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

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DELFLEX® safely and effectively. See full prescribing information for DELFLEX® with attached stay•safe exchange set.

DELFLEX (dextrose) peritoneal dialysis solution with attached stay•safe exchange set for intraperitoneal administration only.

Initial U.S. Approval: 1992

INDICATIONS AND USAGE
For treatment of chronic kidney failure. (1)

DOSAGE AND ADMINISTRATION
(1) For intraperitoneal dialysis only. (2)

DOSAGE FORMS AND STRENGTHS
DELFLEX solutions are available in multiple compositions, calculated osmolarity, pH, and ionic concentrations. See full prescribing information for detailed descriptions of each formulation. (3, 11)

CONTRAINDICATIONS
None (4)

WARNINGS AND PRECAUTIONS
- Monitor patient for electrolyte, fluid, and nutrition imbalances. (5.1)
- Encapsulating Peritoneal Sclerosis (EPS) (5.2)
- Peritonitis: Initiate appropriate antimicrobial therapy (5.2)
- Monitor for Lactic Acidosis in patients at risk. (5.3)

ADVERSE REACTIONS
Adverse reactions may include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, disequilibrium syndrome, muscle cramping, abdominal pain, abdominal distension, and abdominal discomfort. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Medical Care North America at 1-800-323-5188 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 7/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

DELFLEX® is indicated in the treatment of chronic kidney failure in patients being maintained on peritoneal dialysis.

2 DOSAGE AND ADMINISTRATION

2.1 Basic Dosing Information

DELFLEX® is intended for intraperitoneal administration only. Not for intravenous or intra-arterial administration.

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.

Utilize the peritoneal dialysis solution with lowest level of osmolarity consistent with the fluid removal requirements for that exchange.

Do not store solutions containing additives.

2.2 Administration Instructions

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

Do not heat in a microwave oven.

Get Ready

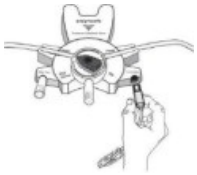
1. Clean work surface and gather supplies:
   - Masks (enough for everyone in the room).
   - Warmed DELFLEX peritoneal dialysis solution bag with attached stay•safe exchange set.
   - stay•safe organizer, a stand-alone item provided separately.
   - Povidone iodine prefilled stay•safe cap, a stand-alone item provided separately.
   - IV Pole (optional).
   - Prescribed medication(s), if ordered by your healthcare provider.
2. After removing the overwrap, check your DELFLEX solution bag(s) for strength, clarity, amount, leaks, and expiration date. Do not use DELFLEX solution if leaks are found, the solution bag is damaged, the solution is cloudy or discolored, and/or the product is expired. Color may vary from clear to slightly yellow but does not affect efficacy and may be used.
3. Prepare supplies:
   i. Retrieve stay•safe catheter extension set and ensure clamp is closed.
   ii. Tear the overwrap from the slit edge down the length of the inner bag to open.
   iii. 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.
   iv. Visually check that the solution bag tubing is free from kinks. If kinks are present, straighten tubing to allow the solution to flow freely.
   Note: Retain DELFLEX peritoneal dialysis bag sample for manufacturer evaluation and notify your healthcare provider if any of the above defects are found.
   v. Put on mask. Wash your hands per facility protocol.
   vi. Position the stay•safe organizer at the edge of your clean work surface or with the stay•safe holder on the IV pole.
4. Remove color-coded cover:
   i. Turn the blue dial as directed by the arrow in the color—coded cover.

ii. Remove the colored—coded cover from the stay•safe DISC. The blue dial will be in Position 1 (●) DRAIN.

5. Prepare organizer and solution bag:
   i. Place the stay•safe DISC and tubing into the organizer and tubing channels on the organizer.

   ii. If you will be adding medication(s):
      a. Clean hands (as per facility's protocol).
      b. Clean the medication port as instructed by your healthcare provider.
      c. Add the medicine(s).
      d. Turn the bag upside down several times to mix the medicine(s).
   iii. Hang the DELFLEX peritoneal dialysis solution bag on the IV pole and place the drain bag with the clear side up on the floor.
   iv. Break cone of the administration port.
6. Remove new stay•safe cap from its package and place stay•safe cap into the left notch of the organizer.

7. Place stay•safe catheter extension set into organizer.
   i. Clean hands (as per facility's protocol).
   ii. Place stay•safe catheter extension set into the right notch of the organizer.
   iii. Ensure clamp of stay•safe catheter extension set is closed.



8. Remove protective cap from stay•safe DISC and set aside.

9. Connect stay•safe catheter extension set to the stay•safe DISC.
    i. Unscrew stay•safe catheter extension set from its cap.
    ii. Immediately connect the stay•safe catheter extension set to the stay•safe DISC.
    iii. Open the white clamp of stay•safe catheter extension set and start DRAIN.
    iv. Place discarded protective cap from stay•safe DISC onto the used stay•safe cap in the stay•safe organizer and discard.

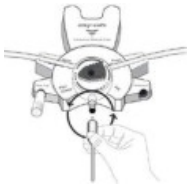
10. When DRAIN is complete:
    i. Turn blue dial to Position 2(●●), FLUSH for about 5 seconds.
    ii. Make sure the line between solution bag and stay•safe DISC is fully primed.

11. When FLUSH is complete:
    i. Turn blue dial to Position 3(○●●), FILL to begin the fill of solution to your abdomen. Flow rate can be adjusted from slow(○) to moderate (◐) to fast (●).

12. When FILL is complete:
    i. Turn blue dial as far as possible in Position 4 (●●●●), PIN/CLOSE until you feel and/or hear a “click”.
    ii. The stay•safe PIN located in the stay•safe DISC will automatically be released into the end of the stay•safe catheter extension set.

13. When PIN/CLOSE is complete:
    i. Close the clamp of the stay•safe catheter extension set.
    ii. Using aseptic technique, mask then wash hands as instructed by your healcare provider.
    iii. Unscrew protective cover from the new stay•safe cap and set aside.

14. Disconnect from stay•safe DISC:
    i. Unscrew the stay•safe catheter extension set from the stay•safe DISC.
    ii. Immediately attach the stay•safe catheter extension set with a PIN to the new stay•safe cap.
    iii. Remove capped catheter extension set from organizer and secure to your abdomen.



15. Complete treatment:
    i. Place protective cover from the new stay•safe cap on the stay•safe DISC connector to prevent drips.
    ii. Weigh drain bag (as per facility's protocol).
    iii. Record exchange results on treatment log.
    iv. If an effluent sample is required:
        a. Use aseptic technique and facility protocols throughout collection.
        b. Scrub the drain bag's sample port hub with friction and an Isopropyl Alcohol 70% swab/prep pad for 15 seconds, and allow to dry for 30 seconds more.
        c. Withdraw the effluent sample directly from the sample port hub with a needle and syringe.
    v. Discard the used tubing and solution (as per facility's protocol).
    vi. Throw away the fluid and used exchange set as instructed by your healthcare provider. **In case of cloudiness, save the fluid and the used exchange set and immediately contact your healthcare provider.**

2.3 Compatible Medications

Compatible medications can be added via the medication port [*see Dosage and Administration (2.2)*]. The following medications have demonstrated stability with DELFLEX solutions: cefazolin, ceftazidime, gentamicin, and vancomycin [*see Clinical Pharmacology (12.3)*].

3 DOSAGE FORMS AND STRENGTHS

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 1.

Table 1. DELFLEX peritoneal dialysis solution with attached stay•safe exchange set sizes and formulations

	2L	2.5L	3L
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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Electrolyte, Fluid and Nutrition Imbalances

Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically and take appropriate clinical action.

Potassium is omitted from DELFLEX solutions because dialysis may be performed to correct hyperkalemia. In situations where 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.

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.

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

5.2 Peritonitis and Encapsulating Peritoneal Sclerosis

Infectious and aseptic peritonitis has been associated with peritoneal dialysis therapy. Following DELFLEX use, inspect the drained fluid for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis. Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis. If peritonitis occurs, treat with appropriate therapy.

Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy.

5.3 Lactic Acidosis

Monitor patients with conditions known to increase the risk of lactic acidosis [e.g., severe hypotension or sepsis that can be associated with acute kidney failure, inborn errors of metabolism, treatment with drugs such as nucleoside/ nucleotide reverse transcriptase inhibitors (NRTIs)] for lactic acidosis before the start of treatment and during treatment with DELFLEX.

Solutions containing the 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.

5.4 Over Infusion

Over infusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat over infusion.

6 ADVERSE REACTIONS

Solution related adverse reactions may include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome, muscle cramping, abdominal pain, abdominal distension, and abdominal discomfort.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

DELFLEX solutions consist of electrolytes, lactate, and bicarbonate at physiological levels, and glucose to facilitate ultrafiltration. While there are no adequate and well controlled studies in pregnant women, appropriate administration of DELFLEX with monitoring of fluid, electrolyte, acid-base and glucose balance, is not expected to cause fetal harm. Animal reproduction studies have not been conducted with DELFLEX.

The estimated background risk of major birth defects and miscarriage for the indicated population are unknown. All pregnancies have a background risk of birth defect, loss or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

The components of DELFLEX solutions are excreted in human milk. Appropriate administration of DELFEX solutions with monitoring of fluid, electrolyte, acid-base and glucose balance, is not expected to harm a nursing infant.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

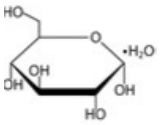
11 DESCRIPTION

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 2.

Table 2. Composition, calculated osmolarity, pH and ionic concentration

	Composition/100mL					Total Osmolarity (mOsmoL/L) (calc)	pH (5.0 - 6.0)	Ionic Concentration (mEq/L)				
	Dextrose Hydrous, USP ($C_6H_{12}O_6•H_2O$)	Sodium Chloride, USP (NaCl)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2•2H_2O$)	Magnesium Chloride, USP ($MgCl_2•6H_2O$)			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	4.25g	538 mg	448 mg	18.4 mg	5.08 mg	483	5.5	132	2.5	0.5	95	40

Dextrose, USP, is chemically designated D-glucose monohydrate ($C_6H_{12}O_6•H_2O$) 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 inner bag is compounded from a specific polyvinyl chloride, water may permeate from the inner bag into the overwrap 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.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

DELFLEX peritoneal dialysis solutions are hypertonic peritoneal dialysis solutions containing dextrose, a monosaccharide, as the primary osmotic agent. An osmotic gradient must be created between the peritoneal membrane and the dialysis solution in order for ultrafiltration to occur. The hypertonic concentration of glucose in DELFLEX solutions exert an osmotic pressure across the peritoneal membrane resulting in transcapillary ultrafiltration. Like other peritoneal dialysis solutions, DELFLEX solutions contain electrolytes to facilitate the correction of acid- base and electrolyte abnormalities. DELFLEX solutions contain a buffer, lactate, to help normalize acid-base abnormalities.

12.3 Pharmacokinetics

Absorption

Glucose can be rapidly absorbed from the peritoneal cavity by diffusion and appears quickly in the circulation due to the high glucose concentration gradient between DELFLEX solutions compared to blood capillary glucose level. Absorption per unit time will be the highest at the start of an exchange and decreases over time. The rate of glucose absorption will be dependent upon the transport characteristics of the patient's peritoneal membrane as determined by a peritoneal equilibration test (PET). Glucose absorption will also depend upon the concentration of glucose used for the exchange and the length of the dwell. Transport of other molecules will be dependent upon the molecular size of the solute, the concentration gradient, and the effective peritoneal surface area as determined by the PET.

Metabolism and Elimination

Glucose is metabolized by normal cellular pathways (i.e., glycolysis). Metabolism of lactate occurs in the liver and results in the generation of the bicarbonate. Glucose not absorbed during PD exchange procedure is removed by drainage of the PD solution from the peritoneal cavity.

Drug Interaction Studies

Antibiotics

No formal clinical drug interaction studies have been performed. In vitro studies of the following medications have demonstrated stability with DELFLEX solutions: cefazolin, ceftazidime, gentamicin, and vancomycin.

13 NONCLINICAL TOXICOLOGY

13.1 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.

16 HOW SUPPLIED/STORAGE AND HANDLING

DELFLEX peritoneal dialysis solutions with attached stay•safe exchange set are available in the sizes and formulations shown in Table 1 [*Dosage Forms and Strengths*].(3)

Table 3. DELFLEX peritoneal dialysis with attached stay•safe exchange set NDC designations

	2L	2.5L	3L
Low Mg/Low Ca 1.5% Dextrose	49230-206-92	49230-206-94	49230-206-95
Low Mg/Low Ca 2.5% Dextrose	49230-209-92	49230-209-94	49230-209-95
Low Mg/Low Ca 4.25% Dextrose	49230-212-92	49230-212-94	49230-212-95

Magnesium (Mg); Calcium (Ca)

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.

17 PATIENT COUNSELING INFORMATION

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

The solution bag should remain in the carton and the overwrap intact until time of use.

Use only after checking for strength, clarity, amount, leaks, and expiration date.

Advise patients that DELFLEX peritoneal dialysis solution should not be heated in a microwave oven.

Disconnect from stay•safe DISC only when the blue dial is in position 4(●●●●) to ensure the fluid path of the stay•safe catheter extension set 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.

FRESENIUS MEDICAL CARE

Fresenius Medical Care North America 920 Winter Street
Waltham, MA 02451
1-800-323-5188

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

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

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

DELFLEX®

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

CAT. NO. 054-30324 — 3000 mL
NDC 49230-212-95 — (Approx. 60 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

89-911-45 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
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 49230-209-94

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)

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

89-911-34 Rev 01/07

Fresenius Medical Care

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

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

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

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
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
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

89-911-35 Rev 01/07

Fresenius Medical Care

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

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

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 49230-212-95

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: 10/2023 Fresenius Medical Care North America