Description
The DELFLEX® peritoneal dialysis solutions (standard and low magnesium/low calcium) are sterile, non-pyrogenic formulations of dextrose and electrolytes in water for injection, USP, for use in peritoneal dialysis. These solutions do not contain antimicrobial agents or additional buffers. Composition, calculated osmolality, pH, and ionic concentrations are shown in Table 1.

Dextrose, USP, is chemically designated D-glucose monohydrate (C\(_6\)H\(_{12}\)O\(_6\)·H\(_2\)O), a hexose sugar freely soluble in water. The structural formula is shown here:

Calcium chloride, USP, is chemically designated calcium chloride dihydrate (CaCl\(_2\)·2H\(_2\)O) white fragments or granules freely soluble in water.

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate (MgCl\(_2\)·6H\(_2\)O) colorless flakes or crystals very soluble in water.

Sodium lactate solution, USP, is chemically designated (CH\(_2\)CH(OH)COONa), a 60% aqueous solution miscible in water.

Sodium chloride, USP, is chemically designated (NaCl), a white, crystalline compound freely soluble in water.

Water for injection, USP, is chemically designated (H\(_2\)O).

Hydrochloric Acid or Sodium Hydroxide may be added for pH adjustment. pH is 5.5 ± 0.5.

Table 1. Composition, Calculated Osmolarity, pH, and Ionic Concentration

<table>
<thead>
<tr>
<th>Composition/100mL</th>
<th>Ionic Concentration (mEq/L)</th>
<th>pH (5.0 - 6.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextrose Hydrolysable-USP (C(<em>6)H(</em>{12})O(_6)·H(_2)O)</td>
<td>Calcium Chloride</td>
<td>Sodium Chloride</td>
</tr>
<tr>
<td>DELFLEX Standard with 1.5% Dextrose</td>
<td>5.08 mg</td>
<td>5.08 mg</td>
</tr>
<tr>
<td>DELFLEX Standard with 2.5% Dextrose</td>
<td>5.08 mg</td>
<td>5.08 mg</td>
</tr>
<tr>
<td>DELFLEX Low Magnesium, Low Calcium with 1.5% Dextrose</td>
<td>4.02 g</td>
<td>4.02 g</td>
</tr>
<tr>
<td>DELFLEX Low Magnesium, Low Calcium with 2.5% Dextrose</td>
<td>4.02 g</td>
<td>4.02 g</td>
</tr>
<tr>
<td>DELFLEX Low Magnesium, Low Calcium with 4.25% Dextrose</td>
<td>4.02 g</td>
<td>4.02 g</td>
</tr>
</tbody>
</table>

Clinical Pharmacology
Peritoneal dialysis is the process of filtering excess water and toxins from the bloodstream through a semi-permeable membrane. This process does not cure the disease, but prevents progression of symptoms. Dialysis for chronic kidney failure is essential to maintain life, unless the patient receives a kidney transplant. A peritoneal dialysis procedure utilizes the peritoneum (lining of the abdomen) as the semi-permeable membrane. The procedure is conducted by instilling peritoneal dialysis solution through a catheter in the abdomen into the peritoneal cavity. Since the peritoneum is heavily supplied with blood vessels, the contact of the solution with the peritoneum causes excess water and toxins in the bloodstream to be drawn across the membrane into the solution. This osmosis and diffusion occurs between the plasma of the patient and the peritoneal dialysis solution.

After a period of time called "dwell time," the solution is then drained from the patient.

This solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

Clinical studies have demonstrated that the use of low magnesium solutions resulted in significant increases in serum CO\(_2\) and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

Indications And Usage
DELFLEX® peritoneal dialysis solutions are indicated in the treatment of chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

Contraindications
None known.

Warnings
Not for Intravenous Injection.
Use Aseptic Technique.

After removing the outerwrap, check for minute leaks by squeezing the solution bag firmly. If leaks are found, discard the solution because the sterility may be impaired. (A small amount of moisture may be present inside the outerwrap, which is normal condensation from the sterilization process).

Peritoneal dialysis should be done with great care, in patients with a number of 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 burns, fecal fistula or colostomy, tense ascites, obesity, large 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.

Solutions containing lactate ion should be used with great care in patients with metabolic or respiratory alkalosis. Lactate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

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.

Excessive use of DELFLEX® peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

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.

Serum calcium levels in patients using low calcium concentrations should be monitored and if found to be low, the peritoneal solution in use should be altered to one with a higher calcium concentration.

Precautions
General
Chronic patients that have been stabilized on peritoneal dialysis therapy should have routine evaluation of electrolyte blood chemistries and hematologic factors measured in order to determine the patient's ongoing condition.

DELFLEX® peritoneal dialysis solutions do not include potassium. Potassium chloride should only be added under the direction of a physician after careful evaluation of both serum and total body potassium.

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

Information for Patients
Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.
The outerwrap should remain intact until time of use.

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Administer only if the solution is clear, all seals are intact, and there is no evidence of leaking. Do not heat in a microwave oven. Microwave ovens heat unevenly and can leave hot spots, which can burn the peritoneum.

Care should be taken to ensure that there is not any leakage around the catheter, since if not controlled, the leakage can create edema from subcutaneous infiltration of the dialysis solution. The leakage will also create an inaccurate fluid balance measurement. If any leakage is identified do not proceed with infusion and notify your physician.

**Laboratory Tests**

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

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long term animal studies with DELFLEX® peritoneal dialysis solutions have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility. Pregnancy Teratology Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with DELFLEX® peritoneal dialysis solutions. It is also not known whether DELFLEX® peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DELFLEX® peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

**Nursing Mothers**

Caution should be exercised when DELFLEX® peritoneal dialysis solutions are administered to a nursing woman.

**Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

**Adverse Reactions**

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

If an adverse reaction does occur, institute appropriate therapeutic procedures according to the patient’s needs and conditions, and save the remainder of the fluid in the bag for evaluation if deemed necessary.

**Dosage And Administration**

DELFLEX® peritoneal dialysis solutions are provided for intraperitoneal administration only. The mode of therapy, frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for the treatment of the individual patient.

To avoid the risk of severe dehydration or hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with lowest level of osmolarity 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 peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions may include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome and muscle cramping.

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**How Supplied**

DELFLEX® peritoneal dialysis solutions are delivered in single-dose flexible bags. All DELFLEX® peritoneal dialysis solutions have overfills declared on the bag label. The flexible bag has the capacity for drainage in excess of their stated fill volume for ultrafiltration from the patient. DELFLEX® peritoneal dialysis solutions are available in the sizes and formulations shown in Table 2.

**Table 2**

<table>
<thead>
<tr>
<th></th>
<th>2 L</th>
<th>3 L</th>
<th>5 L</th>
</tr>
</thead>
<tbody>
<tr>
<td>DELFLEX Standard with 1.5% Dextrose</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>DELFLEX Standard with 2.5% Dextrose</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DELFLEX Low Magnesium, Low Calcium with 1.5% Dextrose</td>
<td>X</td>
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<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>DELFLEX Low Magnesium, Low Calcium with 4.25% Dextrose</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**Storage Conditions**

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (between 59°F and 86°F). See USP Controlled Room Temperature. Brief exposure to temperatures not to exceed 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

**Keep DELFLEX® and all medicines out of the reach of children.**