterile, nonpyrogenic solutions in flexible containers for intraperitoneal administration only. The peritoneal dialysis solutions contain no bacteriostatic or antimicrobial agents.

Composition, calculated osmolarity, pH, and ionic concentrations are shown in Tables 1-6. DIANEAL is a hyperosmolar solution.

The plastic container is fabricated from polyvinyl chloride (PL 146 Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water that can permeate from inside the solution container into the overwrap is insufficient to affect the solution significantly.

Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g. di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by cell culture toxicity studies.

CLINICAL PHARMACOLOGY

Mechanism of Action

DIANEAL is a hypertonic peritoneal dialysis solution containing dextrose, a monosaccharide, as the primary osmotic agent. An osmotic gradient must be created between the peritoneal membrane and the dialysis solution in order for ultrafiltration to occur. The hypertonic concentration of glucose in DIANEAL exerts an osmotic pressure across the peritoneal membrane resulting in transcapillary ultrafiltration. Like other peritoneal dialysis solutions, DIANEAL contains electrolytes to facilitate the correction of electrolyte abnormalities. DIANEAL contains a buffer, lactate, to help normalize acid-base abnormalities.

Pharmacokinetics of DIANEAL

Glucose content in DIANEAL is expressed as dextrose monohydrate and is available in three concentrations: 1.5%, 2.5% and 4.25%.

Glucose is rapidly absorbed from the peritoneal cavity by diffusion and appears quickly in the circulation due to the high glucose concentration gradient between DIANEAL compared to blood capillary glucose level. Absorption per unit time will be the highest at the start of an exchange and decreases over time. The rate of glucose absorption will be dependent upon the transport characteristics of the patient's peritoneal membrane as determined by a peritoneal equilibration test (PET). Glucose absorption will also depend upon the concentration of glucose used for the exchange and the length of the dwell. Glucose is metabolized by normal cellular pathways (e.g. glycolysis) and provides a source of calories and may elevate blood glucose levels.

Transport of other molecules across the peritoneal membrane, such as lactate, will occur by diffusion. Metabolism of lactate occurs in the liver and results in the generation of the bicarbonate. Transport of other molecules will be dependent upon the molecular size of the solute, the concentration gradient, and the effective peritoneal surface area as determined by the PET.

INDICATIONS AND USAGE

DIANEAL peritoneal dialysis solutions are indicated for patients in acute or chronic renal failure when nondialytic medical therapy is judged to be inadequate.

CONTRAINDICATIONS

DIANEAL is contraindicated in patients with pre-existing severe lactic acidosis.

WARNINGS

Encapsulating Peritoneal Sclerosis (EPS) is considered to be a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including DIANEAL. Infrequently, fatal outcomes of EPS have been reported with DIANEAL.

Because Dianeal is a dextrose-based solution, patients with allergy to corn or corn products are at increased risk for allergic reaction, which may include anaphylactic/anaphylactoid reactions. Stop the infusion immediately, drain the solution from the peritoneal cavity and treat appropriately if any signs or symptoms of a suspected hypersensitivity reaction develop.

Patients with severe lactic acidosis should not be treated with lactate-based peritoneal dialysis solutions (See Contraindications). Patients with conditions known to increase the risk of lactic acidosis [e.g., severe hypotension or sepsis that can be associated with acute renal failure, hepatic failure, inborn errors of metabolism, and treatment with drugs such as nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)] must be monitored for the occurrence of lactic acidosis before the start of treatment and during treatment with lactate-based peritoneal dialysis solutions.

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. Serum potassium levels should be monitored carefully in patients treated with cardiac glycosides. For example, rapid potassium removal may create arrhythmias in cardiac patients using digitalis or similar drugs; digitalis toxicity may be masked by hyperkalemia, hypermagnesemia, or hypocalcemia. Correction of electrolytes by dialysis may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal dosages of digitalis if potassium is low or calcium is high.

Diabetics require careful monitoring of insulin requirements and other treatments for hyperglycemia during and following dialysis with dextrose containing solutions.

PRECAUTIONS

General

Peritoneal-Dialysis Related

DIANEAL is intended for intraperitoneal administration only. Not for intravenous administration.

The following conditions may predispose to adverse reactions to peritoneal dialysis procedures: abdominal conditions, including uncorrectable mechanical defects that prevent effective peritoneal dialysis or increase the risk of infection, disruption of the peritoneal membrane and diaphragm by surgery, congenital anomalies or trauma prior to complete healing, abdominal tumors, abdominal wall infections, hernias, fecal fistula, colostomies or ileostomies, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity, such as documented loss of peritoneal function or extensive adhesions that compromise peritoneal function. Conditions that preclude normal nutrition, impaired respiratory function, recent aortic graft placement, and potassium deficiency may also predispose to complications of peritoneal dialysis.

Aseptic technique must be employed throughout the peritoneal dialysis procedure to reduce the possibility of infection.

Following use, the drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.

If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be indicated.

Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Treatment of overinfusion is to drain the peritoneal dialysis solution from the peritoneal cavity.

Need for Trained Physician

Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure.

A patient's volume status should be carefully monitored to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion and hypovolemic shock. An accurate fluid balance record must be kept and the patient's body weight monitored. Excessive use of DIANEAL peritoneal dialysis solution with higher dextrose concentration during a peritoneal dialysis treatment may result in significant removal of water from the patient (see Dosage and Administration).

Significant losses of protein, amino acids, water-soluble vitamins and other medicines may occur during peritoneal dialysis. The patient's nutritional status should be monitored and replacement therapy should be provided as necessary.

Information for Patients

Patients should be instructed not to use solutions if they are cloudy, discolored, contain visible particulate matter, or if they show evidence of leaking containers (see Dosage and Administration).

Aseptic technique must be employed throughout the procedure.

An improper clamping sequence may result in infusion of air into the peritoneum (see Dosage and Administration, Directions for Use).

To reduce possible discomfort during administration, patients should be instructed that solutions may be warmed to 37°C (98°F) prior to use. Only dry heat should be used. It is best to warm solutions within the overwrap using a heating pad. To avoid contamination, solutions should not be immersed in water for warming. Do not use a microwave oven to warm the solution (see Dosage and Administration, Directions for Use).

Laboratory Tests
Serum Electrolytes
DIANEAL does not contain potassium. Evaluate serum potassium prior to administering potassium chloride to the patient. In situations where there is a normal serum potassium level or hypokalemia, addition of potassium chloride (up to a concentration of 4 mEq/L) to the solution may be necessary to prevent severe hypokalemia. This should be made under careful evaluation of serum and total body potassium, and only under the direction of a physician.

Fluid, hematology, blood chemistry, electrolyte concentrations, and bicarbonate should be monitored periodically. If serum magnesium levels are low, magnesium supplements may be used.

Patients receiving DIANEAL solutions should have their calcium levels monitored for the development of hypocalcemia or hypercalcemia. In these circumstances, adjustments to the dosage of the phosphate binders, vitamin D analogs, and/or calcimimetics should be considered by the physician. DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis solution should be considered for use in patients with hypercalcemia.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies to evaluate the carcinogenic or mutagenic potential of this product, or its potential to affect fertility adversely, have not been performed.

Drug Interactions
No clinical drug interaction studies were performed. As with other dialysis solutions, blood concentrations of dialyzable drugs may be reduced by dialysis. Dosage adjustment of concomitant medications may be necessary. In patients using cardiac glycosides (digoxin and others), plasma levels of calcium, potassium and magnesium must be carefully monitored (see Warnings).

Use in Specific Population
Pregnancy
Pregnancy Category C. DIANEAL is a peritoneal dialysis solution of electrolytes, lactate and dextrose and is pharmacologically inactive. Animal reproduction studies have not been conducted with DIANEAL dialysis solution. While there are no adequate and well controlled studies in pregnant women, appropriate administration of DIANEAL with monitoring of fluid, electrolyte, acid-base and glucose balance, is not expected to cause fetal harm, or affect reproductive capacity. Maintenance of normal acid-base balance is important for fetal well being. Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing DIANEAL.

Nursing Mothers
DIANEAL is a dialysis solution of electrolytes, lactate and dextrose and is pharmacologically inactive. The components of DIANEAL are excreted in human milk. Appropriate administration of DIANEAL with monitoring of fluid, electrolyte, acid-base and glucose balance, is not expected to harm a nursing infant. Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing DIANEAL.

Pediatric Use
Safety and effectiveness have been established based on published clinical data. No adequate and well-controlled studies have been conducted with DIANEAL solutions in pediatric patients.

Geriatric Use
Safety and effectiveness have been established based on published clinical data.

ADVERSE REACTIONS

The following adverse reactions have been identified during post approval use of DIANEAL. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship during drug exposure. Adverse reactions are listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity.

INFECTIONS AND INFESTATIONS: Fungal peritonitis, Peritonitis bacterial, Catheter related infection

METABOLISM AND NUTRITION DISORDERS: Hypovolemia, Hypervolemia, Fluid retention, Hypokalemia, Hyponatremia, Dehydration, Hypochloremia

VASCULAR DISORDERS: Hypotension, Hypertension

RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS: Dyspnea

GASTROINTESTINAL DISORDERS: Sclerosing encapsulating peritonitis, Peritonitis, Peritoneal cloudy effluent, Vomiting, Diarrhea, Nausea, Constipation, Abdominal pain, Abdominal distension, Abdominal discomfort

SKIN AND SUBCUTANEOUS DISORDERS: Stevens-Johnson syndrome, Urticaria, Rash, (including pruritic, erythematous and generalized), Pruritus

MUSCULOSKELETAL, CONNECTIVE TISSUE DISORDERS: Myalgia, Muscle spasms, Musculoskeletal pain

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Generalized edema, Pyrexia, Malaise, Infusion site pain, Catheter related complication

DRUG ABUSE AND DEPENDENCE

There has been no observed potential of drug abuse or dependence with DIANEAL solution.

OVERDOSAGE

There is a potential for overdose resulting in hypervolemia, hypovolemia, electrolyte disturbances or hyperglycemia. Excessive use of DIANEAL peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

DOSAGE AND ADMINISTRATION

DIANEAL peritoneal dialysis solutions are intended for intraperitoneal administration only.

The mode of therapy, frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient. DIANEAL should be administered at a rate that is comfortable for the patient, generally over a period of 10-20 minutes for a single exchange.

Patients on continuous ambulatory peritoneal dialysis (CAPD) typically perform 4 cycles per day (24 hours). Patients on automated peritoneal dialysis (APD) typically perform 4-5 cycles at night and up

to 2 cycles during the day. The fill volume depends on body size, usually from 2.0 to 2.5 liters per $1.73m^2$.

To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for that exchange. As the patient's body weight becomes closer to the ideal dry weight, lowering the dextrose concentration of DIANEAL is recommended. DIANEAL 4.25% dextrose-containing solution has the highest osmolarity of the DIANEAL solutions and using it for all exchanges may cause dehydration.

Solutions that are cloudy, discolored, contain visible particulate matter, or show evidence of leakage should not be used.

Following use, the drained fluid should be inspected for the presence of fibrin or cloudiness which may indicate the presence of peritonitis.

For single use only. Discard unused portion.

It is recommended that patients being placed on peritoneal dialysis and/or their caretaker(s) should be appropriately trained.

Addition of Potassium
Potassium is omitted from DIANEAL solutions because dialysis may be performed to correct hyperkalemia. In situations where there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. The decision to add potassium chloride should be made by the physician after careful evaluation of serum potassium.

Addition of Insulin
Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with DIANEAL. Appropriate monitoring of blood glucose should be performed when initiating DIANEAL in diabetic patients and insulin dosage adjusted if needed (see Warnings).

Addition of Heparin
No human drug interaction studies with heparin were conducted. *In vitro* studies demonstrated no evidence of incompatibility of heparin with DIANEAL.

Addition of Antibiotics
No formal clinical drug interaction studies have been performed. *In vitro* studies of the following medications have demonstrated stability with DIANEAL: amphotericin B, ampicillin, cefazolin, cefepime, cefotaxime, ceftazidime, ceftriaxone, ciprofloxacin, clindamycin, deferoxamine, erythromycin, gentamicin, linezolid, mezlocillin, miconazole, moxifloxacin, nafcillin, ofloxacin, penicillin G, piperacillin, sulfamethoxazole/trimethoprim, ticarcillin, tobramycin, and vancomycin. However, aminoglycosides should not be mixed with penicillins due to chemical incompatibility.

Directions for Use
For complete CAPD and APD system preparation, see directions accompanying ancillary equipment.

Aseptic technique must be used throughout the peritoneal dialysis procedure.

Warming
For patient comfort, DIANEAL can be warmed to 37°C (98°F). Only dry heat should be used. It is best to warm solutions within the overwrap using a heating pad. Do not immerse DIANEAL in water for warming. Do not use a microwave oven to warm DIANEAL.

To Open
To open, tear the overwrap down at the slit and remove the solution container. Some opacity of the plastic, due to moisture absorption during the sterilization process, may be observed. This does not affect the solution quality or safety and may often leave a slight amount of moisture within the overwrap. The opacity should diminish gradually.

Inspect for Container Integrity
Inspect the bag connector to ensure the tip protector (pull ring, blue pull tip, or blue twist-off tip) is attached. Do not use if the tip protector is not attached to the connector. Inspect the DIANEAL container for signs of leakage and check for minute leaks by squeezing the container firmly. If the container has frangible(s), inspect that they are positioned correctly and are not broken. Do not use DIANEAL if the frangible(s) are broken or leaks are suspected as sterility may be impaired.

For DIANEAL in ULTRABAG, inspect the tubing and drain container for presence of solution. Small droplets are acceptable, but if solution flows past the frangible prior to use, do not use and discard the units.

Adding Medications
Some drug additives may be incompatible with DIANEAL. See **DOSAGE AND ADMINISTRATION** section for additional information. If the resealable rubber plug on the medication port is missing or partly removed, do not use the product if medication is to be added.
1. Put on mask. Clean and/or disinfect hands.
2. Prepare medication port site using aseptic technique.
3. Using a syringe with a 1-inch long, 25- to 19-gauge needle, puncture the medication port and inject additive.
4. Reposition container with container ports up and evacuate medication port by squeezing and tapping it.
5. Mix solution and additive thoroughly.

Administration instructions for CAPD therapy using ULTRABAG containers (Products listed in Tables 1-2)
Put on mask. Clean and/or disinfect hands. Using aseptic technique;

1) Uncoil tubing and drain bag, ensuring that the transfer set is closed.
2) Immediately attach the solution container to patient connector (transfer set).
3) Break the connector (Y-set) frangible.
4) Remove the tip protector from connector of solution container. Do not reuse the solution or container once the tip protector is removed.
5) Clamp solution line and then break frangible near solution bag. Hang solution container and place the drainage container below the level of the abdomen.
6) Open transfer set to drain the solution from abdomen. If drainage cannot be established, contact your clinician. When drainage complete, close transfer set.
7) Remove clamp from solution line and flush new solution to flow into the drainage container for 5 seconds to prime the line. Clamp drain line after flush complete.
8) Open transfer set to fill. When fill complete, close transfer set.
9) Disconnect ULTRABAG from transfer set and apply MINICAP.
10) Upon completion of therapy, discard any unused portion.

Administration instructions for APD therapy using containers with pull rings or blue pull tips (Products listed in Tables 3-5)
Put on mask. Clean and/or disinfect hands. Using aseptic technique;

1) Remove the tip protector from connector of solution container. Do not reuse the solution or container once the tip protector is removed.
2) Immediately attach the solution container to an appropriate automated peritoneal dialysis set.
3) Continue therapy as instructed in user manual or directions accompanying tubing sets for automated peritoneal dialysis.
4) Upon completion of therapy, discard any unused portion.

Administration instructions for APD therapy using containers with blue twist-off tips (Products listed in Table 6)

Put on mask. Clean and/or disinfect hands. Using aseptic technique;

1) Place and fasten blue outlet port clamp on solution bag administration port, between the blue connector and the solution container.
2) Remove the blue twist-off tip from connector of solution container. Do not reuse the solution or container once the blue twist-off tip is removed.
3) Immediately insert the spike of the automated peritoneal dialysis set into the solution bag port.
4) Continue therapy as instructed in user manual or directions accompanying tubing sets for automated peritoneal dialysis.
5) Upon completion of therapy, discard any unused portion.

HOW SUPPLIED

DIANEAL peritoneal dialysis solutions are available in nominal size flexible containers as shown in Tables 1-6.

All DIANEAL peritoneal dialysis solutions have overfills which are declared on container labeling.

Freezing of solution may occur at temperatures below 0°C (32°F). Allow to thaw naturally in ambient conditions and thoroughly mix contents by shaking.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F): brief exposure up to 40°C (104°F) does not adversely affect the product.

Table 1. DIANEAL PD-2 Peritoneal Dialysis Solution (ULTRABAG CONTAINER for CAPD therapy)

	Composition/100 mL					**OSMOLARITY (mOsmol/L) (calc)**	pH	**Ionic Concentration** (mEq/L)					**How Supplied**			
	*Dextrose, Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)			Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose	1.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**346**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	2000 2500 3000	2000 3000 5000	5B9866 5B9868 5B9857	0941-0426-52 0941-0426-53 0941-0426-55
DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose	2.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**396**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	2000 2500 3000	2000 3000 5000	5B9876 5B9878 5B9858	0941-0427-52 0941-0427-53 0941-0427-55
DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose	4.25 g	538 mg	448 mg	25.7 mg	5.08 mg	**485**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	2000 2500 3000	2000 3000 5000	5B9896 5B9898 5B9859	0941-0429-52 0941-0429-53 0941-0429-55

Table 2. DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (ULTRABAG CONTAINER for CAPD therapy)

	Composition/100 mL					**OSMOLARITY (mOsmol/L) (calc)**	pH	**Ionic Concentration** (mEq/L)					**How Supplied**			
	*Dextrose, Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)			Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose	1.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**344**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9765 5B9766 5B9768 5B9757	0941-0424-51 0941-0424-52 0941-0424-53 0941-0424-55
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose	2.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**395**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9775 5B9776 5B9778 5B9758	0941-0430-51 0941-0430-52 0941-0430-53 0941-0430-55
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	4.25 g	538 mg	448 mg	18.3 mg	5.08 mg	**483**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9795 5B9796 5B9798 5B9759	0941-0433-51 0941-0433-52 0941-0433-53 0941-0433-55

Table 3. DIANEAL PD-2 Peritoneal Dialysis Solution (AMBU-FLEX CONTAINER with pull ring for APD therapy)

	Composition/100 mL							**Ionic Concentration** (mEq/L)					**How Supplied**			
	*Dextrose, Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	**OSMOLARITY (mOsmol/L) (calc)**	pH	Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose **AMBU-FLEX II** CONTAINER	1.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**346**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1000 2000 3000 5000 6000	1000 3000 3000 6000 6000	L5B5163 L5B5166 L5B5169 L5B5193 L5B9710	0941-0411-05 0941-0411-06 0941-0411-04 0941-0411-07 0941-0411-11
DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose **AMBU-FLEX II** CONTAINER	2.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**396**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1000 2000 3000 5000 6000	1000 3000 3000 6000 6000	L5B5173 L5B5177 L5B5179 L5B5194 L5B9711	0941-0413-05 0941-0413-06 0941-0413-04 0941-0413-07 0941-0413-01
DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose **AMBU-FLEX II** CONTAINER	4.25 g	538 mg	448 mg	25.7 mg	5.08 mg	**485**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1000 2000 3000 5000 6000	1000 3000 3000 6000 6000	L5B5183 L5B5187 L5B5189 L5B5195 L5B9712	0941-0415-05 0941-0415-06 0941-0415-04 0941-0415-07 0941-0415-01

Table 4. DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (AMBU-FLEX CONTAINER with pull ring for APD therapy)

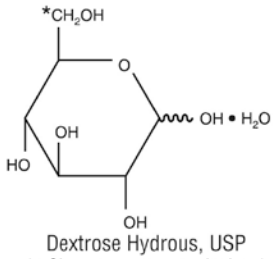
	Composition/100 mL							**Ionic Concentration** (mEq/L)					**How Supplied**			
	*Dextrose, Hydrous, USP	Sodium Chloride, U SP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	**OSMOLARITY (mOsmol/L) (calc)**	pH	Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose **AMBU-FLEX II** CONTAINER	1.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**344**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	2000 3000 5000 6000	3000 3000 6000 6000	L5B4825 L5B9901 L5B4826 L5B9770	0941-0409-06 0941-0409-05 0941-0409-07 0941-0409-01
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose **AMBU-FLEX II** CONTAINER	2.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**395**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	2000 3000 5000 6000	3000 3000 6000 6000	L5B9727 L5B9902 L5B5202 L5B9771	0941-0457-08 0941-0457-02 0941-0457-05 0941-0457-01
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose **AMBU-FLEX II** CONTAINER	4.25 g	538 mg	448 mg	18.3 mg	5.08 mg	**483**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40	2000 3000 5000 6000	3000 3000 6000 6000	L5B9747 L5B9903 L5B5203 L5B9772	0941-0459-08 0941-0459-02 0941-0459-05 0941-0459-01

Table 5. DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution Made in Ireland (Plastic container with blue pull tip for APD therapy)

	Composition/100 mL					**OSMOLARITY (mOsmol/L) (calc)**	pH	**Ionic Concentration** (mEq/L)					**How Supplied**			
	*Dextrose, Hydrous	Sodium Chloride (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride ($MgCl_2 \cdot 6H_2O$)			Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose	1.5 g	538 mg	448 mg	18.4 mg	5.08 mg	**344**	5.0 to 6.5	132	2.5	0.5	95	40	5000	5000	EZPB5245R	0941-0484-01
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose	2.5 g	538 mg	448 mg	18.4 mg	5.08 mg	**395**	5.0 to 6.5	132	2.5	0.5	95	40	5000	5000	EZPB5255R	0941-0487-01
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose	4.25 g	538 mg	448 mg	18.4 mg	5.08 mg	**483**	5.0 to 6.5	132	2.5	0.5	95	40	5000	5000	EZPB5265R	0941-0490-01

Table 6. DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution Made in Mexico (Plastic container with blue twist-off tip for APD therapy)

	Composition/100 mL							**Ionic Concentration** (mEq/L)					**How Supplied**			
	*Dextrose, Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	**OSMOLARITY (mOsmol/L) (calc)**	pH	Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose	1.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**344**	5.0 to 5.6	132	2.5	0.5	95	40	6000	6000	VBB4928US	0941-0472-01
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose	2.5 g	538 mg	448 mg	18.3 mg	5.08 mg	**395**	5.0 to 5.6	132	2.5	0.5	95	40	6000	6000	VBB4931US	0941-0475-01



Dextrose Hydrous, USP
(D-Glucopyranose monohydrate)

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