HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DIANEAL safely and effectively. See full prescribing information for DIANEAL

DIANEAL (dextrose) peritoneal dialysis solution
Initial U.S. Approval: 1981
DIANEAL PD-2 (dextrose) peritoneal dialysis solution
Initial U.S. Approval: 1992
DIANEAL LOW CALCIUM (dextrose) peritoneal dialysis solution
Initial U.S. Approval: 1992

----------INDICATIONS AND USAGE----------
For management of acute or chronic renal failure.

----------DOSAGE AND ADMINISTRATION----------
For intraperitoneal administration only. (2)

----------DOSAGE FORMS AND STRENGTHS----------
DIANEAL is available in multiple combinations of ingredients and in composition, calculated osmolarity, pH, and ionic concentrations. See full prescribing information for detailed descriptions of each formulation. (3)

----------CONTRAINDICATIONS----------
- Pre-existing severe lactic acidosis (4)

----------WARNINGS AND PRECAUTIONS----------
- Encapsulating peritoneal sclerosis (5.1)
- Peritonitis: Initiate appropriate antimicrobial therapy (5.1)
- Monitor for lactic acidosis in patients at risk (5.2)
- Monitor for electrolyte, fluid, and nutrition imbalances (5.4)

To report SUSPECTED ADVERSE REACTIONS, contact Baxter Healthcare Corporation at 1-866-888-2472 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

See 17 for PATIENT COUNSELING INFORMATION

Revised: [11/2016]

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the Full Prescribing Information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

DIANEAL peritoneal dialysis solutions are indicated for patients in acute or chronic renal failure.

2 DOSAGE AND ADMINISTRATION

2.1 Basic Dosing Information

DIANEAL peritoneal dialysis solutions are intended for intraperitoneal administration only. Not for intravenous administration.

Select mode of therapy, frequency of treatment, formulation, fill volume, duration of dwell, and length of dialysis based on the patient's clinical condition, fluid, electrolyte and specific needs.The fill volume depends on body size, usually from 2.0 to 2.5 liters per $1.73m^2$ for adults.

DIANEAL is intended for use in Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD). Refer to directions accompanying ancillary equipment for CAPD and APD system preparation.

Product Selection

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 *[see Dosage Forms and Strengths (3)]*.

2.2 Adding Medications

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.

To add a medication:

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.

2.3 Directions for Use

Warming
DIANEAL can be warmed to 37°C (98.6°F). Only dry heat should be used. For CAPD, 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. Do not use sharp objects to remove the overwrap.

Product Inspection

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use solutions that are cloudy, discolored, contain visible particulate matter, or show evidence of leakage.

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 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.

CAPD therapy using ULTRABAG containers

Select appropriate formulation from Table 1.

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. Break the connector (Y-set) frangible.
3. Remove the tip protector from connector of solution container. Do not reuse the solution or container once the tip protector is removed.
4. Immediately attach the solution container to patient connector (transfer set).
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.

APD therapy using AMBU-FLEX containers with pull rings or plastic containers with blue pull tips

Select appropriate formulation from Table 1 or 2.

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.

APD therapy using plastic containers with blue twist-off tips

Select appropriate formulation from Table 3.

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.

3 DOSAGE FORMS AND STRENGTHS

DIANEAL is formulated with the following ionic concentrations:

Table 1 - DIANEAL PD-2 and Low Calcium Peritoneal Dialysis Solution
ULTRABAG CONTAINER for CAPD therapy
AMBU-FLEX CONTAINER with pull ring for APD therapy

	OSMOLARITY (mOsmol/L) (calc)	pH	**Ionic Concentration** (mEq/L)				
			Sodium	Calcium	Magnesium	Chloride	Lactate
DIANEAL PD-2 1.5% Dextrose	**346**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40
DIANEAL PD-2 2.5% Dextrose	**396**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40
DIANEAL PD-2 4.25% Dextrose	**485**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40
DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose	**344**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40
DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose	**395**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40
DIANEAL Low Calcium (2.5 mEq/L) 4.25% Dextrose	**483**	5.2 (4.0 to 6.5)	132	2.5	0.5	95	40

Table 2 - DIANEAL Low Calcium Peritoneal Dialysis Solution
Plastic container with blue pull tip for APD therapy

	OSMOLARITY (mOsmol/L) (calc)	pH	**Ionic Concentration** (mEq/L)				
			Sodium	Calcium	Magnesium	Chloride	Lactate
DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose	**344**	5.0 to 6.5	132	2.5	0.5	95	40
DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose	**395**	5.0 to 6.5	132	2.5	0.5	95	40
DIANEAL Low Calcium (2.5 mEq/L) 4.25% Dextrose	**483**	5.0 to 6.5	132	2.5	0.5	95	40

Table 3 - DIANEAL Low Calcium Peritoneal Dialysis Solution
Plastic container with blue twist-off tip for APD therapy

	OSMOLARITY (mOsmol/L) (calc)	pH	**Ionic Concentration** (mEq/L)				
			Sodium	Calcium	Magnesium	Chloride	Lactate
DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose	**344**	5.0 to 5.6	132	2.5	0.5	95	40
DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose	**395**	5.0 to 5.6	132	2.5	0.5	95	40

4 CONTRAINDICATIONS

DIANEAL is contraindicated in patients with severe lactic acidosis.

5 WARNINGS AND PRECAUTIONS

5.1 Peritonitis and Encapsulating Peritoneal Sclerosis

Peritonitis has been associated with DIANEAL use. Following use, inspect the drained fluid for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis. Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis. If peritonitis occurs, treat with appropriate therapy.

Encapsulating Peritoneal Sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using DIANEAL

5.2 Lactic Acidosis

Monitor 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)] before the start of treatment and during

treatment with lactate-based peritoneal dialysis solutions. Use of DIANEAL in patients with severe lactic acidosis is contraindicated *[see Contraindications (4)]*.

5.3 Overinfusion

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.

5.4 Electrolyte, Fluid, and Nutrition Imbalances

Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, bicarbonate, calcium, and magnesium levels and volume status. Monitor hematology, electrolytes, blood chemistry and fluid status periodically and take appropriate clinical action.

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, addition of potassium chloride (up to a concentration of 4 mEq/L) to the solution may be necessary to prevent severe hypokalemia. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion and hypovolemic shock.

5.5 Hyperglycemia

DIANEAL contains dextrose and may increase the risk for hyperglycemia in patients with impaired glucose tolerance. Patients may require initiation or modification of antidiabetic therapy during treatment with DIANEAL. Monitor blood glucose.

6 ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in the label:

Peritonitis and Encapsulating Peritoneal Sclerosis *[see Warnings and Precautions (5.1)]*
Electrolyte and Fluid Imbalances *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

There are no data available on adverse reactions from controlled clinical trials conducted to evaluate the safety of DIANEAL.

6.2 Post-Marketing Experience

The following adverse experiences have been identified during post-approval use of DIANEAL or in conjunction with performing the peritoneal dialysis procedure. Because these experiences 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. Most of these adverse experiences are believed to be consequences of peritoneal dialysis.

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

7 DRUG INTERACTIONS

As with other dialysis solutions, blood concentrations of dialyzable drugs may be reduced by dialysis. Dosage adjustment of concomitant medications may be necessary.

Diabetic patients may require dosage adjustments of insulin or other treatments for hyperglycemia *[see Warnings and Precautions (5.5)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

DIANEAL is a pharmacologically inactive solution. While there are no adequate and well controlled studies in pregnant women, appropriate administration of DIANEAL, with appropriate monitoring of hematology, electrolytes, blood chemistry and fluid status is not expected to cause fetal harm. Animal reproduction studies have not been conducted with DIANEAL dialysis solution.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

8.2 Lactation

The components of DIANEAL are excreted in human milk.

8.4 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.

8.5 Geriatric Use

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

10 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.

11 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.

DIANEAL is a hyperosmolar solution.

Table 4 - DIANEAL PD-2 and Low Calcium Peritoneal Dialysis Solution
ULTRABAG CONTAINER for CAPD therapy
AMBU-FLEX CONTAINER with pull ring for APD therapy

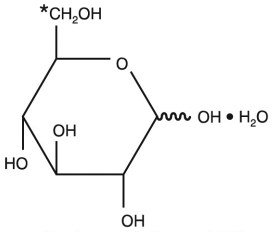
	Composition/100 mL				
	*Dextrose, Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)
DIANEAL PD-2 1.5% Dextrose	1.5 g	538 mg	448 mg	25.7 mg	5.08 mg
DIANEAL PD-2 2.5% Dextrose	2.5 g	538 mg	448 mg	25.7 mg	5.08 mg
DIANEAL PD-2 4.25% Dextrose	4.25 g	538 mg	448 mg	25.7 mg	5.08 mg
DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose	1.5 g	538 mg	448 mg	18.3 mg	5.08 mg
DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose	2.5 g	538 mg	448 mg	18.3 mg	5.08 mg
DIANEAL Low Calcium (2.5 mEq/L) 4.25% Dextrose	4.25 g	538 mg	448 mg	18.3 mg	5.08 mg

Table 5 - DIANEAL Low Calcium Peritoneal Dialysis Solution
Plastic container with blue pull tip for APD therapy

	Composition/100 mL				
	*Dextrose, Hydrous	Sodium Chloride (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride ($MgCl_2 \cdot 6H_2O$)
DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose	1.5 g	538 mg	448 mg	18.4 mg	5.08 mg
DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose	2.5 g	538 mg	448 mg	18.4 mg	5.08 mg
DIANEAL Low Calcium (2.5 mEq/L) 4.25% Dextrose	4.25 g	538 mg	448 mg	18.4 mg	5.08 mg

Table 6 - DIANEAL Low Calcium Peritoneal Dialysis Solution
Plastic container with blue twist-off tip for APD therapy

	Composition/100 mL				
	*Dextrose, Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)
DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose	1.5 g	538 mg	448 mg	18.3 mg	5.08 mg
DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose	2.5 g	538 mg	448 mg	18.3 mg	5.08 mg



Dextrose Hydrous, USP
(D-Glucopyranose monohydrate)

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.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

DIANEAL is a pharmacologically inactive, 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.

12.3 Pharmacokinetics

Absorption

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. 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.

Metabolism and Elimination

Glucose is metabolized by normal cellular pathways (i.e., glycolysis). Metabolism of lactate occurs in the liver and results in the generation of the bicarbonate. Glucose not absorbed during PD exchange procedure is removed by drainage of the PD solution from the peritoneal cavity.

Drug Interaction Studies

Heparin

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

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.

16 HOW SUPPLIED/STORAGE AND HANDLING

DIANEAL peritoneal dialysis solutions are available in the following single-dose containers and fill volumes as shown in Tables 7-8:

Table 7 - DIANEAL Peritoneal Dialysis Solutions for CAPD therapy

Container	Fill Volume (mL)	Container Size (mL)	Product Code	NDC
ULTRABAG	**DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose**			
	2000	2000	5B9866	0941-0426-52
	2500	3000	5B9868	0941-0426-53
	3000	5000	5B9857	0941-0426-55
	DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose			
	2000	2000	5B9876	0941-0427-52
	2500	3000	5B9878	0941-0427-53
	3000	5000	5B9858	0941-0427-55
	DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose			
	2000	2000	5B9896	0941-0429-52
	2500	3000	5B9898	0941-0429-53
	3000	5000	5B9859	0941-0429-55
	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose			
	1500	2000	5B9765	0941-0424-51
	2000	2000	5B9766	0941-0424-52
	2500	3000	5B9768	0941-0424-53
	3000	5000	5B9757	0941-0424-55

	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose			
	1500	2000	5B9775	0941-0430-51
	2000	2000	5B9776	0941-0430-52
	2500	3000	5B9778	0941-0430-53
	3000	5000	5B9758	0941-0430-55
	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose			
	1500	2000	5B9795	0941-0433-51
	2000	2000	5B9796	0941-0433-52
	2500	3000	5B9798	0941-0433-53
	3000	5000	5B9759	0941-0433-55

Table 8 - DIANEAL Peritoneal Dialysis Solutions for APD therapy

Container	**Fill Volume (mL)**	**Container Size (mL)**	**Product Code**	**NDC**
AMBU-FLEX CONTAINER with pull ring	**DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose**			
	1000	1000	L5B5163	0941-0411-05
	2000	3000	L5B5166	0941-0411-06
	3000	3000	L5B5169	0941-0411-04
	5000	6000	L5B5193	0941-0411-07
	6000	6000	L5B9710	0941-0411-11
	DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose			
	1000	1000	L5B5173	0941-0413-05
	2000	3000	L5B5177	0941-0413-06
	3000	3000	L5B5179	0941-0413-04
	5000	6000	L5B5194	0941-0413-07
	6000	6000	L5B9711	0941-0413-01
	DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose			
	1000	1000	L5B5183	0941-0415-05
	2000	3000	L5B5187	0941-0415-06
	3000	3000	L5B5189	0941-0415-04
	5000	6000	L5B5195	0941-0415-07
	6000	6000	L5B9712	0941-0415-01
	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose			
	2000	3000	L5B4825	0941-0409-06
	3000	3000	L5B9901	0941-0409-05
	5000	6000	L5B4826	0941-0409-07
	6000	6000	L5B9770	0941-0409-01
	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose			

	2000	3000	L5B9727	0941-0457-08
	3000	3000	L5B9902	0941-0457-02
	5000	6000	L5B5202	0941-0457-05
	6000	6000	L5B9771	0941-0457-01
	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose			
	2000	3000	L5B9747	0941-0459-08
	3000	3000	L5B9903	0941-0459-02
	5000	6000	L5B5203	0941-0459-05
	6000	6000	L5B9772	0941-0459-01
Plastic container with blue pull tip	**DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose**			
	5000	5000	EZPB5245R	0941-0484-01
	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose			
	5000	5000	EZPB5255R	0941-0487-01
	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose			
	5000	5000	EZPB5265R	0941-0490-01
Plastic container with blue twist-off tip	**DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose**			
	6000	6000	VBB4928US	0941-0472-01
	DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose			
	6000	6000	VBB4931US	0941-0475-01

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.

Store in moisture barrier overwrap and in carton until ready to use.

17 PATIENT COUNSELING INFORMATION

Inspection: Advise patients to inspect DIANEAL before use, and not to use if the solution is cloudy, discolored, contains particulate matter or if there is evidence of leakage.

Administration: Advise patients on proper administration and the importance of using aseptic technique throughout the entire PD procedure. Advise patients only to use dry heat to warm solution to about 37^0C (98^0F) and not to microwave or submerge in water.

Peritonitis: Advise patients to seek medical attention if they experience signs or symptoms of peritonitis.

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