For CAPD application, the stay safe® exchange set is attached to DELFLEX™ peritoneal dialysis solution in various dextrose percentages and volumes. Please see attached brief summary for prescribing details.

DELFLEX™ Peritoneal Dialysis Solution With Attached stay•safe® Exchange Set

<table>
<thead>
<tr>
<th>Fill Volume</th>
<th>Bag Size</th>
<th>Dextrose %</th>
<th>Low Ca²⁺, Low Mg</th>
<th>Std Ca²⁺, Low Mg</th>
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</thead>
<tbody>
<tr>
<td>1500</td>
<td>2000</td>
<td>1.5%</td>
<td>054-15221</td>
<td>054-15220</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.5%</td>
<td>054-15222</td>
<td>054-15221</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.25%</td>
<td>054-15224</td>
<td>054-15222</td>
</tr>
<tr>
<td>2000</td>
<td>2000</td>
<td>1.5%</td>
<td>054-20221</td>
<td>054-20220</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.5%</td>
<td>054-20222</td>
<td>054-20221</td>
</tr>
<tr>
<td></td>
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<td>2500</td>
<td>3000</td>
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<td>054-25321</td>
<td>054-25320</td>
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<tr>
<td></td>
<td></td>
<td>2.5%</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>4.25%</td>
<td>054-25324</td>
<td>054-25322</td>
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<tr>
<td>3000</td>
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<td>1.5%</td>
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<td></td>
<td></td>
<td>4.25%</td>
<td>054-30324</td>
<td>054-30322</td>
</tr>
</tbody>
</table>

DELFLEX™

Dextrose Peritoneal Dialysis Solutions With Attached stay•safe® Exchange Set

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 CO₂ 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 continuous ambulatory peritoneal dialysis, when nondiabetic medical therapy is judged to be inadequate.

CONTRAINDICATIONS

None Known.

WARNINGS

NOT FOR INTRAVENOUS INJECTION.

USE ASEPTIC TECHNIQUE.

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, which carries 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 electrolyte blood chemistries and hematologic factors, as well as other indicators that determine the patient’s ongoing status.

PRECAUTIONS

GENERAL

Do not administer unless the solution is clear; all seals are intact and there is no evidence of leaking. Care should be taken to see that the catheter is inserted completely, since leakage around the catheter, if not controlled, can create edema from subcutaneous infiltration of the dialysis solution. This will also create an inaccurate fluid balance measurement.

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.

Use aseptic technique throughout the procedure and at its termination in order to reduce the possibility of infection.

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

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 reproductive 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 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 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.

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