**Ambe-Flex Container For Peritoneal Dialysis**

**Dianeal PD-2 Peritoneal Dialysis Solution**

For intraperitoneal administration only

---

**Description**

Diameal PD-2 peritoneal dialysis solutions in Ambe-Flex containers are sterile, pyrogen-free preparations for intraperitoneal administration only. They contain no bacteriostatic or antifungal agents or added buffers. Composition, calculated osmolality, pH, and ionic concentrations are shown in Table 1.

Potassium is omitted from Diameal solutions because dialysis may be performed to correct hyperkalemia. In situations where t is a normal serum potassium level or hyperkalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hyperkalemia. Additions of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician. Frequent monitoring of serum electrolytes is indicated.

Because average plasma magnesium levels in some chronic CAPD patients have been observed to be elevated (Nolph et al. 1981), the magnesium concentration of this formulation has been reduced to 0.5 mEq/L. Average plasma magnesium levels have not reported for chronic IPD and COPD patients. Serum magnesium levels should be monitored and, if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.

Because average serum bicarbonate levels in some chronic CAPD patients (Nolph et al. 1981), some chronic IPD patients (La Greca et al. 1980), and some chronic COPD patients (Diaz-Buxo et al. 1980) have been observed to be somewhat lower than normal values, the bicarbonate precursor (lactate) concentration of this formulation has been raised to 40 mEq/L. Serum bicarbonate levels should be monitored.

The osmolarities shown in Table 1 are calculated values. As an example, measured osmolality by freezing point depression determination of Diameal PD-2 peritoneal dialysis solution with 7.5% dextrose is approximately 334 mOsml/kg, compared with measured values in normal human serum of 280 mOsml/kg.

The plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container is insufficient to affect the solution significantly. Solutions in PL 146 plastic have been monitored to avoid over or under hydration with severe consequences including congestive heart failure, volume depletion, and shock.

---

**Clinical Pharmacology**

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for adding in the regulation of fluid and electrolyte balances.

The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. With the exception of lactate, present as a bicarbonate precursor, electrolyte concentrations in the fluid have been formulated to attempt to normalize plasma electrolyte concentrations resulting from osmotic and diffusion across the peritoneal membrane (between the plasma of the patient and the dialysis fluid). Toxic substances and metabolites, present in high concentrations in the blood, cross the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution hyperosmolar to the plasma, creating an oncotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time (ideal time), the fluid is drained from the cavity.

**Indications and Usage**

Peritoneal dialysis is indicated for patients in acute or chronic renal failure when nondialytic medical therapy is judged to be inadequate (Vaamonde and Perez 1977). It may also be indicated in the treatment of certain fluid and electrolyte disturbances, and for patients intoxicated with certain poisons (Knepshield et al. 1977). However, for many substances other methods of detoxification have been reported to be more effective than peritoneal dialysis (Vaamonde and Perez 1977; Chang 1977).

**Central Indications**

Some known

**Warnings**

Peritoneal dialysis should be done with great care, if at all, in patients with a number of abnormal conditions including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or tears, fecal fistula or ostomy, tense ascites, obesity, and large polycystic kidneys (Vaamonde and Perez 1977). Other conditions include recent acute gut replacement and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid or under hydration with severe consequences including congestive heart failure, volume depletion, and shock.

Excessive use of Diameal PD-2 peritoneal dialysis solution with 3.5% or 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient. In acute renal failure patients, plasma electrolyte concentrations should be monitored periodically during the procedure. Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

Because average plasma magnesium levels in chronic CAPD patients have been observed to be elevated (Nolph et al. 1981), the magnesium concentration of this formulation has been reduced to 0.5 mEq/L. Average plasma magnesium levels have not been reported for chronic IPD and COPD patients. Serum magnesium levels should be monitored and, if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.

Because average serum bicarbonate levels in some chronic CAPD patients (Nolph et al. 1981), some chronic IPD patients (La Greca et al. 1980), and some chronic COPD patients (Diaz-Buxo et al. 1980), have been observed to be somewhat lower than normal values, the bicarbonate precursor (lactate) concentration of this formulation has been raised to 40 mEq/L. Serum bicarbonate levels should be monitored.

Nursing use in the treatment of lactate acidosis. Potassium is omitted from Diameal PD-2 solutions because dialysis may be performed to correct hyperkalemia. Additions of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

The use of 5 or 6 liters of dialysis solution is not indicated in a single exchange. Refer to manufacturer’s directions accompanying drugs to obtain full information on additives. When the reusable rubber stopper on the medication port is missing or partially removed, do not use product if medication is to be added.

After the pull ring has been removed, inspect connector of solution container for fluid flow. A few drops of solution within the connector or pull ring may be present due to condensation of water resulting from the sterilization process. If a continuous stream of fluid is noted, discard solution because sterility may be impaired. After removing overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard the solution because the sterility may be impaired.

Freezing of solution may occur at temperatures below 0°C (32°F). Do not flex or manipulate container when frozen. Allow container to thaw naturally in ambient conditions and thoroughly mix contents by shaking.
Precautions

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection. If particulate occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be indicated.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave ovens should not be used to heat solutions because there is a potential for damage to the solution container. Moreover, microwave oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.

Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Propaganda: Therapeutic-Effects Preparatory Category C. Animal reproduction studies have not been conducted with DIANEAL peritoneal dialysis solutions. It is also not known whether viable, peritoneal dialysis solutions can cause harm when administered to a pregnant woman or can affect reproduction capacity. DIANEAL peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Do not administer unless solution is clear and seal is intact.

Adverse Reactions

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a chronic peritoneal catheter, catheter blockage, gability in fluid removal, and leak are among the complications of the procedure. Solution related adverse reactions may include electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypotension, and muscle cramping.

Dosage and Administration

DIANEAL PD-2 solutions are intended for intraperitoneal administration only. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

The mode of therapy (Intermittent Peritoneal Dialysis [IPD], Continuous Ambulatory Peritoneal Dialysis [CAPD], or Continuous Cyclic Peritoneal Dialysis [CCPD]) is based on the preference of treatment, hemodynamic exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

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 solute content with the fluid removal requirements for that exchange.

Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. (See Directions for use)

The addition of heparin to the dialysis solution may be indicated to aid in prevention of catheter blockage in patients with peritonitis, or when the solution is expected to be in the peritoneal cavity for a prolonged period of time. When solutions are used for a prolonged period of time (Moncrief et al. 1986), 1000 to 2000 UI/1000 mL of heparin per liter of solution has been recommended for adults (Furman et al. 1978). For children, 50 to 60 U/kg body weight with a maximum of 2 liters has been recommended (Puffer et al. 1981; Irvin et al. 1981). The solution remains in the cavity for dwell times of 4 to 8 hours during the day and 8 to 12 hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled. The procedure is repeated 3 to 5 times per day, 6 to 7 days per week. Solution exchange volumes and frequency of exchanges should be individualized for adequate biochemical and fluid volume control (Moscoso et al. 1982; Tvarkauskas et al. 1983). The majority of exchanges will utilize 1.5% or 2.5% dextrose containing peritoneal dialysis solutions, with 3.5% or 4.25% dextrose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1979).

In CCPD, the patient receives 3 or 4 dialysis exchanges during the night which range from 2-1/2 to 3 hours dwell duration. Typically 1.5 to 2.0 liters of dialysis solution (depending upon patient size) are delivered each cycle by an automatic peritoneal dialysis cycler machine. After the last outflow during the night, an additional exchange is infused by the cycler machine into the peritoneum. The equipment is then disconnected from the patient, and the dialysate remains in the peritoneum for 14 to 15 hours during the day until the next nocturnal cycle (Chan-Baas et al. 1981). Combinations of 1.5% or 2.5% dextrose containing peritoneal dialysis solutions are usually used for the nighttime exchanges, while 3.5% or 4.25% dextrose is used when extra fluid removal is required such as during the daytime exchange. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1979). In CCPD, it is recommended that patients be placed on chronic peritoneal dialysis or, in the case of pediatric patients, the selected cycler, (as well as the patient, when suitable, should be appropriately trained when under the supervision of a physician. Training materials are available from Baxter Healthcare Corporation, Deerfield, IL 60015 to facilitate this training.

How Supplied

DIANEAL PD-2 peritoneal dialysis solutions are available in nonpyrogenic flexible containers with 10 volumes and dextrose concentrations as indicated in Table 1. All DIANEAL PD-2 peritoneal dialysis solutions have overfills which are declared on container labeling.

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

Directions for Use

The use of a cycler.

For complete system preparation, see directions accompanying ancillary equipment. Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.
To Open
Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. If supplemental medication is desired, follow directions below before preparing for administration. Check for minute leaks by squeezing container firmly.

To Add Medication
Additives may be incompatible. If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.

1. Put on mask. Clean and/or disinfect hands.
2. Prepare medication site using aseptic technique.
3. Using a syringe with a 1 inch long 19 to 25 gauge needle, puncture resealable medication port and inject medication.
4. Position container with ports up and evacuate the medication port by squeezing and tapping it.
5. Mix solution and medication thoroughly.

Preparation for Administration
1. Put on mask. Clean and/or disinfect hands.
2. Place solution container on work surface.
3. Remove pull ring from connector of the solution container. If continuous fluid flow from connector is observed, discard solution container.
4. Remove tip protector from tubing set and immediately attach to connector of the solution container.
5. Continue with therapy set-up as instructed in user manual or directions accompanying tubing sets.
6. Upon completion of therapy, discard unused portion.

References
### Table 1

<table>
<thead>
<tr>
<th>Composition (mL)</th>
<th>Ions Concentrations (mEq/L)</th>
<th>How Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pH</td>
<td>Calcium</td>
</tr>
<tr>
<td>AMBU-FLEX III</td>
<td>7.5</td>
<td>0.5</td>
</tr>
<tr>
<td>2.5% Dextrose</td>
<td>7.5</td>
<td>0.5</td>
</tr>
<tr>
<td>AMBU-FLEX III</td>
<td>7.5</td>
<td>0.5</td>
</tr>
<tr>
<td>3.5% Dextrose</td>
<td>7.5</td>
<td>0.5</td>
</tr>
<tr>
<td>AMBU-FLEX II</td>
<td>7.5</td>
<td>0.5</td>
</tr>
<tr>
<td>4.25% Dextrose</td>
<td>7.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

**Note:**
- Dextrose Hydrous, USP
- Sodium Lactate (C3H5NaO3) 2*2H2O
- Magnesium Chloride, USP (MgCl2*6H2O)
- Calcium Chloride, USP
- Sodium Chloride, USP (NaCl)

**Osmolarity (mOsmol/L) (calc)**

**pH**

**Volume (mL)**

**Fill Container (mL)**

**Carton container (mL)**

**Code**

**NDC**

---

**Baxter Healthcare Corporation**

Deerfield, IL 60015 USA

Printed in USA


All rights reserved.

07-19-59-178

2008/11