Tests for plastic containers as well as by cell culture toxicity studies. of the plastic has been confirmed in tests in animals according to USP biological Transport of other molecules across the peritoneal membrane, such as lactate, and may elevate blood glucose levels. normal cellular pathways (e.g. glycolysis) and provides a source of calories used for the exchange and the length of the dwell. Glucose is metabolized by (PET). Glucose absorption will also depend upon the concentration of glucose patient’s peritoneal membrane as determined by a peritoneal equilibration test of glucose absorption will be dependent upon the transport characteristics of the DIANEAL compared to blood capillary glucose level. Absorption per unit time Glucose is rapidly absorbed from the peritoneal cavity by diffusion and appears available in three concentrations: 1.5%, 2.5% and 4.25%. Glucose content in DIANEAL is expressed as dextrose monohydrate and is Pharmacokinetics of DIANEAL contains a buffer, lactate, to help normalize acid-base abnormalities. Electrolytes to facilitate the correction of electrolyte abnormalities. DIANEAL ultrafiltration. Like other peritoneal dialysis solutions, DIANEAL contains 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. 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 a 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. 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. Intraoperatively, fatal outcomes of EPS have been reported with DIANEAL. 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. acute renal failure, hepatic failure, root errors of metabolism with drugs such as metformin, nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), and sepsis/ shock) 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 digitals or similar drugs; digitals 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 digitals 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 stomas, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large poly cystic 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 precipitate normal nutrition, impaired respiratory function, recent aortic graft placement, and potassium deficiency may also predispose to complications of peritoneal dialysis.
Dosage adjustment of concomitant medications may be necessary. In patients with solutions, blood concentrations of dialyzable drugs may be reduced by dialysis. No clinical drug interaction studies were performed. As with other dialysis Drug Interactions potential to affect fertility adversely, have not been performed.

Carcinogenesis, Mutagenesis, Impairment of Fertility

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 dose of the phosphate binders, vitamin D analogs, and/or calcitriol 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. DIANEAL is a dialysis solution of electrolytes, lactate and dextrose and is pharmaceutically 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 pharmaceutically 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.


UREA DISORDERS: 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).

MUSCULOSKELETAL, CONNECTIVE TISSUE DISORDERS: Myalgia, Muscular pain, 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, hypokalemia, electrolyte disturbances or hyperkalemia. 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.

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 each exchange. Patients on continuous ambulatory peritoneal dialysis (CAPD) typically perform 4-6 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 1.73m².

Typically perform 4 cycles per day (24 hours). Patients on automated peritoneal dialysis (APD) and continuous ambulatory peritoneal dialysis (CAPD) usually 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 1.73m².

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It is recommended that patients being placed on peritoneal dialysis and/or CAPD have their first exchange at home. 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 1.73m².

Diabetic patients generally respond therapeutically to fluids given in large volumes (5-7 liters) over a period of one to two hours. It is recommended that patients be encouraged to perform the first exchange at home. 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 1.73m².

The patient should be instructed to perform at least 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 1.73m².

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For single use only. Discard unused portion.

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

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To Open

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

1. Put on mask. Clean and/or disinfect hands.
2. Place DIANEAL on work surface.
3. For UltraBAG system for manual exchange, uncoil tubing and drain bag. Ensure the patient transfer set is closed. Break the connector (Y-site) fragile.
4. Remove pull ring from connector of solution container. Once the pull ring has been removed do not reuse the solution or container.
5. Immediately attach the solution container to patient connector (transfer set) or appropriate peritoneal dialysis set.
6. For Ambu Flex, continue with therapy as instructed in user manual or directions accompanying tubing sets for automated peritoneal dialysis.

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 partially 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.
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Inspect the patient connector to ensure the pull ring is attached. Do not use if pull ring 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.

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### Table 1. DIANEAL PD-2 Peritoneal Dialysis Solution (AMBU-FLEX CONTAINER)

<table>
<thead>
<tr>
<th>Composition (10 mL)</th>
<th>Ionic Concentrations (mEq/L)</th>
<th>How Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Chloride (mEq/L)</td>
<td>Calcium (mEq/L)</td>
<td>Lactate (mM)</td>
</tr>
<tr>
<td><strong>DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</strong> (AMBU-FLEX II CONTAINER)</td>
<td>4.25</td>
<td>2.5</td>
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<tr>
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</tr>
<tr>
<td><strong>DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose</strong> (AMBU-FLEX II CONTAINER)</td>
<td>3.25</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td><strong>DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose</strong> (AMBU-FLEX III CONTAINER)</td>
<td>3.25</td>
<td>1.5</td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td><strong>DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</strong> (AMBU-FLEX III CONTAINER)</td>
<td>4.25</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose</strong> (AMBU-FLEX III CONTAINER)</td>
<td>4.25</td>
<td>4.25</td>
</tr>
</tbody>
</table>
Table 2. DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (AMBU-FLEX CONTAINER)

<table>
<thead>
<tr>
<th>Container Type</th>
<th>Composition/100 mL</th>
<th>Ionic Concentration (mEq/L)</th>
<th>How Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (AMBU-FLEX III) with 4.25% Dextrose</td>
<td>Calcium (CaCl(_{2}) • 2H(_2)O) 5.08 mg, Dextrose, Hydrous, USP 538 mg, Sodium Chloride, USP 100 mL</td>
<td>Calcium 5.2 2.5 0.5 95 40</td>
<td>Code NDC 0941-0459-06</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (AMBU-FLEX II) with 4.25% Dextrose</td>
<td>Calcium (CaCl(_{2}) • 2H(_2)O) 5.08 mg, Dextrose, Hydrous, USP 538 mg, Sodium Chloride, USP 100 mL</td>
<td>Calcium 5.2 2.5 0.5 95 40</td>
<td>Code NDC 0941-0459-05</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (AMBU-FLEX III) with 2.5% Dextrose</td>
<td>Calcium (CaCl(_{2}) • 2H(_2)O) 5.08 mg, Dextrose, Hydrous, USP 538 mg, Sodium Chloride, USP 100 mL</td>
<td>Calcium 5.2 2.5 0.5 95 40</td>
<td>Code NDC 0941-0459-04</td>
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<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (AMBU-FLEX II) with 2.5% Dextrose</td>
<td>Calcium (CaCl(_{2}) • 2H(_2)O) 5.08 mg, Dextrose, Hydrous, USP 538 mg, Sodium Chloride, USP 100 mL</td>
<td>Calcium 5.2 2.5 0.5 95 40</td>
<td>Code NDC 0941-0459-03</td>
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<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (AMBU-FLEX III) with 1.5% Dextrose</td>
<td>Calcium (CaCl(_{2}) • 2H(_2)O) 5.08 mg, Dextrose, Hydrous, USP 538 mg, Sodium Chloride, USP 100 mL</td>
<td>Calcium 5.2 2.5 0.5 95 40</td>
<td>Code NDC 0941-0459-02</td>
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<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (AMBU-FLEX II) with 1.5% Dextrose</td>
<td>Calcium (CaCl(_{2}) • 2H(_2)O) 5.08 mg, Dextrose, Hydrous, USP 538 mg, Sodium Chloride, USP 100 mL</td>
<td>Calcium 5.2 2.5 0.5 95 40</td>
<td>Code NDC 0941-0459-01</td>
</tr>
</tbody>
</table>

**Composition/100 mL:**
- Calcium (CaCl\(_{2}\) • 2H\(_2\)O) 5.08 mg
- Dextrose, Hydrous, USP 538 mg
- Sodium Chloride, USP 100 mL

**Ionic Concentration (mEq/L):**
- Calcium 5.2, 2.5, 0.5, 95, 40

**How Supplied:**
- Code NDC 0941-0459-06
- Code NDC 0941-0459-05
- Code NDC 0941-0459-04
- Code NDC 0941-0459-03
- Code NDC 0941-0459-02
- Code NDC 0941-0459-01
Table 3. DIANEAL PD-2 Peritoneal Dialysis Solution (ULTRABAG CONTAINER)

<table>
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<tr>
<th>Composition/100 mL</th>
<th>Ionic Concentration (mEq/L)</th>
<th>New Supplied</th>
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<tr>
<td></td>
<td>Calcium</td>
<td>Magnesium</td>
</tr>
<tr>
<td></td>
<td>Chloride</td>
<td>Lactate</td>
</tr>
<tr>
<td></td>
<td>(NaCl)</td>
<td>(C3H5NaO3)</td>
</tr>
<tr>
<td></td>
<td>(mOsmol/L) (calc)</td>
<td>(mL) Code NDC</td>
</tr>
<tr>
<td>DIANEAL PD-2</td>
<td>1.3 g 1300 mg 448 mg</td>
<td>4.25 g 850 mg</td>
</tr>
<tr>
<td>Dialysis Solution</td>
<td>20.7 g 500 mL 4.00 mg</td>
<td>1200 mL 55</td>
</tr>
<tr>
<td>with 4.25% Dextrose</td>
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<tr>
<td></td>
<td>388</td>
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<tr>
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<td>1.3 g 1300 mg 448 mg</td>
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<td>Dialysis Solution</td>
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<td></td>
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<td>1200 mL 55</td>
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<tr>
<td>with 1.5% Dextrose</td>
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<td></td>
<td>485</td>
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Table 4. DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution (ULTRABAG CONTAINER)

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<td>(mOsmol/L) (calc)</td>
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<td>4.25 g 850 mg</td>
</tr>
<tr>
<td>Low Calcium</td>
<td>19.3 g 483 mg 5.08 mg</td>
<td>1200 mL 55</td>
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<td>(2.5 mEq/L)</td>
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<tr>
<td>Peritoneal</td>
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<tr>
<td>Dialysis Solution</td>
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<tr>
<td>with 4.25% Dextrose</td>
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<tr>
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07/2013

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