DEXTROSE PERITONEAL DIALYSIS SOLUTION
With Attached stay® safe® Exchange Set
For Intrapерitoneal Administration Only

No Latex

PERITONEAL DIALYSIS SOLUTIONS

Peritoneal dialysis is a 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 disease 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 solutions into the cavity of the abdomen. The solution then diffuses across the membrane into the bloodstream through the semi-permeable membrane. The process is repeated periodically to remove toxins and excess water from the body. Clinical studies have demonstrated that the use of low magnesium solutions results in significant increases in serum CO2 and decreases in serum magnesium levels. The decrease in serum magnesium levels may be caused by significant hypomagnesemia.

The DEXTROSE® peritoneal dialysis solutions (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. The dihydrate (CaCl2.H2O) a hexose sugar freely soluble in water. The structural formula is shown here.

Calcium chloride, USP is chemically designated calcium chloride dihydrate (CaCl2.H2O) white crystals or granules freely soluble in water. Magnesium chloride, USP is chemically designated magnesium chloride hexahydrate (MgCl2.6H2O) colorless flakes or crystals very soluble in water. Sodium lactate solution, USP is chemically designated (CH3CH(OH)COONa), a 60% aqueous solution miscible in water.

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

<table>
<thead>
<tr>
<th>Solution Description</th>
<th>Composition/100mL</th>
<th>Ionic Concentration (mEq/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Calcium with 2.5% Dextrose</td>
<td>1.5 g 538 mg 448 mg 18.4 mg 5.08 mg</td>
<td>344 5.5 132 2.5 0.5 95 40</td>
</tr>
<tr>
<td>Low Calcium with 2.5% Dextrose</td>
<td>2.5 g 538 mg 448 mg 18.4 mg 5.08 mg</td>
<td>394 5.5 132 2.5 0.5 95 40</td>
</tr>
<tr>
<td>Low Calcium with 4.25% Dextrose</td>
<td>4.25 g 538 mg 448 mg 18.4 mg 5.08 mg</td>
<td>483 5.5 132 2.5 0.5 95 40</td>
</tr>
</tbody>
</table>

- Sodium Chloride, USP is chemically designated (NaCl), a white, crystalline compound freely soluble in water.
- Hydrochloric Acid or Sodium Hydroxide may be added for pH adjustment. pH is 5.5 ± 0.5.
- Exposure to temperatures above 25°C (77°F) during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. Since the flexible inner bag is compounded from a specific polyvinyl chloride, water may permeate from the inner bag into the outer bag in insufficient amounts to affect the solution significantly. Solutions in contact with the plastic inner bag can cause certain chemical components of the bag to leach out in very small amounts; however, the safety of the plastic formulation is supported by biological tests for plastic containers.

**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 disease 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 solutions into the cavity of the abdomen. The solution then diffuses across the membrane into the bloodstream through the semi-permeable membrane. 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 do 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 7.5 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 serum magnesium levels may be caused by significant hypomagnesemia.

**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 infiltration 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 imbalance, hypokalemia, hyperkalemia, hypertension, hypotension, dissequilibration 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.

**Indications and Usage**

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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 osmolality consistent with the fluid removal requirements for that exchange.

Parenteral drug products should be inspected visually for particulate matter and discolored discoloration prior to administration whenever solution and container permit.

Additives may be incompatible. Please refer to manufacturer’s product insert. Do not store solutions containing additives.

For administration see Directions for Use section.

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.

Do not use DELFLEX® solution if:

1. Clean work surface.
2. Get Ready:
3. Warm solution as directed by your health care provider.
4. Store at 20°C to 25°C (68°F to 77°F); however, such exposure should be minimized.
5. Tear the outerwrap from the slit edge down the length of the inner bags to open. Wipe away any moisture from the solution bags. Some opacity may be observed in the plastic of the 5L bag.
6. Aseptically connect the Extension Set to the connector cap, a stand alone item provided separately.
7. Visually inspect the solution to ensure that it is clear and free of particulate matter prior to administration. Color may vary from clear to slightly yellow but does not affect efficacy and may be used.
8. Check the expiration date. Check for correct dextrose concentration.
9. If you will be adding medication(s): Turn blue position indicator on the stay•safe Cap.
10. After approximately 5 seconds, turn the stay•safe® disc position indicator to Position 3 (•••). See Figure E. This will insert the closure pin of the disc into the Extension Set connector and seal the system.
11. When fill is complete, turn the stay•safe® disc position indicator to Position 4 (••••). See Figure E. This will open the extension set.
12. Close the clamp on the Extension Set. Remove the white protective cover from the new stay•safe® Cap. Save for later use.
13. Remove the Extension Set from the stay•safe® disc and attach the new stay•safe® Cap. Twist clockwise to secure the connection.
14. Seal the disc by attaching the white protective cover from the new stay•safe® Cap to the disc connector. Twist clockwise to secure the connection and prevent leakage from the used system.
15. Look at the drained fluid for cloudiness. Measure the amount of fluid drained. Throw away the fluid and used set as instructed by your healthcare provider. In case of cloudiness, save the fluid and the used set and immediately contact your healthcare provider.

Directions for Use (Aseptic technique is required)

Get Ready:
1. Clean work surface.
2. Gather supplies:
   - DELFLEX® Peritoneal Dialysis bag with attached stay•safe® Exchange Set.
   - Povidone iodine prefilled stay•safe® cap, a stand alone item provided separately.
   - stay•safe® Organizer, a stand alone item provided separately (Optional: Fresenius Medical Care North America (FMCNA) recommends its use).
   - Prescribed medication(s), if ordered by your healthcare provider.
3. Put on mask. Wash your hands.
4. Ensure that the Exchange Set coming from your catheter is clamped.
5. Tear the outerwrap from the slit edge down the length of the inner bags to open. Wipe away any moisture from the solution bags. Some opacity may be observed in the plastic of the bag and/or tubing and is due to moisture absorption during the sterilization process. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

Inspect DELFLEX® Solution Bag:
6. Place the DELFLEX® solution set on the work surface. Separate the fill and drain bag.
7. Visually inspect the solution to ensure that it is clear and free of particulate matter prior to administration. Color may vary from clear to slightly yellow but does not affect efficacy and may be used.
8. Check the expiration date. Check for correct dextrose concentration.
9. Firmly squeeze the Solution Bag to check for leaks.

Do not use DELFLEX® solution if:
- Leaks are found
- The solution bag is damaged
- Solution is cloudy or discolored

Note: Retain DELFLEX® peritoneal dialysis bag sample for manufacturer evaluation and notify your healthcare provider if any of the above defects are found.

10. Turn the blue position indicator on the stay•safe® disc counter-clockwise until it fits into the cut-out portion of the colored plastic cover on the disc. See Figure A, Step 1. Remove the colored plastic cover while the indicator is in this position (Position 1: •). See Figure A, Step 2. Once the cover is removed, do not turn counter-clockwise. (This step is done in preparation to allow the fluid in your peritoneal cavity to drain later on in this procedure).

Table 2

<table>
<thead>
<tr>
<th></th>
<th>2 L</th>
<th>2.5 L</th>
<th>3 L</th>
</tr>
</thead>
<tbody>
<tr>
<td>DELFLEX Low Magnesium, Low Calcium with 1.5% Dextrose</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>DELFLEX Low Magnesium, Low Calcium with 2.5% Dextrose</td>
<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). Use USP Controlled Room Temperature. Brief exposure to temperatures up to 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.

Not for Intravenous Injection. Do not microwave.

Warm solution as directed by your health care provider.

Administer DELFLEX® Peritoneal Dialysis Solution

1. If you will be adding medication(s):
   - Clean the medication port as instructed by your healthcare provider.
   - Add the medicine(s).
   - Turn the bag upside down several times to mix the medicine(s).
2. Hang the solution bag from the I.V. pole. Place the drain bag at floor level.
3. Break the fragile in the solution bag outlet port. (If using the Organizer, place the stay•safe® disc in the Organizer as illustrated in Figure B).
4. Remove the new stay•safe® Cap from its package. (The new stay•safe® Cap is the stand alone item provided to the patient separately). (If using the Organizer, place the new stay•safe® Cap in the left notch of the Organizer. Place the existing cap of stay•safe® Exchange Set, connected to the patient’s catheter, in the other notch of the Organizer). See Figure B. This will start the flush from the solution bag to the drain bag.
5. Aseptically remove the connector cap from the stay•safe® disc and throw the cap away. Remove the existing cap from the Extension Set connected to the patient’s catheter by twisting the connection counter-clockwise. (If using the Organizer, leave the capped end of the Extension Set in the Organizer and twist the Extension Set connector counter-clockwise to remove the set from its cap.)
6. Aseptically connect the Extension Set to the connector on the stay•safe® disc. Twist clockwise to secure the connection.
7. Remove your mask. Do not open the system during exchange.
8. Open the Extension Set clamp to start drain.
9. When patient drain is complete, turn the stay•safe® disc position indicator to Position 4 (••••). See Figure E. This will open the extension set.
10. After approximately 5 seconds, turn the stay•safe® disc position indicator to Position 3 (•••). See Figure D. This will start the patient fill.
11. When fill is complete, turn the stay•safe® disc position indicator to Position 4 (••••). See Figure E. This will open the extension set.
12. Close the clamp on the Extension Set. Remove the white protective cover from the new stay•safe® Cap. Save for later use.
13. Remove the Extension Set from the stay•safe® disc and attach the new stay•safe® Cap. Twist clockwise to secure the connection.
14. Seal the disc by attaching the white protective cover from the new stay•safe® Cap to the disc connector. Twist clockwise to secure the connection and prevent leakage from the used system.
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Figure A

Figure B

Figure C

Figure D

Figure E