DELFLEX®

Dextrose Peritoneal Dialysis Solution
For Intraperitoneal Administration Only

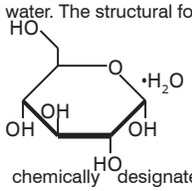
No Latex

MPS 89-905-61

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 osmolarity, pH, and ionic concentrations are shown in Table 1.

Dextrose, USP, is chemically designated D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$) a hexose sugar freely soluble in water. The structural formula is shown here:



Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$) white fragments or granules freely soluble in water.

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$) colorless flakes or crystals very soluble in water.

Sodium lactate solution, USP, is chemically designated ($CH_3CH(OH)COONa$), 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_2O).

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 outerwrap in quantities insufficient 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.

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

Table 1

	Composition/100mL					Total Osmolarity (mOsmoL/L) (calc)	pH (5.0 - 6.0)	Ionic Concentration (mEq/L)				
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)			Sodium	Calcium	Magnesium	Chloride	Lactate
DELFLEX Standard with 1.5% Dextrose	1.5 g	567 mg	392 mg	25.7 mg	15.2 mg	347	5.5	132	3.5	1.5	102	35
DELFLEX Standard with 2.5% Dextrose	2.5 g	567 mg	392 mg	25.7 mg	15.2 mg	398	5.5	132	3.5	1.5	102	35
DELFLEX Low Magnesium, Low Calcium with 1.5% Dextrose	1.5 g	538 mg	448 mg	18.4 mg	5.08 mg	344	5.5	132	2.5	0.5	95	40
DELFLEX Low Magnesium, Low Calcium with 2.5% Dextrose	2.5 g	538 mg	448 mg	18.4 mg	5.08 mg	394	5.5	132	2.5	0.5	95	40
DELFLEX Low Magnesium, Low Calcium with 4.25% Dextrose	4.25 g	538 mg	448 mg	18.4 mg	5.08 mg	483	5.5	132	2.5	0.5	95	40

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 consistent with the fluid removal requirements for that exchange.

Parenteral drug products should be inspected visually for particulate matter and 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.

DELFLEX® peritoneal dialysis solutions are available in the sizes and formulations shown in Table 2.

Table 2

	2 L	2 L/3 L	3 L	5 L
DELFLEX Standard with 1.5% Dextrose				X
DELFLEX Standard with 2.5% Dextrose				X
DELFLEX Low Magnesium, Low Calcium with 1.5% Dextrose	X		X	X
DELFLEX Low Magnesium, Low Calcium with 2.5% Dextrose		X	X	X
DELFLEX Low Magnesium, Low Calcium with 4.25% Dextrose		X	X	X

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 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.

Directions For Use (Aseptic technique is required)

Get Ready

1. Clean work surface.
2. Gather supplies:
   - DELFLEX® Peritoneal Dialysis bag.
   - Prescribed medication(s), if ordered by your healthcare provider.
   - Mask.
3. Put on mask. Wash your hands.
4. Tear the outerwrap from the slit edge down the length of the inner bag 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:

5. 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.
6. Check the expiration date. Check for correct dextrose concentration.
7. 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.

8. DELFLEX® peritoneal dialysis solutions utilize a Safe-Lock® Connection System. This unique system consists of two Safe-Lock® connectors, one located on the administration port of the bag, and the mating connector is located on the fluid delivery set. The Safe-Lock® connectors were designed to prevent touch contamination of the internal connection components.
9. To connect the bag to the fluid delivery set, unscrew the protective caps of the bag connector and fluid delivery set connector. Secure these two connectors with a twisting motion to lock in place, so that the fluid delivery set connector is seated over the bag connector O-ring to assure a firm and tight fit.
10. Once the fluid delivery set is secured, to initiate solution flow, break the cone of the bag connector by placing the thumb firmly on the tube over the cone and pressing towards the outer wall of the tube and away from the bag. Once the cone is broken, a white retaining guide maintains the cone at a specific distance from the connector so it will not impede the flow of solution through the Safe-Lock® connector.
11. Look at the drained fluid for cloudiness. 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.**

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