Dianeal Low Calcium Peritoneal Dialysis Solution

ULTRABAG System For Continuous Ambulatory Peritoneal Dialysis (CAPD) for intraperitoneal administration only

Description

DIANEAL Low Calcium peritoneal dialysis solutions are sterile, nonpyrogenic solutions in ULTRABAG containers for intraperitoneal administration only. They contain no bacteriostatic or antimicrobial agents.

Clinical Pharmacology

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidney, and for aiding in the regulation of fluid and electrolyte balance. The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. Toxic substances and metabolites, present in high concentration 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 osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time (dwell time), the fluid is drained by gravity from the cavity.

Sodium bicarbonate, potassium chloride, calcium chloride, and magnesium chloride, are added to the dialyzing fluid to provide the following concentrations:

- Sodium bicarbonate: 4 mEq/L
- Potassium chloride: 2.5 mEq/L
- Calcium chloride: 4.0 to 6.0 mEq/L
- Magnesium chloride: 1.5 mEq/L

The plastic container “Y” set is fabricated from polyvinyl chloride (PVdC-146 Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in minute 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 overpouch is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach small quantities of plasticizer and antioxidants.

The use of aluminum as a component of the ULTRABAG container is not intended. An improper clamping sequence may result in infusion of air into the peritoneum.

Clinical Studies

Clinical studies have demonstrated that the use of this solution resulted in significant increases in serum CO2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications and Usage

DIANEAL Low Calcium peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when medical therapy is judged to be inadequate.

Contraindications

None known.

Warnings

Not for Intravenous Injection.

Use aseptic technique. Contamination of the leak protector connector may result in peritonitis. An improper clamping sequence may result in infusion of air into the peritoneum.

Pregnancy

DIANEAL Low Calcium peritoneal dialysis solutions are not recommended for CAPD patients with 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.

Drug Interactions

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

Potential for Digitalis and other potassium-sparing diuretics may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal doses of digitalis or related drugs.

Metabolic alkalosis and potassium removal may be masked by elevated bicarbonate levels in the dialysate. The addition of potassium can be monitored by periodic determination of potassium levels. When potassium removal is anticipated, the addition of potassium should be carefully monitored to prevent severe hypokalemia.

Clinical monitoring of insulin requirements during and following dialysis with dextrose containing solutions is necessary to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion, and shock.

Additional information concerning the use of peritoneal dialysis in patients with polycystic kidneys, recent aortic graft replacement, lactic acidosis, 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.

Contraindications

None known.

Warnings

Not for Intravenous Injection.

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Pregnancy

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Drug Interactions

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

Potential for Digitalis and other potassium-sparing diuretics may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal doses of digitalis if potassium is low or calcium high. Atrial arrhythmias require careful monitoring of insulin requirements during and following dialysis with dextrose containing solutions.

Precautions

General: Do not administer unless solution is clear.

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

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

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysate treatment and therapy directed at other existing illnesses. For example, rapid potassium removal may cause arrhythmias in cardiac patients using digitals or oral potassium chloride. Digitalis toxicity may be masked by hydration. Concomitant use of diuretics may intensify potassium depletion by promoting its urinary loss.

During dialysis, serum electrolytes should be monitored periodically. Serum potassium levels should be selectively monitored to prevent severe hypokalemia. Studies have shown that serum potassium levels may be significantly reduced during peritoneal dialysis treatment.

Laboratory Tests

Before electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Composition/100 mL ionic Concentration (mEq/L) How Supplied

<table>
<thead>
<tr>
<th>Solution</th>
<th>Calcium</th>
<th>Magnesium</th>
<th>Dextrose</th>
<th>Lactic Acid</th>
<th>How Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5% 4.25</td>
<td>0.5</td>
<td>0.5</td>
<td>95</td>
<td>40</td>
<td>1500</td>
</tr>
<tr>
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<td>95</td>
<td>40</td>
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ULTRABAG containers are designed with an integrated “Y” set and drain container for instillation and drainage of DIANEAL Low Calcium when discontinuation of the “Y” set from the transfer set during dwell is desired. Composition, calculated electrolyte, pH and ion concentrations are shown in the following table.

The plastic container “Y” set is fabricated from polyvinyl chloride (PVdC-146 Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in minute 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 overpouch is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach small quantities of plasticizer and antioxidants.

The use of aluminum as a component of the ULTRABAG container is not intended. An improper clamping sequence may result in infusion of air into the peritoneum.

Clinical Studies

Clinical studies have demonstrated that the use of this solution resulted in significant increases in serum CO2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications and Usage

DIANEAL Low Calcium peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when medical therapy is judged to be inadequate.

Contraindications

None known.

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DIANEAL Low Calcium peritoneal dialysis solutions are not recommended for CAPD patients with 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.

Drug Interactions

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

Potential for Digitalis and other potassium-sparing diuretics may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal doses of digitalis if potassium is low or calcium high. Atrial arrhythmias require careful monitoring of insulin requirements during and following dialysis with dextrose containing solutions.

Precautions

General: Do not administer unless solution is clear.

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

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

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysate treatment and therapy directed at other existing illnesses. For example, rapid potassium removal may cause arrhythmias in cardiac patients using digitals or oral potassium chloride. Digitalis toxicity may be masked by hydration. Concomitant use of diuretics may intensify potassium depletion by promoting its urinary loss.

During dialysis, serum electrolytes should be monitored periodically. Serum potassium levels should be selectively monitored to prevent severe hypokalemia. Studies have shown that serum potassium levels may be significantly reduced during peritoneal dialysis treatment.

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Carcinogenesis, mutagenesis, impairment of fertility: Long-term animal studies with DIANEAL Low Calcium peritoneal dialysis solution have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy: Teratogenic Effects
Pregnancy Category C Animal reproduction studies have not been conducted with DIANEAL Low Calcium peritoneal dialysis solution. It is not known whether DIANEAL Low Calcium peritoneal dialysis solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. DIANEAL Low Calcium peritoneal dialysis solution should be given to a nursing woman only if clearly needed.

Nursing mothers:
Caution should be exercised when DIANEAL Low Calcium peritoneal dialysis solution is administered to a nursing woman.

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 the peritoneal catheter, catheter site infection, catheter blockage, difficulty in fluid removal, and ileus are complications of the procedure. Solution related adverse reactions may include peritonitis, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypotension, hypertension, disequilibrium syndrome, allergic symptoms, and muscle cramping.

Support the container from under the upper part of the bag after each exchange and lift the corner of the bag and drain the dialysis fluid into the waste fluid bag. Repeat as necessary, until desired amount of treatment is administered. The patient should be awakened and checked afterward.

Dosage and Administration
The solution is used for dialysis therapy by infusing into the peritoneal cavity. Typically, 1.5 to 2 l of dialysis solution is infused into the peritoneal cavity of adults and children over 12 years of age. After the effect is considered to be obtained, the fluid is drained. This procedure is regarded as one cycle. In the case where the excessive body fluid is 1 kg/day or less, 3 to 4 exchanges a day with only DIANEAL Low Calcium 1.5% peritoneal dialysis fluid are conducted continuously. In the case where the excessive body fluid is 1 kg/day or more, 3 to 4 exchanges with DIANEAL Low Calcium 2.5% peritoneal dialysis fluid or 1 to 2 exchanges of DIANEAL Low Calcium 4.25% peritoneal dialysis fluid are usually performed to obtain the desired hematocrit level and to control the body fluid in patients with hyperglycemia. Infusions of 2 to 5 exchanges a day are conducted continuously. Inflow volume, duration of dwell, and frequency of treatment should be appropriately selected based on the condition, blood chemistry, body fluid imbalances, age and body weight of the individual patient to be treated. Intraperitoneal drainage is usually 200 ml or less.

Directions for Use
Use aseptic technique.

Preparation for Administration
1. Tear open side of bag at a slit and remove the solution. Check for minute leaks by squeezing container firmly.
2. Remove the protector from outlet port at the bottom of the container.
3. Attach administration set, according to the direction accompanying the set.
4. Support the container from under the upper part of the bag after each exchange and lift the corner of the bag and drain the dialysis fluid into the waste fluid bag. Repeat as necessary, until desired amount of treatment is administered. The patient should be awakened and checked afterward.

Adverse Reactions
1. Connect the connection tube connector of the ULTRABAG to the tip of connection tube on the patient side.
2. Press the connection tube button at the bottom of the ULTRABAG and fill the connection tube with DIANEAL Low Calcium peritoneal dialysis fluid as specified in the procedure described below. The patient should be awakened and checked afterward.
3. Drain intraperitoneal waste fluid via the waste fluid bag.
4. After drainage, clamp the connection tube on the patient side, and open the seal of the outlet bag of dialysis solution.
5. Wash the circuit with about 100 ml of a fresh dialysis fluid solution for 10 seconds and pour into the waste fluid bag.
6. Subsequently, clamp the waste fluid and release the clamp of the connection tube on the patient side to infuse the fresh dialysis fluid instropointedly.
7. After instillation, detach the connection tube on the patient side from the connection tube connector of the ULTRABAG.
8. After the clamp in the connection tube on the connector side to complete the replacement procedure.

Manufactured by:
Baxter Healthcare SA, Singapore Branch
2 Woodlands Industrial Park D Singapore 738750
An affiliate of Baxter Healthcare Corporation USA
Pickering Singapore
PPU-15224
Issued: February 2003

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"Baxter" DIAANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 1.5% Dextrose (In ULTRABAG Container)

"Baxter" DIAANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose (In ULTRABAG Container)

"Baxter" DIAANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 4.25% Dextrose (In ULTRABAG Container)

**Composition/100 mL**

<table>
<thead>
<tr>
<th>Component</th>
<th>Ion Concentration (mEq/L)</th>
<th>How Supplied</th>
</tr>
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<tbody>
<tr>
<td>Sodium Lactate</td>
<td>4.25 g</td>
<td>18.3 mg</td>
</tr>
<tr>
<td>Dextrose Hydrate, USP (D-Glucopyranose monohydrate)</td>
<td>2.5 g</td>
<td>448 mg</td>
</tr>
<tr>
<td></td>
<td>3.5 g</td>
<td>448 mg</td>
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<td></td>
<td>4.25 g</td>
<td>448 mg</td>
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**Ionic Concentration (mEq/L)**

- Sodium: 132 mEq/L
- Calcium: 2.5 mEq/L
- Magnesium: 0.5 mEq/L
- Chloride: 95 mEq/L
- Potassium: 40 mEq/L

**Fill Volume (mL)**

- Container Size (mL):
  - 1500 mL
  - 2000 mL
  - 2500 mL

**Code**

- FNB9776
- FNB9775
- FNB9798

**Sodium Lactate Dextrose Hydrate, USP**
**Summary in Chinese**

**适应症**

无

**警告**

使用前请详细阅读本说明书。本品为白色冻干粉末，使用前应先恢复至液态。不同年龄和治疗目的的患者，使用剂量不同。由于本品的临床使用特点，可能会出现严重的不良反应，因此在使用前必须详细了解患者的病情，慎重考虑使用。使用时，必须有应急措施和适应症。

**禁忌症**

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**剂量与用法**

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**产品名称**

由 Baxter Healthcare SA, Singapore Branch 提供，产品名称为 DIANEAL，用于透析治疗。

**联系方式**

Baxter Healthcare SA, Singapore Branch
2 Woodlands Industrial Park D, Singapore 738750, Singapore
电话：2378 5000

**产品规格**

DIANEAL, ULTRABAG 及 PL-146 是美国 Baxter 国际有限公司的简称。