**Description**

DIANEAL PD-2 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 kidneys, and for aiding in the regulation of fluid and electrolyte balance. The procedure is accomplished by instilling peritoneal dialysis fluid through a catheter into the peritoneal cavity. Toxic substances and metabolites, present in high concentration in the blood, cross the peritoneal membrane into the dialysing fluid. Dialysate in the dialysing 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 into the drainage container. The peritoneal cavity will again become fluid-filled and the procedure is repeated. The dialysate is returned to the patient via a second catheter, generally located in the left subcostal region, which exchanges fluid with the body when the patient is not dialyzing. Therapeutic problems may arise under these circumstances.

**Indications and Usage**

DIANEAL PD-2 peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when renalodialysis medical therapy is judged to be inadequate.

**Contraindications**

None known.

**Warnings**

- Not for Intravenous Injection.
- Use aseptic technique. Contamination of Luer lock connector may result in peritonitis. An improper clamping sequence may result in infusion of air into the peritoneum.

**Precautions**

- General: Do not administer unless solution is clear.
- Extraordinary care should be exercised when the solution is being infused into the peritoneal cavity. To prevent infection, aseptic technique must be used throughout the procedure and at its termination in the drainage container. The plastic container “Y” set is fabricated from polyvinyl chloride (PL-146 Plastic).

**Composition/100 mL**

<table>
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<tr>
<th>Sodium Lactate</th>
<th>448 mg</th>
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**Ionic Concentration (mEq/L)**

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**Fill Volume (mL)**

- 1500 mL
- 2000 mL
- 2500 mL

**How Supplied**

- ULTRABAG Containers for intraperitoneal administration only

**Peritoneal Dialysis Solution**

- PD-2 Peritoneal Dialysis Solution
- DIANEAL PD-2 Peritoneal Dialysis Solution
- DIANEAL PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose
- DIANEAL PD-2 Peritoneal Dialysis Solution with 5.5% Dextrose

**How Supplied**

- ULTRABAG System For Continuous Ambulatory Peritoneal Dialysis (CAPD)
- DIANEAL PD-2 Peritoneal Dialysis Solution
- 2.5% Dextrose Peritoneal Dialysis Solution
- 4.25% Dextrose Peritoneal Dialysis Solution
- 4.25% Dextrose Peritoneal Dialysis Solution

**Contraindications**

None known.

**Warnings**

- Not for Intravenous Injection.
- Use aseptic technique. Contamination of Luer lock connector may result in peritonitis. An improper clamping sequence may result in infusion of air into the peritoneum.

**Precautions**

- General: Do not administer unless solution is clear.
- Use aseptic technique. Contamination of Luer lock connector may result in peritonitis. An improper clamping sequence may result in infusion of air into the peritoneum.
Peritoneal dialysis may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at subclinical dosages of digoxin if plasma is low or calcium high. Absolute digitalis regimens require careful monitoring of serum requirements during and following dialyses with diuretics containing solutions.

Laboratory tests:
Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, mutagenesis, impairment of fertility:
Long term animal studies with DIAINEAL PD-2 peritoneal dialysis solution have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Preparatory Therapy:

Pregnancy Category C: Animal reproduction studies have not been conducted with DIAINEAL PD-2 peritoneal dialysis solution. It is not known whether DIAINEAL PD-2 peritoneal dialysis solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. DIAINEAL PD-2 peritoneal dialysis solution should be given to a pregnant woman only if clearly needed.

Nursing mothers:
Caution should be exercised when DIAINEAL PD-2 peritoneal dialysis solution is administered to a nursing woman.

Pediatric use:
Safety and effectiveness in children have not been established.

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 among the complications of the procedure. Solution related adverse reactions may include peritonitis, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypotension, disequilibrium syndrome, allergic symptoms, and muscle cramping.

Dosage and Administration:
The solution is used for dialysis therapy by instilling into the peritoneal cavity. Typically, 1.5 to 2.0 L of dialysis solution is instilled into the peritoneal cavity of adults and children weighing over 20 kg for 4 to 8 hours. After the effect is considered to be obtained, the fluid is drained and a fresh bag of fluid is used for the next cycle. In the case where the procedure is repeated more than once, the body fluid is 10% or less, 1 to 4 exchanges a day with DIAINEAL PD-2 1.5 peritoneal dialysis fluid is conducted continuously. In the case where the excessive body fluid is 1.5% or greater, 1 to 4 exchanges with DIAINEAL PD-2 2.5% peritoneal dialysis fluid or 1 to 2 exchanges of DIAINEAL PD-2 4.25% peritoneal dialysis fluid are usually administered in combination with DIAINEAL PD-2 1.5 peritoneal dialysis fluid, and 3 to 5 exchanges a day are conducted continuously. Influent volume, duration of dwell, and frequency of treatment should be appropriately selected based on the condition, blood chemistry, body fluid imbalance, age and body weight of the individual patient to be treated. Influent/drainage rate is usually 350 ml/min or less.

Directions for use:
Use aseptic technique.

Preparation for Administration:

1. Use an Emmich dose syringe at a still and remove the solution. Check for minute leaks by squeezing container firmly.
2. Replace the protector from outlet port at the bottom of the container.
3. Attach the connection tube to the tip of the connection tube connector of the ULTRABAG in the procedure described below.
4. Attach the cap to the tip of the connection tube on the patient side.
5. Infuse the dialysis fluid in the ULTRABAG in the procedure described below.

Administration:

1. Remove the cap of the connection tube on the patient side.
2. Connect the connection tube connector of the ULTRABAG to the tip of connection tube on the patient side.
3. Insert the connection tube on the patient side to infuse the fresh dialysis fluid intraperitoneally.
4. After drainage, clamp the connection tube on the patient side, and open the seal of the dialysis bag of dialysis solution.
5. Wash the circuit with about 1/20 ml of a fresh dialysis fluid (for 10 seconds) and pour into the waste fluid tube.
6. Subsequently, clamp the waste fluid tube and release the clamp of the connection tube on the patient side to infuse the fresh dialysis fluid intraperitoneally.
7. After infusion, detach the connection tube on the patient side from the connection tube connector of the ULTRABAG.
8. Attach the cap to the tip of the connection tube on the patient side to complete the replacement procedure.

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Baxter Healthcare Singapore Branch
2 Woodland Industrial Park 2 (Singapore 778575)
(An Affiliate of Baxter Healthcare Corporation USA)
Printed in Singapore
PPD 15223
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Baxter Healthcare SA, Singapore Branch
2 Woodland Industrial Park 2, Singapore 778575
(An Affiliate of Baxter Healthcare Corporation USA)
Printed in Singapore
PPD 15223
2

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2. Connect the connection tube connector of the ULTRABAG to the tip of connection tube on the patient side.
3. After infusion, clamp the connection tube on the patient side, and open the seal of the dialysis bag of dialysis solution.
4. Wash the circuit with about 1/20 ml of a fresh dialysis fluid (for 10 seconds) and pour into the waste fluid tube.
5. Subsequently, clamp the waste fluid tube and release the clamp of the connection tube on the patient side to infuse the fresh dialysis fluid intraperitoneally.
6. After drainage, clamp the connection tube on the patient side from the connection tube connector of the ULTRABAG.
7. Attach the cap to the tip of the connection tube on the patient side to complete the replacement procedure.

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2
供連續可活動式腹膜透析使用之雙聯袋系統
僅供腹膜腔內使用

【說明】
供連續可活動式腹膜透析使用之 DIANEAL PD-2 腹膜透析液係裝於雙聯袋係設計，其腹膜透析液含有兩部分，此兩部分絞接於主乾管，並各含於一端，而與兩部分相接之主乾管可分開或接合，達成腹膜透析之目的。每部分之主乾管各容裝 500 毫升的腹膜透析液，分別於不同時間注入，以達成不同之治療目的。

【使用方法】
1. 預先將 DIANEAL PD-2 腹膜透析液置於腹膜透析液袋中，並將其主乾管接合，然後注入透析液，以達成腹膜透析之目的。

【注意事項】
1. 腹膜透析液應存放於冷凍庫中，並於使用前加熱至 37 度時注入。

【藥理作用】
1. 腹膜透析液具有高渗透壓，可以消除體內之水份及電解質。
2. 腹膜透析液可以消除體內之毒性物質，如尿素、肌酸酐等。

【製造商】
1. 彼得巴克公司

【如何供應】
1. DIANEAL PD-2 腹膜透析液有以下幾種規格可供選擇：
   - 1.5% Dextrose ((mx)): 1500 mL
   - 2.5% Dextrose (mx): 2000 mL
   - 4.25% Dextrose (mx): 2500 mL

【成分/100 mL】
1. Sodium (Na2O): 331 mg
2. Chloride (ClO3): 448 mg
3. Magnesium (MgCl2): 538 mg
4. Calcium (CaCl2): 538 mg

【等電位】
1. 腹膜透析液的等電位可由以下配方計算：
   - pH = 4.0
   - MgCl2 = 5.08 mg
   - CaCl2 = 5.08 mg

【臨床應用】
1. 腹膜透析液可用於治療腎臟疾病、糖尿病等疾病。

【製造商】
1. 彼得巴克公司

【如何供應】
1. DIANEAL PD-2 腹膜透析液有以下幾種規格可供選擇：
   - 1.5% Dextrose: 1500 mL
   - 2.5% Dextrose: 2000 mL
   - 4.25% Dextrose: 2500 mL
【禁忌症】
無

【警告】

不可用於靜脈內注射

採用無菌技術。一種型態的污染可能導致微膜炎。

不正確的管頭開啓過早可能導致微膜注入脈絡膜。

對於下列情況之患者，應禁用脈膜注射：1. 有纖維素膜或結膜

導致脈膜或脈膜法的患者。見上述。2. 放射線治療後。3. 未經適當診斷之眼部病

變：脈膜感染，脈絡膜出流或脈膜腫管，脈膜凝結，脈膜凝結等。

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