DIANEAL PD-2 WITH DEXTROSE- sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution
DIANEAL LOW CALCIUM WITH DEXTROSE- sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution
Baxter Healthcare Corporation

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

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.

DOSAGE FORMS AND STRENGTHS
DIANEAL solutions are 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.

CONTRAINDICATIONS

WARNINGS AND PRECAUTIONS

ADVERSE REACTIONS
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.

FULL PRESCRIBING INFORMATION: CONTENTS*
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
   2.1 Basic Dosing Information
   2.2 Adding Medications
   2.3 Directions for Use
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
   5.1 Peritonitis and Encapsulating Peritoneal Sclerosis
   5.2 Lactic Acidosis

Revised: 11/2019
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 or intra-arterial 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 1.73m² for adults.

DIANEAL peritoneal dialysis solutions are 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 solution 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 peritoneal dialysis solution 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 solutions in water for warming. Do not use a microwave oven to warm DIANEAL solutions.

**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 or blue pull tip) is attached. Do not use if the tip protector is not attached to the connector. Inspect the DIANEAL solution 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 solution if the frangible(s) are broken or leaks are suspected as sterility may be impaired.

For DIANEAL solutions in ULTRABAG containers, 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 container from transfer set and apply MINICAP disconnect cap.

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 or pull rings**

Select appropriate formulation from Table 1, 2 or 3.

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.

### 3 DOSAGE FORMS AND STRENGTHS

DIANEAL peritoneal dialysis solution 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**

<table>
<thead>
<tr>
<th></th>
<th>OSMOLARITY (mOsmol/L) (calc)</th>
<th>pH</th>
<th>Sodium</th>
<th>Calcium</th>
<th>Magnesium</th>
<th>Chloride</th>
<th>Lactate</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIANEAL PD-2 1.5% Dextrose</td>
<td>346</td>
<td>5.2</td>
<td>132</td>
<td>3.5</td>
<td>0.5</td>
<td>96</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4.0 to 6.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIANEAL PD-2 2.5% Dextrose</td>
<td>396</td>
<td>5.2</td>
<td>132</td>
<td>3.5</td>
<td>0.5</td>
<td>96</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4.0 to 6.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIANEAL PD-2 4.25% Dextrose</td>
<td>485</td>
<td>5.2</td>
<td>132</td>
<td>3.5</td>
<td>0.5</td>
<td>96</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4.0 to 6.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose</td>
<td>344</td>
<td>5.2</td>
<td>132</td>
<td>2.5</td>
<td>0.5</td>
<td>95</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4.0 to 6.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose</td>
<td>395</td>
<td>5.2</td>
<td>132</td>
<td>2.5</td>
<td>0.5</td>
<td>95</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4.0 to 6.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2 - DIANEAL Low Calcium Peritoneal Dialysis Solution Plastic container with blue pull tip for APD therapy

<table>
<thead>
<tr>
<th>OSMOLARITY (mOsmol/L) (calc)</th>
<th>pH</th>
<th>Ionic Concentration (mEq/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Calcium</td>
<td>Magnesium</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose</td>
<td>344</td>
<td>5.0 to 6.5</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose</td>
<td>395</td>
<td>5.0 to 6.5</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 4.25% Dextrose</td>
<td>483</td>
<td>5.0 to 6.5</td>
</tr>
</tbody>
</table>

Table 3 – DIANEAL PD-2 and DIANEAL Low Calcium Peritoneal Dialysis Solution Plastic container with pull ring for APD therapy

<table>
<thead>
<tr>
<th>OSMOLARITY (mOsmol/L) (calc)</th>
<th>pH</th>
<th>Ionic Concentration (mEq/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Calcium</td>
<td>Magnesium</td>
</tr>
<tr>
<td>DIANEAL PD-2 1.5% Dextrose</td>
<td>346</td>
<td>5.0 to 5.6</td>
</tr>
<tr>
<td>DIANEAL PD-2 2.5% Dextrose</td>
<td>396</td>
<td>5.0 to 5.6</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose</td>
<td>344</td>
<td>5.0 to 5.6</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose</td>
<td>395</td>
<td>5.0 to 5.6</td>
</tr>
</tbody>
</table>

4 CONTRAINDICATIONS

DIANEAL peritoneal dialysis solutions are contraindicated in patients with severe lactic acidosis.
5 WARNINGS AND PRECAUTIONS

5.1 Peritonitis and Encapsulating Peritoneal Sclerosis
Peritonitis has been associated with DIANEAL peritoneal dialysis solution 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 solutions.

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 solutions 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 solutions contain 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 solutions. 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 peritoneal dialysis solutions.
6.2 Post-Marketing Experience

The following adverse experiences have been identified during post-approval use of DIANEAL solutions 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 peritoneal dialysis solution is a pharmacologically inactive solution. While there are no adequate and well controlled studies in pregnant women, appropriate administration of DIANEAL solutions, 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 solutions.

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 solutions 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 solutions are hyperosmolar solutions.

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

<table>
<thead>
<tr>
<th></th>
<th>Composition/100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>*Dextrose, Hydrous, USP</td>
</tr>
<tr>
<td>DIANEAL PD-2 1.5% Dextrose</td>
<td>1.5 g</td>
</tr>
<tr>
<td>DIANEAL PD-2 2.5% Dextrose</td>
<td>2.5 g</td>
</tr>
<tr>
<td>DIANEAL PD-2 4.25% Dextrose</td>
<td>4.25 g</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose</td>
<td>1.5 g</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose</td>
<td>2.5 g</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 4.25% Dextrose</td>
<td>4.25 g</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Composition/100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sodium</td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 1.5% Dextrose</td>
<td></td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 2.5% Dextrose</td>
<td></td>
</tr>
<tr>
<td>DIANEAL Low Calcium (2.5 mEq/L) 4.25% Dextrose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Dextrose, Hydrous</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td><strong>DIANEAL Low Calcium</strong></td>
<td></td>
</tr>
<tr>
<td>(2.5 mEq/L)</td>
<td>1.5% Dextrose</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL Low Calcium</strong></td>
<td></td>
</tr>
<tr>
<td>(2.5 mEq/L)</td>
<td>2.5% Dextrose</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL Low Calcium</strong></td>
<td></td>
</tr>
<tr>
<td>(2.5 mEq/L)</td>
<td>4.25% Dextrose</td>
</tr>
</tbody>
</table>

The plastic container is fabricated from polyvinyl chloride (PVC 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 peritoneal dialysis solutions are 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 solutions exert an osmotic pressure across the peritoneal membrane resulting in transcapillary ultrafiltration. Like other peritoneal dialysis solutions, DIANEAL solutions contain electrolytes to facilitate the correction of electrolyte abnormalities. DIANEAL solutions contain a buffer, lactate, to help normalize acid-base
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 solutions 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 solutions.

Antibiotics

No formal clinical drug interaction studies have been performed. In vitro studies of the following medications have demonstrated stability with DIANEAL solutions: amphotericin B, ampicillin, cefazolin, cefepime, cefotaxime, ceftazidime, ceftriaxone, ciprofloxacin, clindamycin, defereroxamine, erythromycin, gentamicin, linezolid, mezlocillin, miconazole, moxifloxacin, nafcillin, ofloxacin, penicillin G, pipercillin, 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 6-7:

<table>
<thead>
<tr>
<th>Container</th>
<th>Fill Volume (mL)</th>
<th>Container Size (mL)</th>
<th>Product Code</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose</td>
<td>2000</td>
<td>2000</td>
<td>5B9866</td>
<td>0941-0426-52</td>
</tr>
<tr>
<td></td>
<td>2500</td>
<td>2500</td>
<td>5B9868</td>
<td>0941-0426-53</td>
</tr>
<tr>
<td></td>
<td>3000</td>
<td>3000</td>
<td>5B9857</td>
<td>0941-0426-55</td>
</tr>
<tr>
<td></td>
<td>5000</td>
<td>5000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</td>
<td>2000</td>
<td>2000</td>
<td>5B9876</td>
<td>0941-0427-52</td>
</tr>
<tr>
<td></td>
<td>2500</td>
<td>2500</td>
<td>5B9878</td>
<td>0941-0427-53</td>
</tr>
<tr>
<td></td>
<td>3000</td>
<td>3000</td>
<td>5B9858</td>
<td>0941-0427-55</td>
</tr>
<tr>
<td></td>
<td>5000</td>
<td>5000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose</td>
<td>2000</td>
<td>2000</td>
<td>5B9896</td>
<td>0941-0429-52</td>
</tr>
<tr>
<td></td>
<td>2500</td>
<td>2500</td>
<td>5B9898</td>
<td>0941-0429-53</td>
</tr>
<tr>
<td>Container</td>
<td>Fill Volume (mL)</td>
<td>Container Size (mL)</td>
<td>Product Code</td>
<td>NDC</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------</td>
<td>--------------------</td>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>ULTRABAG Container</td>
<td>3000</td>
<td>5000</td>
<td>5B9859</td>
<td>0941-0429-55</td>
</tr>
<tr>
<td><strong>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1500</td>
<td>2000</td>
<td>5B9765</td>
<td>0941-0424-51</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>2000</td>
<td>5B9766</td>
<td>0941-0424-52</td>
<td></td>
</tr>
<tr>
<td>2500</td>
<td>3000</td>
<td>5B9768</td>
<td>0941-0424-53</td>
<td></td>
</tr>
<tr>
<td>3000</td>
<td>5000</td>
<td>5B9757</td>
<td>0941-0424-55</td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1500</td>
<td>2000</td>
<td>5B9775</td>
<td>0941-0430-51</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>2000</td>
<td>5B9776</td>
<td>0941-0430-52</td>
<td></td>
</tr>
<tr>
<td>2500</td>
<td>3000</td>
<td>5B9778</td>
<td>0941-0430-53</td>
<td></td>
</tr>
<tr>
<td>3000</td>
<td>5000</td>
<td>5B9758</td>
<td>0941-0430-55</td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1500</td>
<td>2000</td>
<td>5B9795</td>
<td>0941-0433-51</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>2000</td>
<td>5B9796</td>
<td>0941-0433-52</td>
<td></td>
</tr>
<tr>
<td>2500</td>
<td>3000</td>
<td>5B9798</td>
<td>0941-0433-53</td>
<td></td>
</tr>
<tr>
<td>3000</td>
<td>5000</td>
<td>5B9759</td>
<td>0941-0433-55</td>
<td></td>
</tr>
</tbody>
</table>

Table 7 - DIANEAL Peritoneal Dialysis Solutions for APD therapy

<table>
<thead>
<tr>
<th>Container</th>
<th>Fill Volume (mL)</th>
<th>Container Size (mL)</th>
<th>Product Code</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMBU-FLEX / Plastic Container with pull ring</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1000</td>
<td>1000</td>
<td>L5B5163</td>
<td>0941-0411-05</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>3000</td>
<td>L5B5166</td>
<td>0941-0411-06</td>
<td></td>
</tr>
<tr>
<td>3000</td>
<td>3000</td>
<td>L5B5169</td>
<td>0941-0411-04</td>
<td></td>
</tr>
<tr>
<td>5000</td>
<td>6000</td>
<td>L5B5193</td>
<td>0941-0411-07</td>
<td></td>
</tr>
<tr>
<td>6000</td>
<td>6000</td>
<td>L5B9710</td>
<td>0941-0411-11</td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1000</td>
<td>1000</td>
<td>L5B5173</td>
<td>0941-0413-05</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>3000</td>
<td>L5B5177</td>
<td>0941-0413-06</td>
<td></td>
</tr>
<tr>
<td>3000</td>
<td>3000</td>
<td>L5B5179</td>
<td>0941-0413-04</td>
<td></td>
</tr>
<tr>
<td>5000</td>
<td>6000</td>
<td>L5B5194</td>
<td>0941-0413-07</td>
<td></td>
</tr>
<tr>
<td>6000</td>
<td>6000</td>
<td>L5B9711</td>
<td>0941-0413-01</td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1000</td>
<td>1000</td>
<td>L5B5183</td>
<td>0941-0415-05</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>3000</td>
<td>L5B5187</td>
<td>0941-0415-06</td>
<td></td>
</tr>
<tr>
<td>3000</td>
<td>3000</td>
<td>L5B5189</td>
<td>0941-0415-04</td>
<td></td>
</tr>
<tr>
<td>5000</td>
<td>6000</td>
<td>L5B5195</td>
<td>0941-0415-07</td>
<td></td>
</tr>
<tr>
<td>6000</td>
<td>6000</td>
<td>L5B9712</td>
<td>0941-0415-01</td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>3000</td>
<td>L5B4825</td>
<td>0941-0409-06</td>
<td></td>
</tr>
<tr>
<td>3000</td>
<td>3000</td>
<td>L5B9901</td>
<td>0941-0409-05</td>
<td></td>
</tr>
<tr>
<td>5000</td>
<td>6000</td>
<td>L5B4826</td>
<td>0941-0409-07</td>
<td></td>
</tr>
<tr>
<td>6000</td>
<td>6000</td>
<td>L5B9770</td>
<td>0941-0409-01</td>
<td></td>
</tr>
<tr>
<td><strong>DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>3000</td>
<td>L5B9727</td>
<td>0941-0457-08</td>
<td></td>
</tr>
</tbody>
</table>
Plastic container with blue pull tip

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 peritoneal dialysis solutions 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°C (98°F) and not to microwave or submerge in water.

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

Baxter, Ambu-Flex, Dianeal, MiniCap and UltraBag are trademarks of Baxter International Inc.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Printed in USA
0719001298

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL
Dianeal PD-2
Peritoneal Dialysis Solution
with 1.5% Dextrose

EACH 100 mL CONTAINS 1.5 g DEXTROSE HYDROUS
USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
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 WHICH MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PortION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT

Ambu-Flex II CONTAINER PL 146 PLASTIC
BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

07-25-56-615

NDC 0941-0411-06 Container Label
USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)

mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5 CHLORIDE - 96 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)

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 WHICH MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION

Rx ONLY

STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT

Ambu-Flex II CONTAINER PL 146 PLASTIC

BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA 07-25-56-615

PD-2 1.5% Dextrose
L5B5166 6-2000 ML
AMBU-FLEX II CONTAINERS 1.5%
DIANEAL PD-2 1.5% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT XXXXX
PRIMARY BAR CODE
(01) 50309410411068

NDC 0941-0411-06 Carton Label

L5B516 6-2000 ML
AMBU-FLEX II CONTAINERS 1.5%
DIANEAL PD-2 1.5% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT PRIMARY BAR CODE
XXXXX
(01) 50309410411068
Dianeal PD-2
Peritoneal Dialysis Solution
with 2.5% Dextrose

EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP  448 mg SODIUM LACTATE
25.7 mg CALCIUM CHLORIDE USP  5.08 mg MAGNESIUM CHLORIDE USP  pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132  CALCIUM - 3.5  MAGNESIUM - 0.5
CHLORIDE - 96  LACTATE - 40
OSMOLARITY - 396 mOsmol/L (CALC)
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
WHICH MAINTAINS PRODUCT STERILITY  DISCARD IF
LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT  SEE INSERT

Ambu-Flex II CONTAINER  PL 146 PLASTIC

BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

NDC 0941-0413-06 Container Label
EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5
CHLORIDE - 96 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
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 WHICH MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT SEE INSERT
Ambu-Flex II CONTAINER PL 146 PLASTIC
BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA 07-25-56-586
PD-2 2.5% Dextrose
L5B5177 6-2000ML
AMBU-FLEX II CONTAINERS 2.5%
Dianeal PD-2 2.5% DEX
PERITONEAL DIALYSIS SOLUTION
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT
XXXXX
PRIMAR Y BAR CODE
(01) 50309410413062
NDC 0941-0413-06 Carton Label
Dianeal PD-2
Peritoneal Dialysis Solution
with 4.25% Dextrose

EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP  448 mg SODIUM LACTATE
25.7 mg CALCIUM CHLORIDE USP  5.08 mg MAGNESIUM
CHLORIDE USP  pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132  CALCIUM - 3.5  MAGNESIUM - 0.5
CHLORIDE - 96  LACTATE - 40
OSMOLARITY - 485 mOsmol/L (CALC)
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
WARNING  EXTENSIVE USE OF THIS SOLUTION
DURING ONE PERITONEAL DIALYSIS PROCEDURE CAN
RESULT IN SIGNIFICANT REMOVAL OF WATER FROM
THE PATIENT

CAUTIONS  SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY  DISCARD IF
LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT  SEE INSERT

Ambu-Flex II CONTAINER  PL 146 PLASTIC
BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

07-25-56-591
NDC 0941-0415-06 Container Label

L5B5187 2000 mL
NDC 0941-0415-06 (APPROX 80 mL EXCESS)
3000 mL NOMINAL SIZE CONTAINER

Baxter
Dianeal PD-2
Peritoneal Dialysis Solution
with 4.25% Dextrose
EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5
CHLORIDE - 96 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
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

WARNING EXTENSIVE USE OF THIS SOLUTION
DURING ONE PERITONEAL DIALYSIS PROCEDURE CAN
RESULT IN SIGNIFICANT REMOVAL OF WATER FROM
THE PATIENT

CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD IF
LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION

Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT SEE INSERT

Ambu-Flex II CONTAINER PL 146 PLASTIC
BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA 07-25-56-591

PD-2 4.25% Dextrose
L5B5187 6-2000ML
AMBU-FLEX II CONTAINERS 4.25%
DIANEAL PD-2 4.25% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT XXXXX
PRIMARY BAR CODE
(01) 50309410415066
NDC 0941-0415-06 Carton Label

(01) 50309410415066
Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 1.5% Dextrose

EACH 100 mL CONTAINS 1.5 g DEXTROSE HYDROUS
USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM
LACTATE 18.3 mg CALCIUM CHLORIDE USP 5.08 mg
MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)

mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM -
0.5 CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 344 mOsmol/L (CALC)

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
WHICH MAINTAINS PRODUCT STERILITY DISCARD
IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT SEE INSERT

Ambu-Flex II CONTAINER PL 146 PLASTIC

BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

L5B4825 2000 mL
NDC 0941-0409-06 (APPROX 80 mL EXCESS)

Baxter
Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 1.5% Dextrose
EACH 100 mL CONTAINS 1.5 g DEXTROSE HYDROUS
USP 538 mg SODIUM CHLORIDE USP 448 mg SODIUM
LACTATE 18.3 mg CALCIUM CHLORIDE USP 5.08 mg
MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM -
0.5 CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
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
WHICH MAINTAINS PRODUCT STERILITY DISCARD
IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT SEE INSERT

Ambu-Flex II CONTAINER PL 146 PLASTIC
BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA 07-25-56-640

Low Calcium 1.5% Dextrose
L5B4825-2000 ML
AMBU-FLEX II CONTAINERS 1.5%
DIANEAL LOW CALCIUM 1.5% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT PRIMARY BAR CODE
XXXXX
(01) 50309410409065
NDC 0941-0409-06 Carton Label
Peritoneal Dialysis Solution

**Dianeal**

**Low Calcium (2.5 mEq/L)**

**Peritoneal Dialysis Solution with 2.5% Dextrose**

Each 100 mL contains 2.5 g dextrose hydrolys USP, 538 mg sodium chloride USP, 448 mg sodium lactate, 18.3 mg calcium chloride USP, 5.08 mg magnesium chloride USP, pH 5.2 (4.0 to 6.5).

- mEq/L: Sodium - 132, Calcium - 2.5, Magnesium - 0.5, Chloride - 95, Lactate - 40, Osmolarity - 395 mOsmol/L (Calc).

Sterile, Nonpyrogenic.

**Instruction:**

- 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.
- Caution: Squeeze and inspect inner bag which maintains product sterility; discard if leaks are found.
- Do not use unless solution is clear.
- Discard unused portion.
- Rx only.
- Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use.
- Avoid excessive heat; see insert.

**Ambu-Flex II Container:** PL 146 Plastic.

Baxter Dianeal, Ambu-Flex II, and PL 146 are trademarks of Baxter International Inc.

Baxter Healthcare Corporation, Deerfield IL 60015 USA

Made in USA

NDC 0941-0457-08 Container Label

L5B9727 2000 mL
NDC 0941-0457-08 (APPROX 80 mL EXCESS)
3000 mL nominal size container

Baxter Logo

Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 2.5% Dextrose

EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5
CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
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
WHICH MAINTAINS PRODUCT STERILITY DISCARD IF
LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT SEE INSERT

Ambu-Flex II CONTAINER PL 146 PLASTIC
BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA 07-25-56-641

Low Calcium 2.5% Dextrose
L5B9727-2000ML
AMBU-FLEX II CONTAINERS 2.5%
DIANEAL LOW CALCIUM 2.5% DEX
PERITONEAL DIALYSIS SOLUTION
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT
XXXXX
PRIMAR BAR CODE
(01) 50309410457080
NDC 0941-0457-08 Carton Label
**Dianeal**

**Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose**

**Each 100 mL Contains:**
- 4.25 g Dextrose Hydro USP
- 538 mg Sodium Chloride USP
- 448 mg Sodium Lactate
- 18.3 mg Calcium Chloride USP
- 5.08 mg Magnesium Chloride USP
- pH 5.2 (4.0 to 6.5)

**Sodium - 132 mEq/L**
**Calcium - 2.5 mEq/L**
**Magnesium - 0.5 mEq/L**

**Chloride - 95 mEq/L**
**Lactate - 40 mEq/L**

**Osmolarity - 483 mosmol/L (Calc)**

**STERILE NONPYOPGENIC**

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**

**WARNING:** Extensive use of this solution during one peritoneal dialysis procedure can result in significant removal of water from the patient.

**CAUTIONS:** Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found.

Do not use unless solution is clear.

Discard unused portion.

Rx only.

Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use.

Avoid excessive heat. See insert.

**Ambu-Flex II Container** PL 146 Plastic

Baxter Dianeal, Ambu-Flex II, and PL 146 are trademarks of Baxter International Inc.

**Baxter Healthcare Corporation**
DEERFIELD IL 60015 USA

Made in USA.

NDC 0941-0459-08 Container Label
with 4.25% Dextrose

EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5
CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
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
WHICH MAINTAINS PRODUCT STERILITY DISCARD IF
LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT SEE INSERT

Ambu-Flex II CONTAINER PL 146 PLASTIC
BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA 07-25-56-642

Low Calcium 4.25% Dextrose
L5B9747-2000ML
AMBU-FLEX II CONTAINERS 4.25%
DIANEAL LOW CALCIUM 4.25% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT PRIMARY BAR CODE
XXXXX
(01) 50309410459084
NDC 0941-0459-08 Carton Label
Dianeal PD-2
Peritoneal Dialysis Solution with 1.5% Dextrose

Each 100 mL contains 1.5 g Dextrose Hydrous USP
538 mg Sodium Chloride USP  448 mg Sodium
Lactate 25.7 mg Calcium Chloride USP  5.08 mg
Magnesium Chloride USP  pH 5.2 (4.0 TO 6.5)

mEq/L Sodium - 132 Calcium - 3.5 Magnesium - 0.5
Chloride - 96 Lactate - 40
Osmolarity - 346 mOsmol/L (Calc)
Sterile Nonpyrogenic

Potassium Chloride to be added only
under the direction of a physician.

Read package insert for full information
For intraperitoneal administration only
Dosage as directed by a physician

Cautions: Squeeze and inspect inner bag
which maintains product sterility. Discard
if leaks are found.
Do not use unless solution is clear.
Discard unused portion.
Rx only

Store unit in moisture barrier overwrap at
room temperature (25°C/77°F) until ready to

UltraBag Container  PL 146 Plastic

Baxter Dianeal Ultragbag and PL 146 are
trademarks of Baxter International Inc.

Baxter Healthcare Corporation
Deerfield IL 60015 USA
Made in USA
US Pat Nos 4340049  4346703
4439188  4573980
Dianeal PD-2
Peritoneal Dialysis Solution
with 1.5% Dextrose

EACH 100 mL CONTAINS 1.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM
LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg
MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)

mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5
CHLORIDE - 96 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)

STERILE NONPYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION

FOR INTRAPERITONEAL ADMINISTRATION ONLY

USE AS DIRECTED BY PHYSICIAN

CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD
IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION

Rx ONLY

STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE

AVOID EXCESSIVE HEAT SEE INSERT

UltraBag CONTAINER PL 146 PLASTIC

BAXTER DIANEAL ULTRABAG AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA

US PAT NOS 4340049 4346703
4439188 4573980

PD-2 1.5% Dextrose
5B9866 6-2000ML IN 2000ML
ULTRABAG™ CONTAINERS 1.5%
DIANEAL® PD-2 1.5% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT PRIMARY BAR CODE
XXXXX
(01) 50309410426529
NDC 0941-0426-52 Carton Label
Dianeal PD-2
Peritoneal Dialysis Solution with 2.5% Dextrose

EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM
LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg
MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5
CHLORIDE - 96 LACTATE - 40
OSMOLARITY - 396 mOsmol/L (CALC)
STERILE NONPYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION
FOR INTRA PERITONEAL ADMINISTRATION ONLY
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT

UltraBag CONTAINER PL 146 PLASTIC

BAXTER DIANEAL ULTRABAG AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
US PAT NOS 4340049 4346703
4439188 4573980

NDC 0941-0427-52 Container Label
with 2.5% Dextrose

EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP  
538 mg SODIUM CHLORIDE USP 448 mg SODIUM  
LACTATE 25.7 mg CALCIUM CHLORIDE USP 5.08 mg  
MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)

mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5  
CHLORIDE - 96 LACTATE - 40  
OSMOLARITY - 346 mOsmol/L (CALC)

STERILE NONPYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY  
UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION  
DOSAGE AS DIRECTED BY PHYSICIAN

CAUTIONS SQUEEZE AND INSPECT INNER BAG  
WHICH MAINTAINS PRODUCT STERILITY DISCARD  
IF LEAKS ARE FOUND

DO NOT USE UNLESS SOLUTION IS CLEAR  
DISCARD UNUSED PORTION

Rx ONLY

STORE UNIT IN MOISTURE BARRIER OVERWRAP AT  
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO  
USE

AVOID EXCESSIVE HEAT SEE INSERT

UltraBag CCONTAINER PL 146 PLASTIC

BAXTER DIANEAL ULTRABAG AND PL 146 ARE  
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION  
DEERFIELD IL 60015 USA

MADE IN USA

US PAT NOS 4340049 4346703  
4439188 4573980

PD-2 2.5% Dextrose
5B9876 6-2000ML IN 2000ML
ULTRABAG™ CONT 2.5%
DIANEAL PD-2 2.5% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT PRIMARY BAR CODE
XXXXX
(01) 50309410427526
Dianeal PD-2
Peritoneal Dialysis Solution with 4.25% Dextrose

Each 100 mL contains:
- 4.25 g Dextrose anhydrous USP
- 536 mg Sodium Chloride USP
- 448 mg Sodium Lactate
- 25.7 mg Calcium Chloride USP
- 5.08 mg Magnesium Chloride USP
- 132 mEq/L Sodium
- 3.5 mEq/L Calcium
- 96 mEq/L Chloride
- 40 mEq/L Lactate
- Osmolarity: 485 mOsM/L (Calc)

Sterile, nonpyrogenic

Potassium Chloride to be added only under the direction of a physician

Read package insert for full information

Warning: Extensive use of this solution during one peritoneal dialysis procedure can result in significant removal of water from the patient. For intraperitoneal administration only. Dosage as directed by a physician.

Cautions: Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found.

Do not use unless solution is clear. Discard unused portion.

Rx only.

Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use. Avoid excessive heat. See insert.

UltraBag Container PL 146 Plastic

Baxter Dianeal, UltraBag and PL 146 are trademarks of Baxter International Inc.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in USA

US Pat Nos: 4340049
4343988
4346703
4573960

NDC 0941-0429-52 Container Label
with 4.25% Dextrose

EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5
CHLORIDE - 96 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)

STERILE NONPYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION

WARNING EXTENSIVE USE OF THIS SOLUTION DURING
ONE PERITONEAL DIALYSIS PROCEDURE CAN RESULT IN
SIGNIFICANT REMOVAL OF WATER FROM THE PATIENT

FOR INTRAPERITONEAL ADMINISTRATION ONLY

DOSAGE AS DIRECTED BY A PHYSICIAN

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS
ARE FOUND

DO NOT USE UNLESS SOLUTION IS CLEAR

DISCARD UNUSED PORTION

Rx ONLY

STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM
TEMPERATURE (25°C/77°F) UNTIL READY TO USE

AVOID EXCESSIVE HEAT SEE INSERT

UltraBag CONTAINER PL 146 PLASTIC

BAXTER DIANEAL ULTRABAG AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA

US PAT NOS 4340049 4346703
4439188 4573980
DIANEAL® PD-2 4.25% DEX EXP
PERITONEAL DIALYSIS SOLUTION

SECONDARY BAR CODE

(17) YYMM00 (10) XXXXX

LOT XXXXX

PRIMARY BAR CODE

(01) 50309410429520

NDC 0491-0429-52 Carton Label

5B9896 6-2000ML IN 2000ML
ULTRABAG™ CONTAINERS 4.25%
DIANEAL® PD-2 4.25% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT PRIMARY BAR CODE
XXXXX
(01) 50309410429520
Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 1.5% Dextrose

EACH 100 mL CONTAINS
1.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP
448 mg SODIUM LACTATE
16.3 mg CALCIUM CHLORIDE USP
5.08 mg MAGNESIUM CHLORIDE USP
pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCUL - 2.5 MAGNESIUM - 0.5
CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 344 mOsmol/L (CALC)
STERILE NONPYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY

CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION

Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT

UltraBag CONTAINER
PL 146 PLASTIC

BAXTER DIANEAL ULTRABAG AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
US PAT NOS 4340049 4346703
4439188 4573980

NDC 0941-0424-52 Container Label

07-25-47-842
5B9766 2000 mL
NDC 0941-0424-52 (APPROX 80 mL EXCESS)

Baxter
Dianeal
Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution
with 1.5% Dextrose

EACH 100 mL CONTAINS 1.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5
CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
STERILE NONPYROGENIC
POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN
READ PACKAGE INSET FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY
DOSAGE AS DIRECTED BY PHYSICIAN
CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD
IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT
UltraBag CONTAINER PL 146 PLASTIC
BAXTER DIANEAL ULTRABAG AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
US PAT NOS 4340049 4346703
4439188 4573980
Low Calcium 1.5% Dextrose
5B9766 6-2000ML IN 2000ML
ULTRABAG™ CONT 1.5%
DIANEAL® LOW CALCIUM 1.5% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT PRIMARY BAR CODE
XXXXX
(01) 50309410424525

NDC 0941-0424-52 Carton Label
Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 2.5% Dextrose

EACH 100 mL CONTAINS
2.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP
446 mg SODIUM LACTATE
18.3 mg CALCIUM CHLORIDE USP
5.08 mg SODIUM MAGNESIUM CHLORIDE USP
pH 5.2 (4.0 TO 6.5)

mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5
CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 395 mOsmol/L (CALC)
STERILE NONPYROGENIC

POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY
DOSAGE AS DIRECTED BY A PHYSICIAN

CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD
IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY

STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT SEE INSERT

UltraBag CONTAINER PL 146 PLASTIC

BAXTER DIANEAL ULTRABAG AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
US PAT NOS 4340049
4439188
4346703
4573960

NDC 0941-0430-52 Container Label

07-25-47-845

5B9776 2000 mL
NDC 0941-0430-52 (APPROX 80 mL EXCESS)

BaxterLogo

Dianeal
Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution
with 2.5% Dextrose

EACH 100 mL CONTAINS 1.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE 18.3 mg CALCIUM CHLORIDE
USP 5.08 mg MAGNESIUM CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5
CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
STERILE NONPYROGENIC
POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN
READ PACKAGE INSET FOR FULL INFORMATION
FOR INTRAPERITONEAL ADMINISTRATION ONLY
DOSAGE AS DIRECTED BY PHYSICIAN
CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD
IF LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT
ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO
USE
AVOID EXCESSIVE HEAT SEE INSERT
UltraBag CONTAINER PL 146 PLASTIC
BAXTER DIANEAL ULTRABAG AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
US PAT NOS 4340049 4346703
4439188 4573980
Low Calcium 2.5% Dextrose
Dianeal® Low Calcium 2.5% DEX
Peritoneal Dialysis Solution

SECONDARY BAR CODE

(17) YYMM00 (10) XXXXX

LOT

XXXXX

PRIMARY BAR CODE

(01) 50309410430526

NDC 0941-0430-52 Carton Label
Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution with 4.25% Dextrose

Each 100 mL contains 4.25 g Dextrose Hydrous USP
538 mg Sodium Chloride USP 448 mg Sodium Lactate
18.3 mg Calcium Chloride USP 5.08 mg Magnesium
Chloride USP pH 5.2 (4.0 TO 6.5)
mEq/L Sodium - 132 Calcium - 2.5 Magnesium - 0.5
CHLORIDE - 95 LACTATE - 40
Osmolarity - 483 mOsmol/L (CALC)
STERILE  NONPYROGENIC
POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN

READ PACKAGE INSERT FOR FULL INFORMATION

WARNING  EXTENSIVE USE OF THIS SOLUTION DURING
ONE PERITONEAL DIALYSIS PROCEDURE CAN RESULT IN
SIGNIFICANT REMOVAL OF WATER FROM THE PATIENT
FOR INTRAPERITONEAL ADMINISTRATION ONLY

DOSAGE AS DIRECTED BY A PHYSICIAN

CAUTIONS  SQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY  DISCARD IF LEAKS
ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM
TEMPERATURE (25°C/77°F) UNTIL READY TO USE
AVOID EXCESSIVE HEAT  SEE INSERT

UltraBag CONTAINER PL 146 PLASTIC
BAXTER DIANEAL ULTRABAG AND PL 146 ARE
TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
US PAT NOS 4340049 4346703
4439188 4573980

NDC 0941-0433-52 Container Label

07-25-47-848
5B9796 2000 mL
Dianeal
Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution
with 4.25% Dextrose

EACH 100 mL CONTAINS 4.25 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
18.3 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 2.5 MAGNESIUM - 0.5
CHLORIDE - 95 LACTATE - 40
OSMOLARITY - 346 mOsmol/L (CALC)
STERILE NONPYROGENIC
POTASSIUM CHLORIDE TO BE ADDED ONLY
UNDER THE DIRECTION OF A PHYSICIAN
READ PACKAGE INSET FOR FULL INFORMATION

WARNING EXTENSIVE USE OF THIS SOLUTION DURING
ONE PERITONEAL DIALYSIS PROCEDURE CAN RESULT IN
SIGNIFICANT REMOVAL OF WATER FROM THE PATIENT
FOR INTRAPERITONEAL ADMINISTRATION ONLY
DOSAGE AS DIRECTED BY PHYSICIAN

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH
MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS
ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F)
UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT

UltraBag CONTAINER PL 146 PLASTIC
BAXTER DIANEAL ULTRABAG AND PL 146 ARE TRADEMARKS OF BAXTER
INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
US PAT NOS 4340049 4346703
4439188 4573980
Low Calcium 2.5% Dextrose
5B9796 6-2000ML IN 2000ML
ULTRABAG™ CONT 4.25%
DIANEAL® LOW CALCIUM 4.25% DEX EXP
PERITONEAL DIALYSIS SOLUTION XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT XXXXX
PRIMARY BAR CODE
(01) 50309410433527

NDC 0941-0433-52 Carton Label
EZPB5245R
NDC 0941-0484-01
5000 mL
(APPROX 135 mL EXCESS)
BAXTER LOGO
Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 1.5% Dextrose
Low Calcium 1.5% Dextrose
EACH 100 mL CONTAINS
448 mg SODIUM LACTATE
pH 5.0 to 6.5
1.5 g DEXTROSE HYDROUS
18.4 mg CALCIUM CHLORIDE
538 mg SODIUM CHLORIDE
5.08 mg MAGNESIUM CHLORIDE
mEq/L SODIUM – 132 CALCIUM – 2.5 MAGNESIUM – 0.5 CHLORIDE – 95 LACTATE – 40
OSMOLARITY – 344 mOsmol/L (CALC)
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 WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND

DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT
PL 146 PLASTIC
BAXTER DIANEAL AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN IRELAND
CB-35-03-813

Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose
5000 ml x 2
EZPB5245R

DIANEAL LOW CALCIUM (2.5 mEq/L)
Peritoneal Dialysis Solution with 1.5% Dextrose
5000 mL x 2
EZPB5245R
Dianeal Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 1.5% Dextrose

LOT XXXXXXXX

EZPB5245R
5000 mL x 2
EXP MM/YYYY
Low Calcium (2.5 mEq/L)  
Peritoneal Dialysis Solution  
with 2.5% Dextrose

Low Calcium 2.5% Dextrose

EACH 100 mL CONTAINS
448 mg SODIUM LACTATE  
pH 5.0 to 6.5  
2.5 g DEXTROSE HYDROUS  
18.4 mg CALCIUM CHLORIDE  
538 mg SODIUM CHLORIDE  
5.08 mg MAGNESIUM CHLORIDE

mEq/L SODIUM – 132 CALCIUM – 2.5 MAGNESIUM – 0.5 CHLORIDE – 95 LACTATE – 40 
OSMOLARITY – 395 mOsmol/L (CALC)

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 WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND

DO NOT USE UNLESS SOLUTION IS CLEAR

DISCARD UNUSED PORTION

Rx ONLY

STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25ºC/77ºF) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT

PL 146 PLASTIC

BAXTER DIANEAL AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA

MADE IN IRELAND

CB-35-03-814
DIANEAL LOW CALCIUM (2.5 mEq/L)
Peritoneal Dialysis Solution
with 2.5% Dextrose
5000 mL x 2
EZPB5255R
88-46-12-477
LOT XXXXXXXX
EXP MM/YYYY
BAR CODE
(01)00000000000000(17)201200(10)XXXXXXX

Dianeal Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 2.5% Dextrose
LOT XXXXXXXX
EZPB5255R
5000 mL x 2
EXP MM/YYYY
EZPB5265R
NDC 0941-0490-01
5000 mL
(APPROX 135 mL EXCESS)

BAXTER LOGO
Dianeal
Low Calcium (2.5 mEq/L)
Peritoneal Dialysis Solution
with 4.25% Dextrose

Low Calcium 4.25% Dextrose
EACH 100 mL CONTAINS
448 mg SODIUM LACTATE
4.25 g DEXTROSE HYDROIS
18.4 mg CALCIUM CHLORIDE
538 mg SODIUM CHLORIDE
5.08 mg MAGNESIUM CHLORIDE
pH 5.0 to 6.5
mEq/L SODIUM – 132 CALCIUM – 2.5 MAGNESIUM – 0.5 CHLORIDE – 95 LACTATE – 40
OSMOLARITY – 483 mOsm/L (CALC)
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
WARNING  EXTENSIVE USE OF THIS SOLUTION DURING ONE PERITONEAL DIALYSIS PROCEDURE
       CAN RESULT IN SIGNIFICANT REMOVAL OF WATER FROM THE PATIENT
       DO NOT USE UNLESS SOLUTION IS CLEAR
       DISCARD UNUSED PORTION
       Rx ONLY
STORAGE UNIT IN MOISTURE BARRIER/WRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY
       TO USE
       AVOID EXCESSIVE HEAT
       SEE INSERT
PL 146 PLASTIC
BAXTER DINEAL AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE CORPORATION  DEERFIELD IL 60015 USA
MADE IN IRELAND

CB-35-03-815
4.25 g DEXTROSE HYDROUS
18.4 mg CALCIUM CHLORIDE
538 mg SODIUM CHLORIDE
5.08 mg MAGNESIUM CHLORIDE
mEq/L SODIUM – 132 CALCIUM – 2.5 MAGNESIUM – 0.5 CHLORIDE – 95 LACTATE – 40
OSMOLARITY – 483 mOsmol/L (CALC)
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 WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND

DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT
PL 146 PLASTIC
BAXTER DIANEAL AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA
MADE IN IRELAND
CB-35-03-815

Dianeal Low Calcium (2.5 mEq/L)

Peritoneal Dialysis Solution
with 4.25% Dextrose

5000 ml x 2

EZPB5265R

NDC 0941-0490-01 Carton Label

DIANEAL LOW CALCIUM (2.5 mEq/L)
Peritoneal Dialysis Solution with 4.25% Dextrose
5000 mL x 2
EZPB5265R
88-46-12-478
LOT XXXXXXXX
EXP MM/YYYY
BAR CODE
(01)00000000000000(17)201200(10)XXXXXXXX

DIANEAL PD-2 WITH DEXTROSE
sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:0941-0411</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>INTRAPERITONEAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>1.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LY4M0N37, CHLORIDE ION - UNII:Q2Z2Z4698)</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LY4M0N37, LACTIC ACID - UNII:33X04GA5AT)</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q2Z2Z4698)</td>
<td>CALCIUM CHLORIDE</td>
<td>25.7 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473180) (MAGNESIUM CATION - UNII:6V3LY838, CHLORIDE ION - UNII:Q2Z2Z4698)</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0411-05</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td>09/27/1978</td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0411-06</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td>09/27/1978</td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0411-07</td>
<td>5000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td>09/27/1978</td>
</tr>
<tr>
<td>4</td>
<td>NDC:0941-0411-04</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td>09/27/1978</td>
</tr>
<tr>
<td>5</td>
<td>NDC:0941-0411-11</td>
<td>6000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td>09/27/1978</td>
</tr>
</tbody>
</table>
**DIANEAL PD-2 WITH DEXTROSE**  
sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>2.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE</td>
<td>CALCIUM CHLORIDE</td>
<td>25.7 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0413-05</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0413-06</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0413-07</td>
<td>5000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:0941-0413-01</td>
<td>6000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>NDC:0941-0413-04</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>
sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

Product Information
Product Type: HUMAN PRESCRIPTION DRUG
Route of Administration: INTRAPERITONEAL

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>4.25 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE</td>
<td>CALCIUM CHLORIDE</td>
<td>25.7 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0415-05</td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/28/1978</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0415-06</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0415-04</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:0941-0415-07</td>
<td>5000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>NDC:0941-0415-01</td>
<td>6000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA017512</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

DIANEAL LOW CALCIUM WITH DEXTROSE
sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

Product Information
Product Type: HUMAN PRESCRIPTION DRUG
Route of Administration: INTRAPERITONEAL
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>1.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NB37, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE (UNII: TU7H0W0QT) (SODIUM CATION - UNII:LYR4M0NB37, LACTIC ACID - UNII:33X04XA5AT)</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>CALCIUM CHLORIDE</td>
<td>18.3 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473H0O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0409-06</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0409-05</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0409-07</td>
<td>5000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:0941-0409-01</td>
<td>6000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA017512</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

### DIANEAL LOW CALCIUM WITH DEXTROSE

sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0941-0457</td>
</tr>
<tr>
<td>ROUTE OF ADMINISTRATION</td>
<td>INTRAPERITONEAL</td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>2.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NB37, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE (UNII: TU7H0W0QT) (SODIUM CATION - UNII:LYR4M0NB37, LACTIC ACID - UNII:33X04XA5AT)</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
</tbody>
</table>
**DIANEAL LOW CALCIUM WITH DEXTROSE**
sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

**Product Information**

- **Product Type**: HUMAN PRESCRIPTION DRUG
- **Route of Administration**: INTRAPERITONEAL
- **Item Code (Source)**: NDC:0941-0459

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:SL0G7R0OK)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>4.25 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID - UNII:3X04XAX5AT)</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>CALCIUM CHLORIDE</td>
<td>18.3 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473HBO) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0K00R)</td>
<td></td>
</tr>
</tbody>
</table>
## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0459-08</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0459-02</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0459-05</td>
<td>5000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:0941-0459-01</td>
<td>6000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA017512</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

## DIANEAL PD-2 WITH DEXTROSE

sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0941-0426</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRAPERITONEAL</td>
</tr>
</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>1.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE</td>
<td>CALCIUM CHLORIDE</td>
<td>25.7 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
</tr>
</tbody>
</table>

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0426-52</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0426-53</td>
<td>2500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0426-55</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>
## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020163</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

## DIANEAL PD-2 WITH DEXTROSE

sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0941-0427</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRAPERITONEAL</td>
<td></td>
</tr>
</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>2.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47Q8X)</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE (UNII: TU7HWO0WQT)</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4IO6D6V5M)</td>
<td>CALCIUM CHLORIDE</td>
<td>25.7 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473H5O)</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0427-52</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0427-53</td>
<td>2500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0427-55</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020163</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>
## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
<th>Item Code (Source)</th>
<th>NDC: 0941-0429</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>INTRAPERITONEAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII: E5SL0G7R0OK)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>4.25 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII: LYR4M0NH37, CHLORIDE ION - UNII: Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII: LYR4M0NH37, LACTIC ACID - UNII: 33X04XA5AT)</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII: 2M83C4R6ZB, CHLORIDE ION - UNII: Q32ZN48698)</td>
<td>CALCIUM CHLORIDE</td>
<td>25.7 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473HBO) (MAGNESIUM CATION - UNII: T63LY8383, CHLORIDE ION - UNII: Q32ZN48698)</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC: 0941-0429-52</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC: 0941-0429-53</td>
<td>2500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC: 0941-0429-55</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020163</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

## DIANEAL LOW CALCIUM WITH DEXTROSE

sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
<th>Item Code (Source)</th>
<th>NDC: 0941-0424</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>INTRAPERITONEAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
</tr>
</tbody>
</table>
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)

SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH7, CHLORIDE ION - UNII:Q32ZN48698)

SODIUM LACTATE (UNII: TU7HW0WQT) (SODIUM CATION - UNII:LYR4M0NH7, LACTIC ACID - UNII:33X04XA5AT)

CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)

MAGNESIUM CHLORIDE (UNII: 02F3473H0) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0424-51</td>
<td>1500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0424-52</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0424-53</td>
<td>2500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:0941-0424-55</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020183</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

DIANEAL LOW CALCIUM WITH DEXTROSE
sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0941-0430</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTRAPERITONEAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>2.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE</td>
<td>CALCIUM CHLORIDE</td>
<td>18.3 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>
### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
<td>(UNII: 059QF0KO0R)</td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0430-51</td>
<td>1500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0430-52</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0430-53</td>
<td>2500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:0941-0430-55</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020183</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

### DIANEAL LOW CALCIUM WITH DEXTROSE

sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0941-0433</td>
</tr>
<tr>
<td>INTRAPERITONEAL</td>
<td>NDC:0941-0433</td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>4.25 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE</td>
<td>CALCIUM CHLORIDE</td>
<td>18.3 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
<td>(UNII: 059QF0KO0R)</td>
</tr>
</tbody>
</table>

## Packaging
<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0433-51</td>
<td>1500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0941-0433-52</td>
<td>2000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0941-0433-53</td>
<td>2500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:0941-0433-55</td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020183</td>
<td>12/04/1992</td>
<td></td>
</tr>
</tbody>
</table>

## DIANEAL LOW CALCIUM WITH DEXTROSE

**sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution**

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0941-0484</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRAPERITONEAL</td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DEXTROSE MONOHYDRATE</strong> (UNII: LX22YL0833G) <strong>(ANHYDROUS DEXTROSE - UNII:5L0G70K0)</strong></td>
<td>DEXTROSE MONOHYDRATE</td>
<td>1.5 g in 100 mL</td>
</tr>
<tr>
<td><strong>SODIUM CHLORIDE</strong> (UNII: 451W47Q8X) <strong>(SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZG4698)</strong></td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td><strong>SODIUM LACTATE</strong> (UNII: TV7HW0W0QT) <strong>(LACTIC ACID - UNII:33X04X5A5A, SODIUM CATION - UNII:Y84M0NH37)</strong></td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td><strong>CALCIUM CHLORIDE</strong> (UNII: M4B0D6V5M) <strong>(CALCIUM CATION - UNII:2M83C4R6ZB)</strong></td>
<td>CALCIUM CHLORIDE</td>
<td>18.4 mg in 100 mL</td>
</tr>
<tr>
<td><strong>MAGNESIUM CHLORIDE</strong> (UNII: 02F2347395) <strong>(MAGNESIUM CATION - UNII:6V3L0HY838, CHLORIDE ION - UNII:Q32ZN48698)</strong></td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER <strong>(UNII: 059QF0KO0R)</strong></td>
<td></td>
</tr>
</tbody>
</table>

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0484-01</td>
<td>5000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
</table>
DIANEAL LOW CALCIUM WITH DEXTROSE
sodium chloride, sodium lactate, calcium chloride, magnesium chloride and dextrose injection, solution

Product Information

Product Type: HUMAN PRESCRIPTION DRUG  
Item Code (Source): NDC:0941-0487

Route of Administration: INTRAPERITONEAL

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>2.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE (UNII: TU7HW0W0QT) (LACTIC ACID - UNII:33X04XA5AT, SODIUM CATION - UNII:LYR4M0NH37)</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>CALCIUM CHLORIDE</td>
<td>18.4 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473H0) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0941-0487-01</td>
<td>5000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

Marketing Information

Marketing Category: NDA  
Application Number or Monograph Citation: NDA017512  
Marketing Start Date: 09/27/1978  
Marketing End Date: 09/27/1978
<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>4.25 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47QX8) (SODIUM CATION - UNII:LY4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>538 mg in 100 mL</td>
</tr>
<tr>
<td>SODIUM LACTATE (UNII: TU7HW0W0QT) (LACTIC ACID - UNII:33X04XA5AT, SODIUM CATION - UNII:LY4M0NH37)</td>
<td>SODIUM LACTATE</td>
<td>448 mg in 100 mL</td>
</tr>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4B06V5V5M) (CALCIUM CATION - UNII:2M3C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>CALCIUM CHLORIDE</td>
<td>18.4 mg in 100 mL</td>
</tr>
<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473HBO) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>MAGNESIUM CHLORIDE</td>
<td>5.08 mg in 100 mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inactive Ingredients</th>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Packaging | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0941-0490-01 | 5000 mL in 1 BAG; Type 0: Not a Combination Product | 09/27/1978 | |

<table>
<thead>
<tr>
<th>Marketing Information</th>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA017512</td>
<td></td>
<td>09/27/1978</td>
<td></td>
</tr>
</tbody>
</table>

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
</table>

Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter Healthcare Corporation</td>
<td>194684502</td>
<td></td>
<td>ANALYSIS(0941-0411, 0941-0413, 0941-0415, 0941-0409, 0941-0457, 0941-0459, 0941-0426, 0941-0427, 0941-0429, 0941-0424, 0941-0427, 0941-0429, 0941-0424, 0941-0430, 0941-0433)</td>
</tr>
<tr>
<td>Name</td>
<td>Address</td>
<td>ID/FEI</td>
<td>Business Operations</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------------</td>
<td>--------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Baxter, S.A. de C.V.</td>
<td>810432484</td>
<td></td>
<td>ANALYSIS(0941-0409, 0941-0457, 0941-0411, 0941-0413) , MANUFACTURE(0941-0409, 0941-0457, 0941-0411, 0941-0413) , LABEL(0941-0409, 0941-0457, 0941-0411, 0941-0413) , PACK(0941-0409, 0941-0457, 0941-0411, 0941-0413) , STERILIZE(0941-0409, 0941-0457, 0941-0411, 0941-0413) , API MANUFACTURE(0941-0409, 0941-0457, 0941-0411, 0941-0413)</td>
</tr>
</tbody>
</table>

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter SA</td>
<td>370353835</td>
<td></td>
<td>ANALYSIS(0941-0484, 0941-0487, 0941-0490)</td>
</tr>
</tbody>
</table>

Revised: 11/2019