DELFLEX- dextrose monohydrate, sodium chloride, sodium lactate, calcium chloride, magnesium chloride solution
Fresenius Medical Care North America

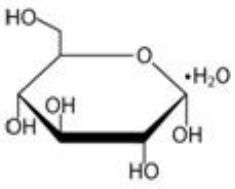
DELFLEX ®

Dextrose Peritoneal Dialysis Solution
With Attached stay•safe ® Exchange Set
For Intraperitoneal Administration Only
MPS 89-908-85
No Latex

Description

The DELFLEX ® 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 stay•safe ® Exchange Set utilizes an easy to use dial designed to eliminate the use of clamps and to prevent touch contamination of internal connection components. 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							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 ($MgCl_2 \cdot 6H_2O$)	Total Osmolarity (mOsmoL/L) (calc)	pH (5.0 - 6.0)	Sodium	Calcium	Magnesium	Chloride	Lactate
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 electrolyte blood chemistries and hematologic factors, as well as other indicators that determine the patient's ongoing 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.

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.

Disconnect from disk only when knob is in position 4 (••••) to ensure patient connector is sealed.

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 with an attached stay•safe ® Exchange Set are available in the sizes and formulations shown in Table 2.

Table 2

	2 L	2.5 L/3 L	3 L
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 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.
   - Mask.
3. Put on mask. Wash your hands.
4. Ensure that the Extension 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 bag. 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).

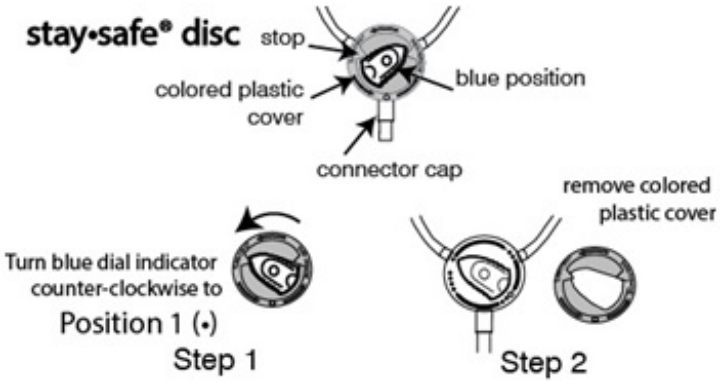


Figure A

<u>Administer DELFLEX ® Peritoneal Dialysis Solution</u>

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 frangible in the solution bag outlet port. (If using the Organizer, place the stay•safe ® disc in the Organizer as illustrated in Figure B)

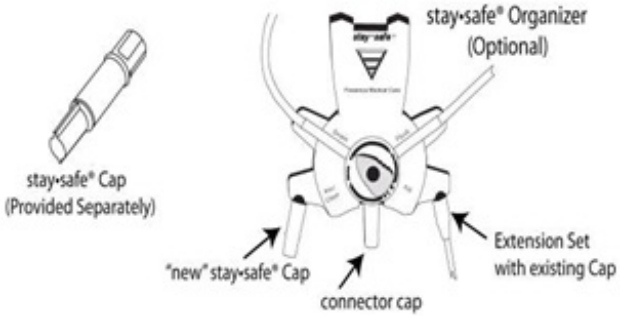


Figure B

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 ® Extension Set, connected to the patient's catheter, in the other notch of the Organizer). See **Figure B**.
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 2 (••). See **Figure C**. This will start flush from the solution bag to the drain bag.

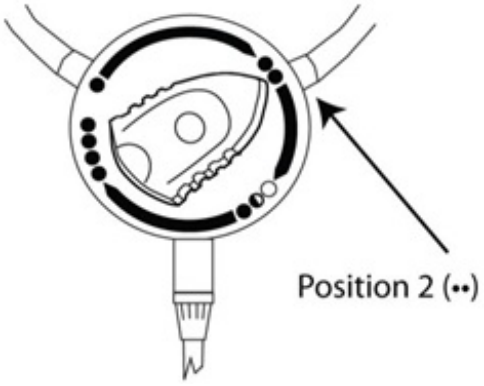


Figure C

10. After approximately 5 seconds turn the stay•safe ® disc position indicator to Position 3 (•••). See **Figure D**. This will start the patient fill.

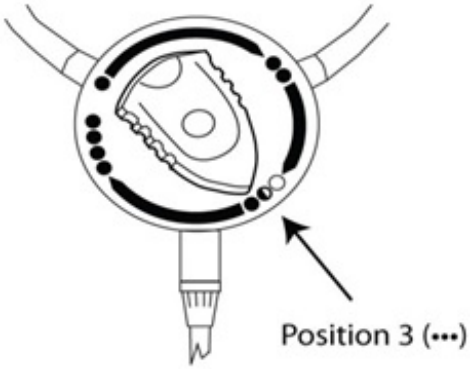


Figure D

11. When fill is complete, turn the stay•safe ® disc position indicator to Position 4 (••••). See **Figure E**. This will insert the closure pin of the disc into the Extension Set connector and seal the system.

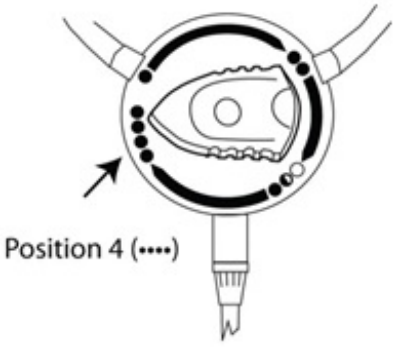


Figure E

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.**

Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

1-800-323-5188

89-908-85 REV 02/15

Principal Display Panel - Delflex Double Bag - NDC 49230-206-92

DELFLEX®
PERITONEAL DIALYSIS SOLUTION
With
1.5% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM
and attached
stay•safe® Exchange Set

CAT. NO. 054-20221 — 2000 mL
NDC 49230-206-92 — (Approx. 40 mL excess)

Each 100 mL contains:

Dextrose Hydrous, USP	1.5 g
Sodium Chloride, USP	538 mg
Sodium Lactate	448 mg
Calcium Chloride, USP	18.4 mg
Magnesium Chloride, USP	5.1 mg
Water for Injection, USP	q.s.
pH 5.5 (5.0 - 6.0)	344 mOsmol/Liter (calc)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

Approximate Milliequivalents per Liter:
Sodium 132 Magnesium 0.5 Calcium 2.5 Chloride 95 Lactate 40
Potassium Chloride to be added only under the direction of a physician.

Sterile, Non Pyrogenic, For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready to use. See Insert.

Inspect inner bag by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solution is clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert

No Latex: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only

89-911-16 Rev 01/07

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Principal Display Panel - Delflex Double Bag - NDC 49230-206-94

DELFLEX®

PERITONEAL DIALYSIS SOLUTION
With
1.5% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM
and attached
stay•safe® Exchange Set

CAT. NO. 054-25321
NDC 49230-206-94

2500 mL /3 Liter Bag
(Approx. 50 mL excess)

Each 100 mL contains:

Dextrose Hydrous, USP	1.5 g
Sodium Chloride, USP	538 mg
Sodium Lactate	448 mg
Calcium Chloride, USP	18.4 mg
Magnesium Chloride, USP	5.1 mg
Water for Injection, USP	q.s.
pH 5.5 (5.0 - 6.0)	344 mOsmol/Liter (calc)

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Potassium Chloride to be added only under the direction of a physician.

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Inspect inner bag by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solution is clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert

No Latex: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

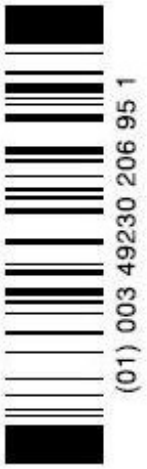
Rx only

89-911-34 Rev 01/07

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Principal Display Panel - Delflex Double Bag - NDC 49230-206-95



DELFLEX®

PERITONEAL DIALYSIS SOLUTION
With
1.5% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM
and attached
stay•safe® Exchange Set

CAT. NO. 054-30321 — 3000 mL
NDC 49230-206-95 — (Approx. 60 mL excess)

Each 100 mL contains:

Dextrose Hydrous, USP	1.5 g
Sodium Chloride, USP	538 mg
Sodium Lactate	448 mg
Calcium Chloride, USP	18.4 mg
Magnesium Chloride, USP	5.1 mg
Water for Injection, USP	q.s.
pH 5.5 (5.0 - 6.0)	344 mOsmol/Liter (calc)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

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Sodium 132 Magnesium 0.5 Calcium 2.5 Chloride 95 Lactate 40
Potassium Chloride to be added only under the direction of a physician.

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Store in outerwrap at 25°C (77°F) until ready to use. See Insert.

Inspect inner bag by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solution is clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert

No Latex: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only

89-911-43 Rev 01/07

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Principal Display Panel - Delflex Double Bag - NDC 49230-209-92

DELFLEX®

PERITONEAL DIALYSIS SOLUTION
With
2.5% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM
and attached
stay•safe® Exchange Set

CAT. NO. 054-20222 — 2000 mL
NDC 49230-209-92 — (Approx. 40 mL excess)

Each 100 mL contains:

Dextrose Hydrous, USP	2.5 g
Sodium Chloride, USP	538 mg
Sodium Lactate	448 mg
Calcium Chloride, USP	18.4 mg
Magnesium Chloride, USP	5.1 mg
Water for Injection, USP	q.s.
pH 5.5 (5.0 - 6.0)	394 mOsmol/Liter (calc)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

Approximate Milliequivalents per Liter:
Sodium 132 Magnesium 0.5 Calcium 2.5 Chloride 95 Lactate 40
Potassium Chloride to be added only under the direction of a physician.

Sterile. Non Pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready to use. See Insert.

Inspect inner bag by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solution is clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert

No Latex: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only

89-911-17 Rev 01/07

Fresenius Medical Care

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Waltham, MA 02451
1-800-323-5188

Principal Display Panel - Delflex Double Bag - NDC 49230-209-94

DELFLEX®

PERITONEAL DIALYSIS SOLUTION
With
2.5% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM
and attached
stay•safe® Exchange Set

CAT. NO. 054-25322
NDC 49230-209-94

2500 mL /3 Liter Bag
(Approx. 50 mL excess)

Each 100 mL contains:

Dextrose Hydrous, USP	2.5 g
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Sodium Lactate	448 mg
Calcium Chloride, USP	18.4 mg
Magnesium Chloride, USP	5.1 mg
Water for Injection, USP	q.s.
pH 5.5 (5.0 - 6.0)	394 mOsmol/Liter (calc)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

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Potassium Chloride to be added only under the direction of a physician.

Sterile, Non Pyrogenic, For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready to use. See Insert.

Inspect inner bag by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solution is clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert

No Latex: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

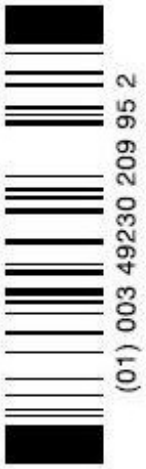
Rx only

89-911-35 Rev 01/07

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Principal Display Panel - Delflex Double Bag - NDC 49230-209-95



DELFLEX®

PERITONEAL DIALYSIS SOLUTION
With
2.5% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM
and attached
stay•safe® Exchange Set

CAT. NO. 054-30322 — 3000 mL
NDC 49230-209-95 — (Approx. 60 mL excess)

Each 100 mL contains:

Dextrose Hydrous, USP	2.5 g
Sodium Chloride, USP	538 mg
Sodium Lactate	448 mg
Calcium Chloride, USP	18.4 mg
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Usual Dosage: See Insert

No Latex: This product and its packaging do not contain any latex materials.

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Rx only

89-911-44 Rev 01/07

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Principal Display Panel - Delflex Double Bag - NDC 49230-212-92

DELFLEX®

PERITONEAL DIALYSIS SOLUTION
With
4.25% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM
and attached
stay•safe® Exchange Set

CAT. NO. 054-20224 — 2000 mL
NDC 49230-212-92 — (Approx. 40 mL excess)

Each 100 mL contains:

Dextrose Hydrous, USP	4.25 g
Sodium Chloride, USP	538 mg
Sodium Lactate	448 mg
Calcium Chloride, USP	18.4 mg
Magnesium Chloride, USP	5.1 mg
Water for Injection, USP	q.s.
pH 5.5 (5.0 - 6.0)	483 mOsmol/Liter (calc)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

Approximate Milliequivalents per Liter:
Sodium 132 Magnesium 0.5 Calcium 2.5 Chloride 95 Lactate 40
Potassium Chloride to be added only under the direction of a physician.

Sterile, Non Pyrogenic, For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready to use. See Insert.

Inspect inner bag by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solution is clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert

No Latex: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only

89-911-18 Rev 01/07

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Principal Display Panel - Delflex Double Bag - NDC 49230-212-94

DELFLEX®

PERITONEAL DIALYSIS SOLUTION
With
4.25% DEXTROSE
LOW MAGNESIUM / LOW CALCIUM
and attached
stay•safe® Exchange Set

CAT. NO. 054-25324
NDC 49230-212-94

2500 mL /3 Liter Bag
(Approx. 50 mL excess)

Each 100 mL contains:

Dextrose Hydrous, USP	4.25 g
Sodium Chloride, USP	538 mg
Sodium Lactate	448 mg
Calcium Chloride, USP	18.4 mg
Magnesium Chloride, USP	5.1 mg
Water for Injection, USP	q.s.
pH 5.5 (5.0 - 6.0)	483 mOsmol/Liter (calc)

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

Approximate Milliequivalents per Liter:
Sodium 132 Magnesium 0.5 Calcium 2.5 Chloride 95 Lactate 40
Potassium Chloride to be added only under the direction of a physician.

Sterile, Non Pyrogenic, For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready to use. See Insert.

Inspect inner bag by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solution is clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert

No Latex: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

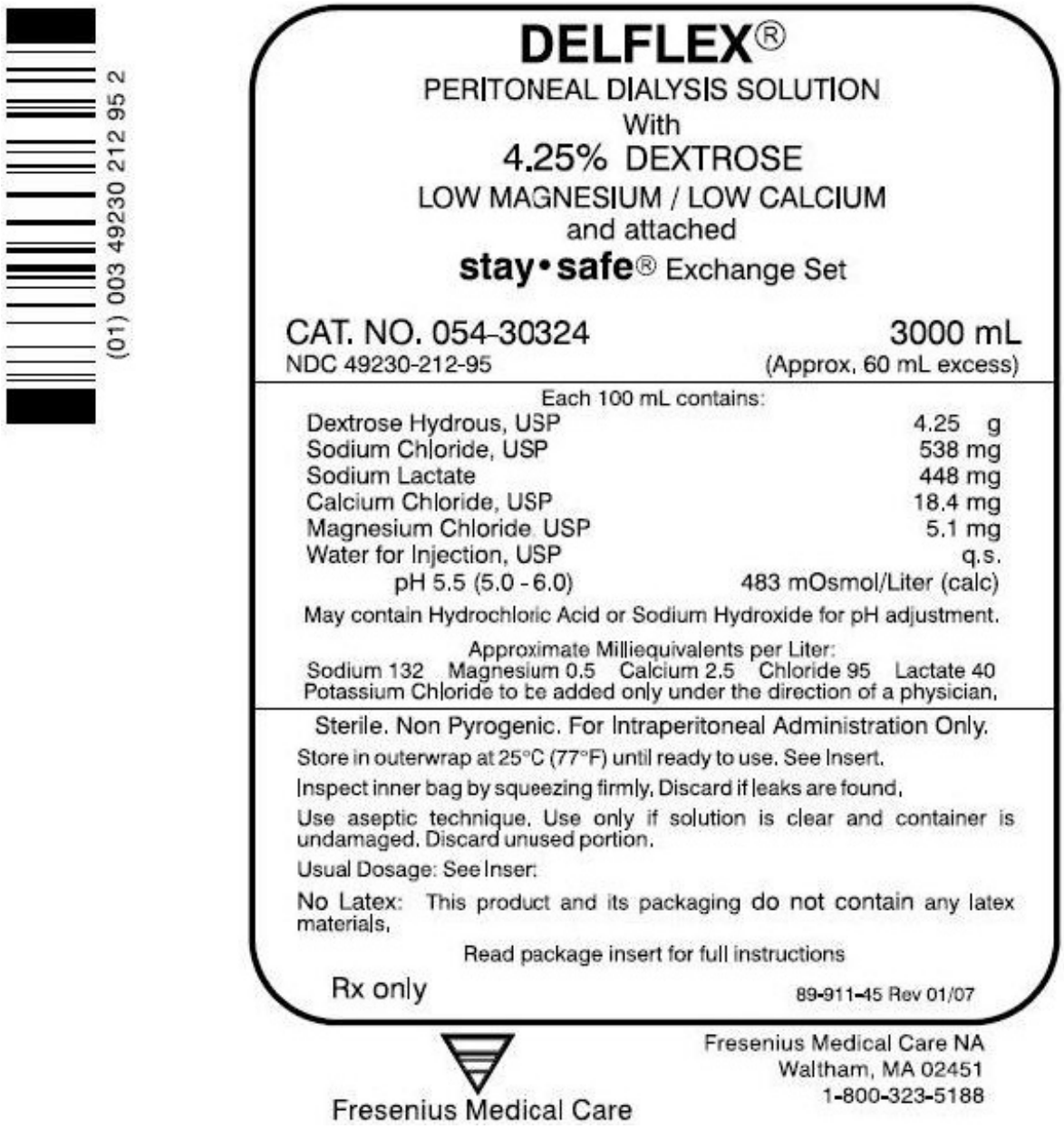
Rx only

89-911-36 Rev 01/07

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Principal Display Panel - Delflex Double Bag - NDC 49230-212-95



DELFLEX

dextrose monohydrate, sodium chloride, sodium lactate, calcium chloride, magnesium chloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49230-206
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	1.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	538 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	448 mg in 100 mL

CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	18.4 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.08 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49230-206-92	5 in 1 CARTON	08/19/1992	
1		2000 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:49230-206-94	5 in 1 CARTON	08/19/1992	
2		2500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:49230-206-95	4 in 1 CARTON	08/19/1992	
3		3000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020171	08/19/1992	

DELFLEX

dextrose monohydrate, sodium chloride, sodium lactate, calcium chloride, magnesium chloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49230-209
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	2.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	538 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	448 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	18.4 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.08 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49230-209-92	5 in 1 CARTON	08/19/1992	
1		2000 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:49230-209-94	5 in 1 CARTON	08/19/1992	
2		2500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:49230-209-95	4 in 1 CARTON	08/19/1992	
3		3000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020171	08/19/1992	

DELFLEX

dextrose monohydrate, sodium chloride, sodium lactate, calcium chloride, magnesium chloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49230-212
Route of Administration	INTRAPERITONEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	4.25 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	538 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	448 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	18.4 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	5.08 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49230-212-92	5 in 1 CARTON	08/19/1992	
1		2000 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:49230-212-94	5 in 1 CARTON	08/19/1992	
2		2500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:49230-212-95	4 in 1 CARTON	08/19/1992	
3		3000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020171	08/19/1992	

Labeler - Fresenius Medical Care North America (958291411)

Revised: 10/2019

Fresenius Medical Care North America