PRISMASOL BGK0/2.5- calcium chloride, magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, and sodium bicarbonate injection
PRISMASOL BGK4/2.5- calcium chloride, magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection
PRISMASOL BGK2/3.5- calcium chloride, magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection
PRISMASOL BGK2/0- magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection
PRISMASOL B22GK4/0- magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection
PRISMASOL BK0/0/1.2- magnesium chloride, lactic acid, sodium chloride, and sodium bicarbonate injection
PRISMASOL BGK4/0/1.2- magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection
PHOXILLUM BK4/2.5- calcium chloride, magnesium chloride, sodium chloride, sodium bicarbonate, potassium chloride, and sodium phosphate dibasic dihydrate injection
PHOXILLUM B22K4/0- magnesium chloride, sodium chloride, sodium bicarbonate, potassium chloride, and sodium phosphate dibasic dihydrate injection
Vantive US Healthcare LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PRISMASOL and PHOXILLUM safely and effectively. See full prescribing information for PRISMASOL and PHOXILLUM.

PRISMASOL renal replacement solution
PRISMASOL Initial U.S. Approval: 2006

PHOXILLUM renal replacement solution
PHOXILLUM Initial U.S. Approval: 2015

INDICATIONS AND USAGE

PRISMASOL and PHOXILLUM solutions are indicated:

- As a replacement solution in Continuous Renal Replacement Therapy (CRRT) and in case of drug poisoning when CRRT is used to remove dialyzable substances (1)

DOSAGE AND ADMINISTRATION

- Therapy must be individualized based on the patient's clinical condition, fluid, electrolyte, acid-base and glucose balance (2.2)
- Solution must be mixed prior to use (2.2)
- Use only with extracorporeal dialysis equipment appropriate for CRRT (2.3)

DOSAGE FORMS AND STRENGTHS

PRISMASOL and PHOXILLUM are available in multiple combinations of ingredients and in multiple variations of strengths. See full Prescribing Information for detailed descriptions of each formulation. (2, 3, 11)

CONTRAINDICATIONS

Known hypersensitivities to PRISMASOL and PHOXILLUM solutions (4)

WARNINGS AND PRECAUTIONS

- Monitor hemodynamic status and fluid inputs and outputs, potassium, phosphorus, other electrolytes and acid-base balance. Abnormalities may be corrected by the use of appropriate formulations and dosage of PRISMASOL and PHOXILLUM solutions (5.1)
- Treatment may affect glucose levels. Monitor blood glucose levels.
- Antidiabetic therapy adjustment or other corrective measures may be required during treatment (5.2)

To report SUSPECTED ADVERSE REACTIONS, contact Vantive US Healthcare LLC at 1855-857-0003 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Revised: 3/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

PRISMASOL and PHOXILLUM solutions are indicated in pediatric and adult patients for use as a replacement solution in Continuous Renal Replacement Therapy (CRRT) to replace plasma volume removed by ultrafiltration and to correct electrolyte and acid-base imbalances. They may also be used in case of drug poisoning when CRRT is used to remove dialyzable substances.

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

Visually inspect PRISMASOL and PHOXILLUM for particulate matter and discoloration prior to administration.

Administration should only be under the direction of a physician competent in intensive care treatment including CRRT. Use only with extracorporeal dialysis equipment appropriate for CRRT.

The prepared solution is for single patient use only.

Aseptic technique should be used throughout administration to the patient.

Discard any unused solution.

2.2 Dosing Considerations

PRISMASOL replacement solutions contain 4 different combinations of active ingredients (7 different products with varying ingredient amounts). PHOXILLUM replacement solutions contain 2 different combinations of active ingredients (2 different products with varying ingredient amounts). PRISMASOL and PHOXILLUM are supplied in a two-compartment bag that must be mixed immediately prior to use *[see Dosage and Administration (2.3)]:*

- Small compartment A (250 mL) containing an electrolyte solution, and
- Large compartment B (4750 mL) containing the buffer solution.

See Table 1for the concentrations of the active ingredients (after mixing) in these 9 different replacement solutions (total volume is 5 Liters).

Table 1: Concentrations of Active Ingredients in the 7 PRISMASOL and 2 PHOXILLUM Replacement Solutions after Mixing

	Ca^{2+} mEq/L	HCO_3^- mEq/L	K^+ mEq/L	Mg^{2+} mEq/L	Na^+ mEq/L	HPO_4^{2-} mmol/L	Cl^- mEq/L	Lactate mEq/L	Dextrose mg/dL	Osmolarity mOsm/L
PRISMASOL Replacement Solutions										
BGK0/2.5	2.5	32	0	1.5	140	0	109	3	100	292
BGK4/2.5	2.5	32	4	1.5	140	0	113	3	100	300
BGK2/3.5	3.5	32	2	1	140	0	111.5	3	100	296
BGK2/0	0	32	2	1	140	0	108	3	100	291
B22GK4/0	0	22	4	1.5	140	0	120.5	3	100	296
BGK4/0/1.2	0	32	4	1.2	140	0	110.2	3	100	295
BK0/0/1.2	0	32	0	1.2	140	0	106.2	3	0	282
PHOXILLUM Replacement Solutions										
BK4/2.5	2.5	32	4	1.5	140	1	114.5	0	0	294
B22K4/0	0	22	4	1.5	140	1	122	0	0	290

Ca^{2+}= calcium, HCO_3^-= bicarbonate, K^+= potassium, Mg^{2+}= magnesium, Na^+= sodium, HPO_4^{2-}= phosphate, Cl- = chloride; osmolarity is estimated

The mode of therapy, solute formulation, flow rates, and length of PRISMASOL and PHOXILLUM replacement therapy in CRRT should be established by a physician based on the patient's clinical condition, blood concentration of phosphate and other electrolytes, acid-base and glucose balance. Administer either PRISMASOL or PHOXILLUM into the extracorporeal circuit:

- Before (pre-dilution) the hemofilter or hemodiafilter,
- After (post-dilution) the hemofilter or hemodiafilter, or
- Before and after the hemofilter or hemodiafilter.

2.3 Preparing the Solution

Use only if the overwrap is not damaged, all seals are intact, peel seal is not broken, and the solution is clear.

The solution may be warmed to 37°C/98.6°F prior to removing the overwrap to enhance patient comfort. However, only dry heat should be used. Solutions should not be heated in water or in a microwave oven. After heating, verify that the solution remains clear and

contains no particulate matter.

The solutions are supplied in two different two-compartment bags made of polyolefin with a peel seal separating compartment A and B (see Figure 1).

Follow the instructions below when connecting the solution bags for correct use of the access ports.

Instructions for preparing solutions supplied in a two-compartment, polyolefin bag with a peel seal:

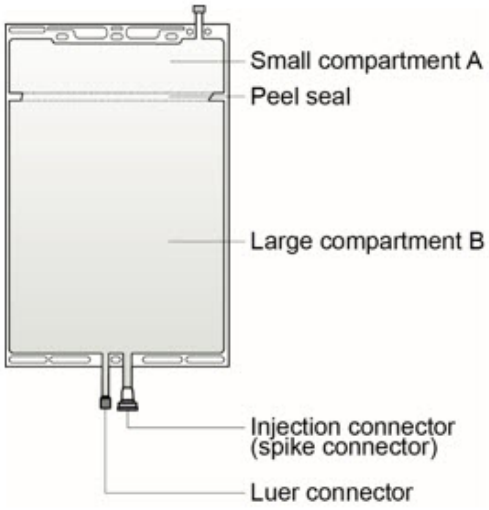
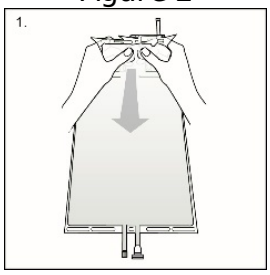
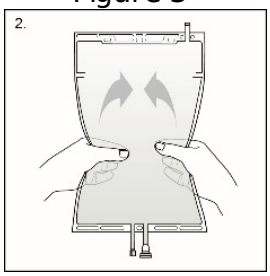
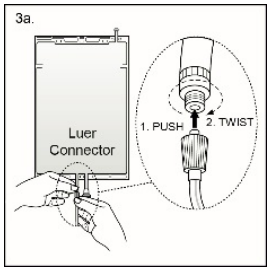
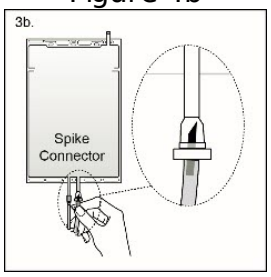


Figure 2 	**Step 1**Immediately before use, remove the overwrap from the bag and mix the solutions in the two different compartments. After removing the overwrap, inspect the bag for leakage by pressing firmly on the bag. Discard the bag if any leakage is detected since sterility cannot be assured. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the mixed solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Hold the small compartment with both hands and squeeze it until an opening is created in the peel seal. (See Figure 2beside)
Figure 3 	**Step 2**Squeeze with both hands on the large compartment until the peel seal between the two compartments is entirely open. Shake gently to mix. (See Figure 3beside) The solution is now ready to use and the bag can be hung on the equipment.
Figure 4a	**Step 3**The replacement line may be connected to the bag through



either of the luer connector or the injection connector (spike connector).
Step 3a The luer connector is a needle-less and swabbable connector. Remove the cap with a twist and pull motion, and connect the male luer lock on the replacement line to the female luer receptor on the bag. (See Figure 4a beside)
Ensure that the connection is fully seated and tighten. The connector is now open. Verify that the fluid is flowing freely during use.
When the replacement line is disconnected from the luer connector, the connector will close and the flow of the solution will stop.

Figure 4b



Step 3b If the injection connector (spike connector) is used, first remove the snap-off cap. Then introduce the replacement line spike through the swabbable rubber septum of the bag connector. (See Figure 4b beside)
Ensure that the spike is fully inserted and verify that the fluid is flowing freely during use.

2.4 Adding Drugs to the Solutions

After mixing, additional drugs may be added to the bag via injection connector (spike connector) in large compartment B. In general, administer drugs other than phosphate through a different access line.

When introducing drugs, use aseptic techniques and mix thoroughly prior to connecting the solution bag to the extracorporeal circuit.

Do not use if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals after addition of medication.

Phosphate: Up to 1.2 mmol/L of phosphate can be added to the bag as potassium phosphate or sodium phosphate. The total potassium concentration of PRISMASOL solution should not exceed 4 mEq/L. Use sodium phosphate to add phosphate if the total potassium concentration in PRISMASOL solution is 4 mEq/L.

PHOXILLUM Solutions:

Phosphate:Phosphate up to 0.2 mmol/L may be added to the solution. Use sodium phosphate if adding phosphate to bag. The total phosphate concentration should not exceed 1.2 mmol/L.

3 DOSAGE FORMS AND STRENGTHS

See Table 1for the concentrations of the active ingredients (after mixing) in these 9 different replacement solutions *[see Dosage and Administration (2.2)]* **.**

4 CONTRAINDICATIONS

PHOXILLUM and PRISMASOL replacement solutions are contraindicated in patients with known hypersensitivities to these products.

5 WARNINGS AND PRECAUTIONS

5.1 Electrolyte and Volume Abnormalities

PHOXILLUM and PRISMASOL solutions can affect electrolytes and volume and may result in hyperkalemia or hyperphosphatemia. Monitor hemodynamic status and fluid inputs and outputs, potassium, phosphorous, calcium, other electrolytes and acid-base balance throughout the procedure. Abnormalities may be corrected by changing the formulation of replacement solution and/or dialysate, supplementation, or adjusting flow rates appropriately [*see Dosage and Administration (2)*].

PHOXILLUM replacement solutions contain hydrogen phosphate, a weak acid that may increase the risk of metabolic acidosis.

5.2 Blood Glucose Abnormalities

The use of PRISMASOL and PHOXILLUM replacement solutions can affect blood glucose levels resulting in hypo- or hyper-glycemia depending upon the dextrose content of the replacement solution. Monitor blood glucose levels regularly. Patients may require initiation of or modification of antidiabetic therapy or other corrective measures during treatment.

6 ADVERSE REACTIONS

The following adverse reactions have been identified during postapproval use with these or other similar products and therefore may occur with use of PHOXILLUM or PRISMASOL. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Metabolic acidosis
- Hypotension
- Acid-base disorders
- Electrolyte imbalance including calcium ionized increased (reported in PRISMASOL solutions containing calcium), hyperphosphatemia, and hypophosphatemia
- Fluid imbalance

7 DRUG INTERACTIONS

As with the use of other replacement solutions, blood concentrations of dialyzable drugs may be reduced by CRRT due to their removal by the hemofilter or hemodiafilter. The blood concentrations of certain drugs may need to be monitored and appropriate therapy implemented to correct for removal during treatment.

7.1 Citrate

When used as an anticoagulant, citrate contributes to the overall buffer load and can reduce plasma calcium levels. Select the PRISMASOL/PHOXILLUM formulation(s) accordingly.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

PRISMASOL and PHOXILLUM are pharmacologically inactive solutions. While there are no adequate and well controlled studies in pregnant women, appropriate administration of PRISMASOL and PHOXILLUM solutions 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 PRISMASOL and PHOXILLUM solutions.

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.

Clinical Considerations

Maintenance of normal acid-base balance is important for fetal well-being.

8.2 Lactation

Risk Summary

The components of PRISMASOL and PHOXILLUM solutions are excreted in human milk. Appropriate administration of PRISMASOL and PHOXILLUM 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 have been established based on published clinical data of CRRT replacement solutions with compositions similar to PRISMASOL and PHOXILLUM used in adults and two hemofiltration studies in pediatric patients, including a study of newborns to 17 years old.

8.5 Geriatric Use

The experience with PRISMASOL and PHOXILLUM solutions in geriatric patients has not identified novel concerns.

11 DESCRIPTION

PRISMASOL and PHOXILLUM solutions are clear, sterile, free of bacterial endotoxins and contain no bacteriostatic or antimicrobial agents. These solutions are used in Continuous Renal Replacement Therapies (CRRT) as a replacement solution in hemofiltration and hemodiafiltration. Depending on the product (see Table 2), the two compartments contain:

Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$).

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$).

Sodium chloride, USP, is chemically designated NaCl.

Potassium chloride, USP, is chemically designated KCl.

Sodium bicarbonate, USP, is chemically designated $NaHCO_3$.

Dextrose, USP, is chemically designated D-Glucose anhydrous ($C_6H_{12}O_6$) or D-Glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$).

Lactic acid, USP, is chemically designated $CH_3CH(OH)COOH$.

Dibasic sodium phosphate, USP, is chemically designated as disodium hydrogen phosphate, dihydrate ($Na_2HPO_4 \cdot 2H_2O$)

Table 2 - Compartment Composition (Before Mixing)

	Compartment A (g/L)				Compartment B (g/L)			
	Calcium Chloride · $2H_2O$	**Magnesium Chloride · $6H_2O$**	**Dextrose anhydrous (as monohydrate)**	**Lactic Acid**	**Sodium Chloride**	**Sodium bicarbonate**	**Potassium Chloride**	**Sodium Phosphate · $2H_2O$**
PRISMASOL SOLUTIONS								
BGK 0/2.5	3.68	3.05	20 (22)	5.40	6.46	3.09	0	0
BGK 4/2.5	3.68	3.05	20 (22)	5.40	6.46	3.09	0.314	0
BGK 2/3.5	5.15	2.03	20 (22)	5.40	6.46	3.09	0.157	0
BGK 2/0	0	2.03	20 (22)	5.40	6.46	3.09	0.157	0
B22GK 4/0	0	3.05	20 (22)	5.40	7.07	2.21	0.314	0
BK 0/0/1.2	0	2.44	0 (0)	5.40	6.46	3.09	0	0
BGK 4/0/1.2	0	2.44	20 (22)	5.40	6.46	3.09	0.314	0
PHOXILLUM SOLUTIONS								
BK 4/2.5	3.68	3.05	0 (0)	0	6.34	3.09	0.314	0.187
B22K 4/0	0	3.05	0 (0)	0	6.95	2.21	0.314	0.187

The pH of the final solution is in the range of 7.0 to 8.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

PRISMASOL and PHOXILLUM solutions are pharmacologically inactive. The electrolyte concentrations in the solutions are chosen to restore plasma levels to clinically desired concentrations or maintain plasma levels at the desired concentrations.

PRISMASOL and PHOXILLUM solutions are used as replacement solution to replace water and electrolytes removed during hemofiltration and hemodiafiltration. Bicarbonate (or precursor lactate) in the solution is used as an alkalinizing buffer to restore acid-base balance to a clinically desirable level.

12.3 Pharmacokinetics

The distribution of electrolytes, bicarbonate, and dextrose is determined by the patient's clinical condition, metabolic status, and residual renal function.

The elimination and replacement of water, electrolytes and buffer depend on the patient's electrolyte and acid-base balance, metabolic status, residual renal function and ongoing physiologic losses through intestinal, respiratory and cutaneous routes.

16 HOW SUPPLIED/STORAGE AND HANDLING

PRISMASOL and PHOXILLUM solutions are supplied in a two-compartment bag made of

polyolefin. The 5000 mL bag is composed of a small compartment (250 mL) and a large compartment (4750 mL). The two compartments are separated by a peel seal.

The bag is overwrapped with a transparent overwrap. See Table 2for the concentrations of the active ingredients in each compartment for each product *[see Description (11)].*

Container	**Fill Volume**	**NDC**
PRISMASOL Solutions		
PRISMASOL BGK0/2.5	5000 mL	24571-108-06
PRISMASOL BGK4/2.5	5000 mL	24571-105-06
PRISMASOL BGK2/3.5	5000 mL	24571-103-06
PRISMASOL BGK2/0	5000 mL	24571-102-06
PRISMASOL B22GK4/0	5000 mL	24571-111-06
PRISMASOL BK0/0/1.2	5000 mL	24571-113-06
PRISMASOL BGK4/0/1.2	5000 mL	24571-114-06
PHOXILLUM Solutions		
PHOXILLUM BK4/2.5	5000 mL	24571-116-06
PHOXILLUM B22K4/0	5000 mL	24571-117-06

Not all formulations may be marketed.

Storage conditions

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15ºC to 30ºC (59ºF to 86ºF). *[See USP Controlled Room Temperature]*

Do not freeze or expose to excessive heat. Do not use if precipitate has formed or if container seals have been damaged.

Manufactured for:
Vantive US Healthcare LLC
One Baxter Parkway
Deerfield, Illinois 60015

07-19-00-8247

Package/Label Display Panel

Mixing steps:

1. **SQUEEZE TOP** corners to break seal
2. Squeeze **BAG SIDES** to fully open seal

NDC# 24571-108-06

0K⁺ mEq/L

2.5Ca²⁺ mEq/L

PrismaSol BGK0/2.5

Rx only

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	A	B
Calcium chloride • 2 H_2O	3.68	
Magnesium chloride • 6 H_2O	3.05	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		6.46
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections qs, Carbon dioxide for pH adjustment		

A 250 mL

B 4750 mL

After reconstitution, A + B	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^{+}	Chloride Cl^{-}	Lactate $C_3H_5O_3^{-}$	Bicarbonate HCO_3^{-}	Potassium K^{+}	Dextrose
mmol/L	1.25	0.75	140	109.0	3.0	32	0	5.5
mEq/L	2.5	1.5	140	109.0	3.0	32	0	(100 mg/dL)

Theoretical osmolarity: 292 mOsm/L pH: 7.0 – 8.5

Mix both compartments before use.
See package insert for dosage information and further instructions.
Sterile and free from bacterial endotoxins.
Confirm the integrity of the packaging. Use only if solution is clear. For single use only.
DISCARD ANY UNUSED SOLUTION.
Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]

Do not freeze or expose to excessive heat.
As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

5000 mL

EAN-14: 07332414091613 Product No: 110240

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield, IL 60015 USA
Made in Italy

Vantive

REPLACEMENT Solution for Continuous Renal Replacement Therapy

07-25-00-5278

Mixing steps

① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Barcode
NDC# 24571-108-06

OK ⁺
mEq/L

2.5 Ca^{2+}
mEq/L

PrismaSol BGK0/2.5
Rx only
Barcode
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	**A**	**B**
Calcium chloride • $2H_2O$	3.68	
Magnesium chloride • $6H_2O$	3.05	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		6.46
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for pH adjustment		

A
250 mL

B
4750 mL

After reconstitution, A + B								
	Calcium Ca^{2+}	**Magnesium Mg^{2+}**	**Sodium Na^{+}**	**Chloride Cl^{-}**	**Lactate $C_3H_5O_3^{-}$**	**Bicarbonate HCO_3^{-}**	**Potassium K^{+}**	**Dextrose**
mmol/L	**1.25**	**0.75**	**140**	**109.0**	**3.0**	**32**	**0**	**5.5**
mEq/L	**2.5**	**1.5**	**140**	**109.0**	**3.0**	**32**	**0**	**(100 mg/dL)**
• **Theoretical osmolarity: 292 mOsm/L pH: 7.0 – 8.5**								

Mix both compartments before use. See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]	Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is

	not made with natural rubber latex.

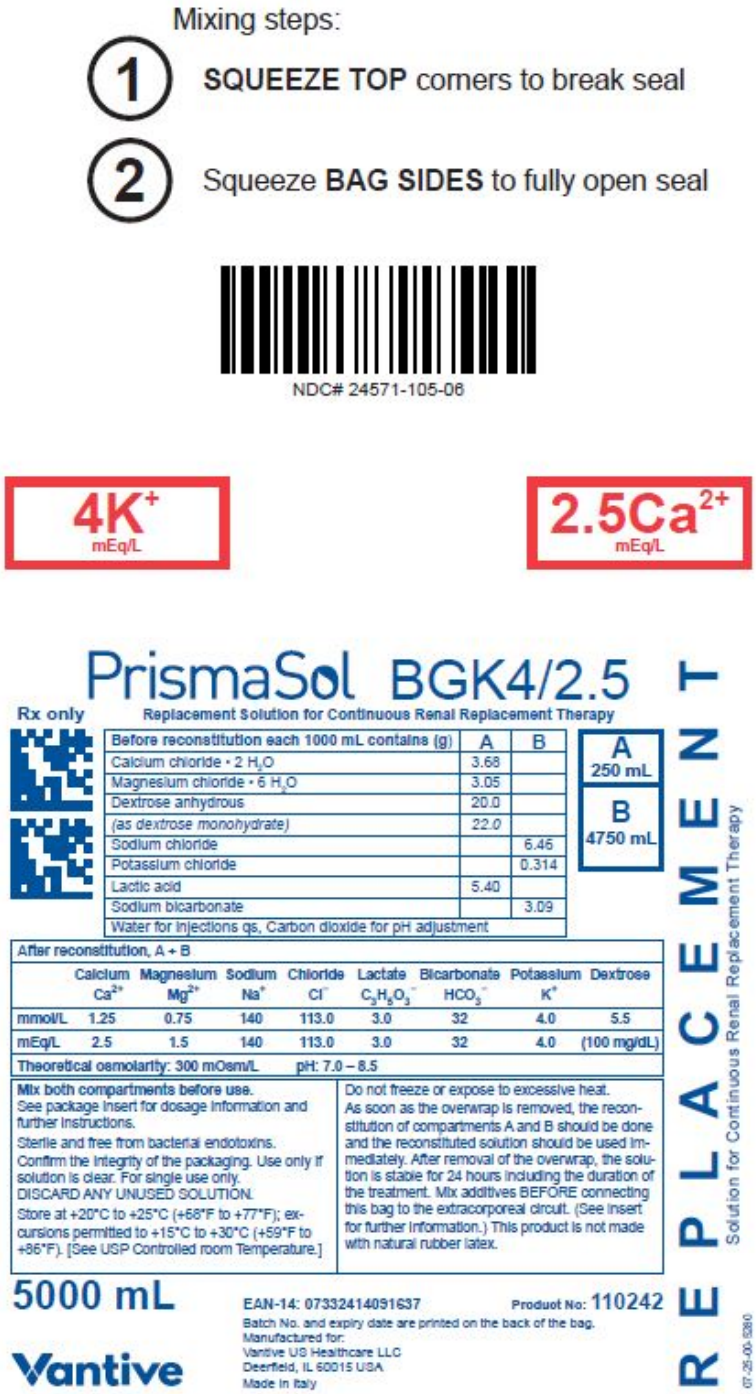
5000 mL
EAN-14: 07332414091613
Product # 110240

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5278



Mixing steps

① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Barcode
NDC# 24571-105-06

4K $^{+}$
mEq/L

2.5 Ca $^{2+}$
mEq/L

PrismaSol BGK4/2.5
Rx only

Barcode
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	**A**	**B**
Calcium chloride • $2H_2O$	3.68	
Magnesium chloride • $6H_2O$	3.05	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		6.46
Potassium chloride		0.314
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for pH adjustment		

A
250 mL

B
4750 mL

After reconstitution, A + B								
	Calcium Ca^{2+}	**Magnesium Mg^{2+}**	**Sodium Na^{+}**	**Chloride Cl^{-}**	**Lactate $C_3H_5O_3^{-}$**	**Bicarbonate HCO_3^{-}**	**Potassium K^{+}**	**Dextrose**
mmol/L	**1.25**	**0.75**	**140**	**113.0**	**3.0**	**32**	**4.0**	**5.5**
mEq/L	**2.5**	**1.5**	**140**	**113.0**	**3.0**	**32**	**4.0**	**(100 mg/dL)**
• **Theoretical osmolarity: 300 mOsm/L pH: 7.0 – 8.5**								

Mix both compartments before use. See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]	Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

5000 mL

EAN-14: 07332414091637
Product # 110242

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy
07-25-00-5280

Mixing steps:

1. **SQUEEZE TOP** corners to break seal
2. Squeeze **BAG SIDES** to fully open seal

NDC# 24571-103-06

2K⁺ mEq/L

3.5Ca²⁺ mEq/L

PrismaSol BGK2/3.5

Rx only

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	A	B
Calcium chloride • 2 H_2O	5.15	
Magnesium chloride • 6 H_2O	2.03	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	22.0	
Sodium chloride		6.46
Potassium chloride		0.157
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections qs, Carbon dioxide for pH adjustment		

A 250 mL

B 4750 mL

After reconstitution, A + B	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^{+}	Chloride Cl^{-}	Lactate $C_3H_6O_3^{-}$	Bicarbonate HCO_3^{-}	Potassium K^{+}	Dextrose
mmol/L	1.75	0.5	140	111.5	3.0	32	2.0	5.5
mEq/L	3.5	1.0	140	111.5	3.0	32	2.0	(100 mg/dL)

Theoretical osmolarity: 296 mOsm/L pH: 7.0 – 8.5

Mix both compartments before use.
See package insert for dosage information and further instructions.
Sterile and free from bacterial endotoxins.
Confirm the integrity of the packaging. Use only if solution is clear. For single use only.
DISCARD ANY UNUSED SOLUTION.
Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]

Do not freeze or expose to excessive heat.
As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

5000 mL

EAN-14: 07332414091644 Product No: 110243

Batch No. and expiry date are printed on the back of the bag.

Manufactured for:
Vantive US Healthcare LLC
Deerfield, IL 60015 USA
Made in Italy

Vantive

REPLACEMENT Solution for Continuous Renal Replacement Therapy

07-25-00-5281

Mixing steps

① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Barcode
NDC# 24571-103-06

2K ⁺

mEq/L

3.5 Ca^{2+}
mEq/L

PrismaSol BGK2/3.5
Rx only
Barcode
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	**A**	**B**
Calcium chloride • $2H_2O$	5.15	
Magnesium chloride • $6H_2O$	2.03	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		6.46
Potassium chloride		0.157
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for pH adjustment		

Rx only
A
250 mL

B
4750 mL

After reconstitution, A + B								
	Calcium Ca^{2+}	**Magnesium Mg^{2+}**	**Sodium Na^{+}**	**Chloride Cl^{-}**	**Lactate $C_3H_5O_3^{-}$**	**Bicarbonate HCO_3^{-}**	**Potassium K^{+}**	**Dextrose**
mmol/L	**1.75**	**0.5**	**140**	**111.5**	**3.0**	**32**	**2.0**	**5.5**
mEq/L	**3.5**	**1.0**	**140**	**111.5**	**3.0**	**32**	**2.0**	**(100 mg/dL)**
• **Theoretical osmolarity: 296 mOsm/L pH: 7.0 – 8.5**								

Mix both compartments before use. See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]	Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit.

	(See insert for further information.) This product is not made with natural rubber latex.

5000 mL
EAN-14: 07332414091644
Product # 110243

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy
07-25-00-5281

Mixing steps:

1. **SQUEEZE TOP** corners to break seal
2. Squeeze **BAG SIDES** to fully open seal

NDC# 24571-102-06

2K⁺ mEq/L

0Ca²⁺ mEq/L

PrismaSol BGK2/0

Rx only

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	A	B
Magnesium chloride • 6 H_2O	2.03	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		6.46
Potassium chloride		0.157
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections qs, Carbon dioxide for pH adjustment		

A 250 mL

B 4750 mL

After reconstitution, A + B	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^+	Chloride Cl^-	Lactate $C_3H_6O_3^-$	Bicarbonate HCO_3^-	Potassium K^+	Dextrose
mmol/L	0	0.5	140	108.0	3.0	32	2.0	5.5
mEq/L	0	1.0	140	108.0	3.0	32	2.0	(100 mg/dL)

Theoretical osmolarity: 291 mOsm/L pH: 7.0 – 8.5

Mix both compartments before use.
See package insert for dosage information and further instructions.
Sterile and free from bacterial endotoxins.
Confirm the integrity of the packaging. Use only if solution is clear. For single use only.
DISCARD ANY UNUSED SOLUTION.
Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]

Do not freeze or expose to excessive heat.
As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

5000 mL

Vantive

EAN-14: 07332414091651 Product No: 110244

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield, IL 60015 USA
Made in Italy

REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-5282

Mixing steps

① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Barcode
NDC# 24571-102-06

2K ⁺
mEq/L

0Ca^{2+}
mEq/L

PrismaSol BGK2/0
Rx only
Barcode
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	**A**	**B**
Magnesium chloride • 6H_2O	2.03	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		6.46
Potassium chloride		0.157
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for pH adjustment		

A
250 mL

B
4750 mL

After reconstitution, A + B								
	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^{+}	Chloride Cl^{-}	Lactate $C_3H_5O_3^{-}$	Bicarbonate HCO_3^{-}	Potassium K^{+}	Dextrose
mmol/L	0	0.5	140	108.0	3.0	32	2.0	5.5
mEq/L	0	1.0	140	108.0	3.0	32	2.0	(100 mg/dL)
• Theoretical osmolarity: 291 mOsm/L pH: 7.0 – 8.5								

Mix both compartments before use. See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]	Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is

	not made with natural rubber latex.

5000 mL
EAN-14: 07332414091651
Product # 110244

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5282

Mixing steps:

1. **SQUEEZE TOP** corners to break seal
2. Squeeze **BAG SIDES** to fully open seal

NDC# 24571-111-06

$4K^+$ mEq/L	Bicarbonate 22	$0Ca^{2+}$ mEq/L

PrismaSol B22GK4/0

Rx only

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	A	B
Magnesium chloride • 6 H_2O	3.05	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	22.0	
Sodium chloride		7.07
Potassium chloride		0.314
Lactic acid	5.40	
Sodium bicarbonate		2.21
Water for injections qs, Carbon dioxide for pH adjustment		

A 250 mL

B 4750 mL

After reconstitution, A + B

	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^+	Chloride Cl^-	Lactate $C_3H_5O_3^-$	Bicarbonate HCO_3^-	Potassium K^+	Dextrose
mmol/L	0	0.75	140	120.5	3.0	22	4.0	5.5
mEq/L	0	1.5	140	120.5	3.0	22	4.0	(100 mg/dL)

Theoretical osmolarity: 296 mOsm/L pH: 7.0 – 8.5

Mix both compartments before use.
See package insert for dosage information and further instructions.
Sterile and free from bacterial endotoxins.
Confirm the integrity of the packaging. Use only if solution is clear. For single use only.
DISCARD ANY UNUSED SOLUTION.
Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]

Do not freeze or expose to excessive heat.
As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

5000 mL

EAN-14: 07332414116781 Product No: 115001

Batch No. and expiry date are printed on the back of the bag.

Manufactured for:
Vantive US Healthcare LLC
Deerfield, IL 60015 USA
Made in Italy

Vantive

REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-5285

Mixing steps

① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Barcode
NDC# 24571-111-06

$4K^+$
mEq/L

-

Bicarbonate 22

0Ca $^{2+}$
mEq/L

PrismaSol B22GK4/0
Rx only
Barcode
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	**A**	**B**
Magnesium chloride • 6H $_2$O	3.05	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		7.07
Potassium chloride		0.314
Lactic acid	5.40	
Sodium bicarbonate		2.21
Water for injections q.s, Carbon dioxide for pH adjustment		

A
250 mL

B
4750 mL

After reconstitution, A + B								
	Calcium Ca^{2+}	**Magnesium Mg^{2+}**	**Sodium Na^{+}**	**Chloride Cl^{-}**	**Lactate $C_3H_5O_3^{-}$**	**Bicarbonate HCO_3^{-}**	**Potassium K^{+}**	**Dextrose**
mmol/L	**0**	**0.75**	**140**	**120.5**	**3.0**	**22**	**4.0**	**5.5**
mEq/L	**0**	**1.5**	**140**	**120.5**	**3.0**	**22**	**4.0**	**(100 mg/dL)**
• **Theoretical osmolarity: 296 mOsm/L pH: 7.0 – 8.5**								

Mix both compartments before use. See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]	Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert

	for further information.) This product is not made with natural rubber latex.

5000 mL
EAN-14: 07332414116781
Product # 115001

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5285

Mixing steps:

1. **SQUEEZE TOP** corners to break seal
2. Squeeze **BAG SIDES** to fully open seal

NDC# 24571-113-06

0 K^+ mEq/L

0 Ca^{2+} mEq/L

PrismaSol BK0/0/1.2

Rx only

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	A	B
Magnesium chloride • 6 H_2O	2.44	
Sodium chloride		6.46
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections qs, Carbon dioxide for pH adjustment		

A 250 mL

B 4750 mL

After reconstitution, A + B	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^+	Chloride Cl^-	Lactate $C_3H_5O_3^-$	Bicarbonate HCO_3^-	Potassium K^+	Dextrose
mmol/L	0	0.6	140	106.2	3.0	32	0	0
mEq/L	0	1.2	140	106.2	3.0	32	0	(0 mg/dL)

Theoretical osmolarity: 282 mOsm/L pH: 7.0 – 8.5

Mix both compartments before use.
See package insert for dosage information and further instructions.
Sterile and free from bacterial endotoxins.
Confirm the integrity of the packaging. Use only if solution is clear. For single use only.
DISCARD ANY UNUSED SOLUTION.
Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]

Do not freeze or expose to excessive heat.
As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

5000 mL

EAN-14: 07332414091309 Product No: 110239

Batch No. and expiry date are printed on the back of the bag.

Manufactured for:
Vantive US Healthcare LLC
Deerfield, IL 60015 USA
Made in Italy

Vantive

REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-5277

Mixing steps

① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Barcode
NDC# 24571-113-06

0K +
mEq/L

0Ca^{2+}
mEq/L

PrismaSol BK0/0/1.2
Rx only
Barcode
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	**A**	**B**
Magnesium chloride • 6H_2O	2.44	
Sodium chloride		6.46
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for pH adjustment		

A
250 mL

B
4750 mL

After reconstitution, A + B								
	Calcium Ca^{2+}	**Magnesium Mg^{2+}**	**Sodium Na^{+}**	**Chloride Cl^{-}**	**Lactate $C_3H_5O_3^{-}$**	**Bicarbonate HCO_3^{-}**	**Potassium K^{+}**	**Dextrose**
mmol/L	**0**	**0.6**	**140**	**106.2**	**3.0**	**32**	**0**	**0**
mEq/L	**0**	**1.2**	**140**	**106.2**	**3.0**	**32**	**0**	**(0 mg/dL)**
• **Theoretical osmolarity: 282 mOsm/L pH: 7.0 – 8.5**								

Mix both compartments before use. See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]	Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

5000 mL
EAN-14: 07332414091309
Product # 110239

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5277

Mixing steps:

1. **SQUEEZE TOP** corners to break seal
2. Squeeze **BAG SIDES** to fully open seal

NDC# 24571-114-06

4K+ mEq/L

0Ca2+ mEq/L

PrismaSol BGK4/0/1.2

Rx only

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	A	B
Magnesium chloride • 6 H_2O	2.44	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		6.46
Potassium chloride		0.314
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections qs, Carbon dioxide for pH adjustment		

A 250 mL

B 4750 mL

After reconstitution, A + B

	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^{+}	Chloride Cl^{-}	Lactate $C_3H_6O_3^{-}$	Bicarbonate HCO_3^{-}	Potassium K^{+}	Dextrose
mmol/L	0	0.6	140	110.2	3.0	32	4.0	5.5
mEq/L	0	1.2	140	110.2	3.0	32	4.0	(100 mg/dL)

Theoretical osmolarity: 295 mOsm/L **pH: 7.0 – 8.5**

Mix both compartments before use.
See package insert for dosage information and further instructions.
Sterile and free from bacterial endotoxins.
Confirm the integrity of the packaging. Use only if solution is clear. For single use only.
DISCARD ANY UNUSED SOLUTION.
Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]

Do not freeze or expose to excessive heat.
As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

5000 mL

EAN-14: 07332414091620 Product No: 110241

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield, IL 60015 USA
Made in Italy

Vantive

REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-5279

Mixing steps

① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Barcode
NDC# 24571-114-06

4K +

mEq/L

0Ca^{2+}
mEq/L

PrismaSol BGK4/0/1.2
Rx only
Barcode
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	**A**	**B**
Magnesium chloride • $6H_2O$	2.44	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	*22.0*	
Sodium chloride		6.46
Potassium chloride		0.314
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for pH adjustment		

A
250 mL

B
4750 mL

After reconstitution, A + B								
	Calcium Ca^{2+}	**Magnesium Mg^{2+}**	**Sodium Na^{+}**	**Chloride Cl^{-}**	**Lactate $C_3H_5O_3^{-}$**	**Bicarbonate HCO_3^{-}**	**Potassium K^{+}**	**Dextrose**
mmol/L	**0**	**0.6**	**140**	**110.2**	**3.0**	**32**	**4.0**	**5.5**
mEq/L	**0**	**1.2**	**140**	**110.2**	**3.0**	**32**	**4.0**	**(100 mg/dL)**
• **Theoretical osmolarity: 295 mOsm/L pH: 7.0 – 8.5**								

Mix both compartments before use. See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled room Temperature.]	Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert

	for further information.) This product is not made with natural rubber latex.

5000 mL
EAN-14: 07332414091620
Product # 110241

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5279

Mixing steps

1 **SQUEEZE TOP** corners to break seal

2 Squeeze **BAG SIDES** to fully open seal

Compartment B

NDC# 24571-116-06

4 K^+ mEq/L

1 Phosphate mmol/L

2.5 Ca^{2+} mEq/L

Phoxillum BK4/2.5

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution, each 1000 mL contains (g):	A	B
Calcium chloride • $2H_2O$	3.68	
Magnesium chloride • $6H_2O$	3.05	
Sodium chloride		6.34
Potassium chloride		0.314
Sodium bicarbonate		3.09
Dibasic sodium phosphate • $2H_2O$		0.187
Water for injections q.s		

Rx only

A 250 mL

B 4750 mL

After reconstitution, A + B

	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^+	Chloride Cl^-	Bicarbonate HCO_3^-	Potassium K^+	Phosphate HPO_4^{2-}	Dextrose
mmol/L	1.25	0.75	140	114.5	32	4.0	1	0
mEq/L	2.5	1.5	140	114.5	32	4.0	(1 mmol/L)	(0 mg/dL)

Theoretical osmolarity: 294 mOsm/L **pH: 7.0 – 8.5**

Mix both compartments before use.

See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled Room Temperature]. Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex. Carbon dioxide and diluted hydrochloric acid added for pH adjustment.

5000 mL

EAN-14: 07332414116040 **Product# 114905**

Batch No. and expiry date are printed on the back of the bag.

Manufactured for:
Vantive US Healthcare LLC
Deerfield, IL 60015 USA
Made in Italy

Vantive

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5283

Mixing steps
① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Compartment B

Barcode
NDC# 24571-116-06

4K $^{+}$
mEq/L

1 Phosphate
mmol/L

2.5 Ca $^{2+}$
mEq/L

Phoxillum BK4/2.5
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution, each 1000 mL contains (g):	A	B
Calcium chloride • 2H $_2$O	3.68	
Magnesium chloride • 6H $_2$O	3.05	
Sodium chloride		6.34
Potassium chloride		0.314
Sodium bicarbonate		3.09
Dibasic sodium phosphate • 2H $_2$O		0.187
Water for injections q.s		

Rx only
A
250 mL

B
4750 mL

After reconstitution, A + B

	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^{+}	Chloride Cl^{-}	Bicarbonate HCO_3^{-}	Potassium K^{+}	Phosphate HPO_4^{2-}	Dextrose
mmol/L	1.25	0.75	140	114.5	32	4.0	1	0
mEq/L	2.5	1.5	140	114.5	32	4.0	(1 mmol/L)	(0 mg/dL)

- Theoretical osmolarity: 294 mOsm/L pH: 7.0 – 8.5

Mix both compartments before use.
See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins.
Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UN-
USED SOLUTION. Store at +20ºC to +25ºC (+68ºF to +77ºF); excursions permitted to +15ºC - +30ºC (+59ºF
to +86ºF). [See USP Controlled Room Temperature]. Do not freeze or expose to excessive heat. As soon as the
overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted
solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for
further information.) This product is not made with natural rubber latex. Carbon dioxide and diluted hydrochloric

acid added for pH adjustment.

5000 mL
EAN-14: 07332414116040
Product # 114905

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5283

Mixing steps

1 **SQUEEZE TOP** corners to break seal

2 Squeeze **BAG SIDES** to fully open seal

Compartment B

NDC# 24571-117-06

4 K^+ mEq/L	0 Ca^{2+} mEq/L	22 Bicarbonate mEq/L	1 Phosphate mmol/L

Phoxillum B22K4/0

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution, each 1000 mL contains (g):	A	B
Magnesium chloride • $6H_2O$	3.05	
Sodium chloride		6.95
Potassium chloride		0.314
Sodium bicarbonate		2.21
Dibasic sodium phosphate • $2H_2O$		0.187
Water for injections q.s		

Rx only

A 250 mL

B 4750 mL

After reconstitution, A + B

	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^+	Chloride Cl^-	Bicarbonate HCO_3^-	Potassium K^+	Phosphate HPO_4^{2-}	Dextrose
mmol/L	0	0.75	140	122.0	22	4.0	1	0
mEq/L	0	1.5	140	122.0	22	4.0	(1 mmol/L)	(0 mg/dL)

Theoretical osmolarity: 290 mOsm/L **pH: 7.0 – 8.5**

Mix both compartments before use.
See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled Room Temperature]. Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the reconstituted solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex. Carbon dioxide and diluted hydrochloric acid added for pH adjustment.

5000 mL

EAN-14: 07332414116057 Product# 114906

Batch No. and expiry date are printed on the back of the bag.

Manufactured for:
Vantive US Healthcare LLC
Deerfield, IL 60015 USA
Made in Italy

Vantive

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5284

Mixing steps

① **SQUEEZE TOP**corners to break seal

②Squeeze **BAG SIDES**to fully open seal

Compartment B

Barcode
NDC# 24571-117-06

4K $^{+}$
mEq/L

0 Ca $^{2+}$
mEq/L

22 Bicarbonate
mEq/L

1 Phosphate
mmol/L

Phoxillum B22K4/0
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution, each 1000 mL contains (g):	A	B
Magnesium chloride • 6H $_2$O	3.05	
Sodium chloride		6.95
Potassium chloride		0.314
Sodium bicarbonate		2.21
Dibasic sodium phosphate • 2H $_2$O		0.187
Water for injections q.s		

Rx only
A
250 mL

B
4750 mL

After reconstitution, A + B

	Calcium Ca^{2+}	Magnesium Mg^{2+}	Sodium Na^{+}	Chloride Cl^{-}	Bicarbonate HCO_3^{-}	Potassium K^{+}	Phosphate HPO_4^{2-}	Dextrose
mmol/L	0	0.75	140	122.0	22	4.0	1	0
mEq/L	0	1.5	140	122.0	22	4.0	(1 mmol/L)	(0 mg/dL)

- Theoretical osmolarity: 290 mOsm/L pH: 7.0 – 8.5

Mix both compartments before use.

See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins.
Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UN-
USED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F
to +86°F). [See USP Controlled Room Temperature]. Do not freeze or expose to excessive heat. As soon as the
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should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration
of the treatment. Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for

further information.) This product is not made with natural rubber latex. Carbon dioxide and diluted hydrochloric
acid added for pH adjustment.

5000 mL
EAN-14: 07332414116057
Product # 114906

VANTIVE Logo

Batch No. and expiry date are printed on the back of the bag.
Manufactured for:
Vantive US Healthcare LLC
Deerfield IL 60015 USA
Made in Italy

REPLACEMENT
Solution for Continuous Renal Replacement Therapy

07-25-00-5284

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PRISMASOL and PHOXILLUM safely and effectively.
See full prescribing information for PRISMASOL and PHOXILLUM.

PRISMASOL renal replacement solution
PRISMASOL Initial U.S. Approval: 2006

PHOXILLUM renal replacement solution
PHOXILLUM Initial U.S. Approval: 2015

----------INDICATIONS AND USAGE----------
PRISMASOL and PHOXILLUM solutions are indicated:
- As a replacement solution in Continuous Renal Replacement Therapy (CRRT) and in case of drug poisoning when CRRT is used to remove dialyzable substances (1)

---------DOSAGE AND ADMINISTRATION---------
- Therapy must be individualized based on the patient's clinical condition, fluid, electrolyte, acid-base and glucose balance (2.2)
- Solution must be mixed prior to use (2.2)
- Use only with extracorporeal dialysis equipment appropriate for CRRT (2.3)

------DOSAGE FORMS AND STRENGTHS------
PRISMASOL and PHOXILLUM are available in multiple combinations of ingredients and in multiple variations of strengths. See full Prescribing Information for detailed descriptions of each formulation. (2, 3, 11)

----------CONTRAINDICATIONS----------
- Known hypersensitivities to PRISMASOL and PHOXILLUM solutions (4)

---------WARNINGS AND PRECAUTIONS---------
- Monitor hemodynamic status and fluid inputs and outputs, potassium, phosphorus, other electrolytes and acid-base balance. Abnormalities may be corrected by the use of appropriate formulations and dosage of PRISMASOL and PHOXILLUM solutions (5.1)
- Treatment may affect glucose levels. Monitor blood glucose levels. Antidiabetic therapy adjustment or other corrective measures may be required during treatment (5.2)

To report SUSPECTED ADVERSE REACTIONS, contact Vantive US Healthcare LLC at 1-855-857-0003 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Revised: 10/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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

Vantive

07-19-00-8247

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

PRISMASOL and PHOXILLUM solutions are indicated in pediatric and adult patients for use as a replacement solution in Continuous Renal Replacement Therapy (CRRT) to replace plasma volume removed by ultrafiltration and to correct electrolyte and acid-base imbalances. They may also be used in case of drug poisoning when CRRT is used to remove dialyzable substances.

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

Visually inspect PRISMASOL and PHOXILLUM for particulate matter and discoloration prior to administration.
Administration should only be under the direction of a physician competent in intensive care treatment including CRRT. Use only with extracorporeal dialysis equipment appropriate for CRRT.
The prepared solution is for single patient use only.
Aseptic technique should be used throughout administration to the patient.
Discard any unused solution.

2.2 Dosing Considerations

PRISMASOL replacement solutions contain 4 different combinations of active ingredients (7 different products with varying ingredient amounts). PHOXILLUM replacement solutions contain 2 different combinations of active ingredients (2 different products with varying ingredient amounts). PRISMASOL and PHOXILLUM are supplied in a two-compartment bag that must be mixed immediately prior to use *[see Dosage and Administration (2.3)]*:

- Small compartment A (250 mL) containing an electrolyte solution, and
- Large compartment B (4750 mL) containing the buffer solution.

See **Table 1** for the concentrations of the active ingredients (after mixing) in these 9 different replacement solutions (total volume is 5 Liters).

Table 1: Concentrations of Active Ingredients in the 7 PRISMASOL and 2 PHOXILLUM Replacement Solutions after Mixing

	Ca^{2+} mEq/L	HCO_3^- mEq/L	K^+ mEq/L	Mg^{2+} mEq/L	Na^+ mEq/L	HPO_4^{2-} mmol/L	Cl^- mEq/L	Lactate mEq/L	Dextrose mg/dL	Osmolarity mOsm/L
PRISMASOL Replacement Solutions										
BGK0/2.5	2.5	32	0	1.5	140	0	109	3	100	292
BGK4/2.5	2.5	32	4	1.5	140	0	113	3	100	300
BGK2/3.5	3.5	32	2	1	140	0	111.5	3	100	296
BGK2/0	0	32	2	1	140	0	108	3	100	291
B22GK4/0	0	22	4	1.5	140	0	120.5	3	100	296
BGK4/0/1.2	0	32	4	1.2	140	0	110.2	3	100	295
BK0/0/1.2	0	32	0	1.2	140	0	106.2	3	0	282
PHOXILLUM Replacement Solutions										
BK4/2.5	2.5	32	4	1.5	140	1	114.5	0	0	294
B22K4/0	0	22	4	1.5	140	1	122	0	0	290

Ca^{2+} = calcium, HCO_3^- = bicarbonate, K^+ = potassium, Mg^{2+} = magnesium, Na^+ = sodium, HPO_4^{2-} = phosphate, Cl^- = chloride; osmolarity is estimated

The mode of therapy, solute formulation, flow rates, and length of PRISMASOL and PHOXILLUM replacement therapy in CRRT should be established by a physician based on the patient's clinical condition, blood concentration of phosphate and other electrolytes, acid-base and glucose balance. Administer either PRISMASOL or PHOXILLUM into the extracorporeal circuit:

- Before (pre-dilution) the hemofilter or hemodiafilter,
- After (post-dilution) the hemofilter or hemodiafilter, or
- Before and after the hemofilter or hemodiafilter.

2.3 Preparing the Solution

Use only if the overwrap is not damaged, all seals are intact, peel seal is not broken, and the solution is clear.
The solution may be warmed to 37°C/98.6°F prior to removing the overwrap to enhance patient comfort. However, only dry heat should be used. Solutions should not be heated in water or in a microwave oven. After heating, verify that the solution remains clear and contains no particulate matter.
The solutions are supplied in two different two-compartment bags made of polyolefin with a peel seal separating compartment A and B (**see Figure 1**).

Follow the instructions below when connecting the solution bags for correct use of the access ports.

Instructions for preparing solutions supplied in a two-compartment, polyolefin bag with a peel seal:

Figure 1

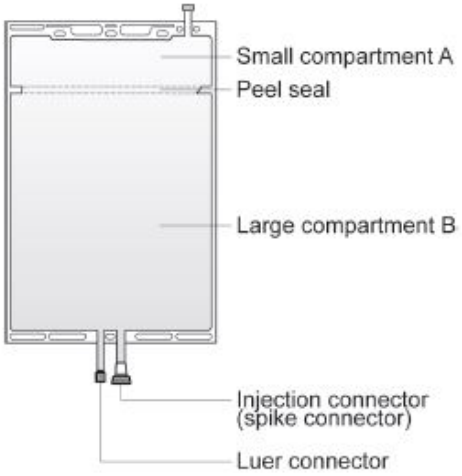
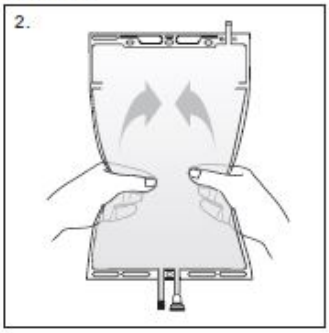


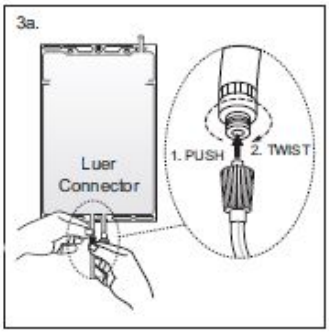
Figure 3



Step 2 Squeeze with both hands on the large compartment until the peel seal between the two compartments is entirely open. Shake gently to mix. (See **Figure 3** beside)

The solution is now ready to use and the bag can be hung on the equipment.

Figure 4a



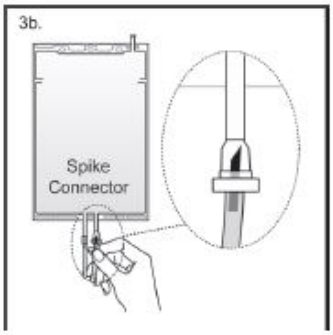
Step 3 The replacement line may be connected to the bag through either of the luer connector or the injection connector (spike connector).

Step 3a The luer connector is a needle-less and swabbable connector. Remove the cap with a twist and pull motion, and connect the male luer lock on the replacement line to the female luer receptor on the bag. (See **Figure 4a** beside)

Ensure that the connection is fully seated and tighten.
The connector is now open. Verify that the fluid is flowing freely during use.

When the replacement line is disconnected from the luer connector, the connector will close and the flow of the solution will stop.

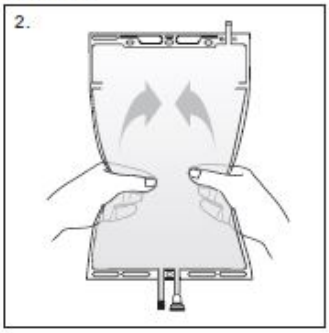
Figure 4b



Step 3b If the injection connector (spike connector) is used, first remove the snap-off cap. Then introduce the replacement line spike through the swabbable rubber septum of the bag connector. (See **Figure 4b** beside)

Ensure that the spike is fully inserted and verify that the fluid is flowing freely during use.

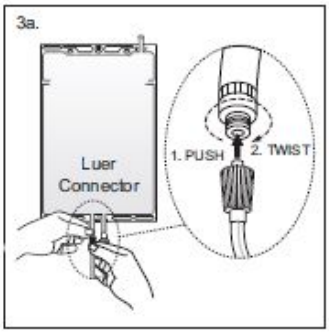
Figure 3



Step 2 Squeeze with both hands on the large compartment until the peel seal between the two compartments is entirely open. Shake gently to mix. (See **Figure 3** beside)

The solution is now ready to use and the bag can be hung on the equipment.

Figure 4a



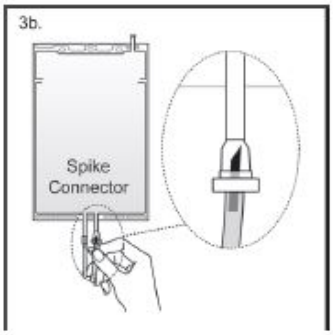
Step 3 The replacement line may be connected to the bag through either of the luer connector or the injection connector (spike connector).

Step 3a The luer connector is a needle-less and swabbable connector. Remove the cap with a twist and pull motion, and connect the male luer lock on the replacement line to the female luer receptor on the bag. (See **Figure 4a** beside)

Ensure that the connection is fully seated and tighten.
The connector is now open. Verify that the fluid is flowing freely during use.

When the replacement line is disconnected from the luer connector, the connector will close and the flow of the solution will stop.

Figure 4b



Step 3b If the injection connector (spike connector) is used, first remove the snap-off cap. Then introduce the replacement line spike through the swabbable rubber septum of the bag connector. (See **Figure 4b** beside)

Ensure that the spike is fully inserted and verify that the fluid is flowing freely during use.

2.4 Adding Drugs to the Solutions

After mixing, additional drugs may be added to the bag via injection connector (spike connector) in large compartment B. In general, administer drugs other than phosphate through a different access line.

When introducing drugs, use aseptic techniques and mix thoroughly prior to connecting the solution bag to the extracorporeal circuit.

Do not use if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals after addition of medication.

Phosphate: Up to 1.2 mmol/L of phosphate can be added to the bag as potassium phosphate or sodium phosphate. The total potassium concentration of PRISMASOL solution should not exceed 4 mEq/L. Use sodium phosphate to add phosphate if the total potassium concentration in PRISMASOL solution is 4 mEq/L.

PHOXILLUM Solutions:

Phosphate: Phosphate up to 0.2 mmol/L may be added to the solution. Use sodium phosphate if adding phosphate to bag. The total phosphate concentration should not exceed 1.2 mmol/L.

3 DOSAGE FORMS AND STRENGTHS

See **Table 1** for the concentrations of the active ingredients (after mixing) in these 9 different replacement solutions *[see Dosage and Administration (2.2)]*.

4 CONTRAINDICATIONS

PHOXILLUM and PRISMASOL replacement solutions are contraindicated in patients with known hypersensitivities to these products.

5 WARNINGS AND PRECAUTIONS

5.1 Electrolyte and Volume Abnormalities

PHOXILLUM and PRISMASOL solutions can affect electrolytes and volume and may result in hyperkalemia or hyperphosphatemia. Monitor hemodynamic status and fluid inputs and outputs, potassium, phosphorous, calcium, other electrolytes and acid-base balance throughout the procedure. Abnormalities may be corrected by changing the formulation of replacement solution and/or dialysate, supplementation, or adjusting flow rates appropriately [*see Dosage and Administration (2)*].

PHOXILLUM replacement solutions contain hydrogen phosphate, a weak acid that may increase the risk of metabolic acidosis.

5.2 Blood Glucose Abnormalities

The use of PRISMASOL and PHOXILLUM replacement solutions can affect blood glucose levels resulting in hypo- or hyper-glycemia depending upon the dextrose content of the replacement solution. Monitor blood glucose levels regularly. Patients may require initiation of or modification of antidiabetic therapy or othercorrective measures during treatment.

6 ADVERSE REACTIONS

The following adverse reactions have been identified during postapproval use with these or other similar products and therefore may occur with use of PHOXILLUM or PRISMASOL. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Metabolic acidosis
- Hypotension
- Acid-base disorders
- Electrolyte imbalance including calcium ionized increased (reported in PRISMASOL solutions containing calcium), hyperphosphatemia, and hypophosphatemia
- Fluid imbalance

7 DRUG INTERACTIONS

As with the use of other replacement solutions, blood concentrations of dialyzable drugs may be reduced by CRRT due to their removal by the hemofilter or hemodiafilter. The blood concentrations of certain drugs may need to be monitored and appropriate therapy implemented to correct for removal during treatment.

7.1 Citrate

When used as an anticoagulant, citrate contributes to the overall buffer load and can reduce plasma calcium levels. Select the PRISMASOL/PHOXILLUM formulation(s) accordingly.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

PRISMASOL and PHOXILLUM are pharmacologically inactive solutions. While there are no adequate and well controlled studies in pregnant women, appropriate administration of PRISMASOL and PHOXILLUM solutions 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 PRISMASOL and PHOXILLUM solutions.

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.

Clinical Considerations

Maintenance of normal acid-base balance is important for fetal well-being.

8.2 Lactation

Risk Summary

The components of PRISMASOL and PHOXILLUM solutions are excreted in human milk. Appropriate administration of PRISMASOL and PHOXILLUM 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 have been established based on published clinical data of CRRT replacement solutions with compositions similar to PRISMASOL and PHOXILLUM used in adults and two hemofiltration studies in pediatric patients, including a study of newborns to 17 years old.

8.5 Geriatric Use

The experience with PRISMASOL and PHOXILLUM solutions in geriatric patients has not identified novel concerns.

11 DESCRIPTION

PRISMASOL and PHOXILLUM solutions are clear, sterile, free of bacterial endotoxins and contain no bacteriostatic or antimicrobial agents. These solutions are used in Continuous Renal Replacement Therapies (CRRT) as a replacement solution in hemofiltration and hemodiafiltration. Depending on the product (see **Table 2**), the two compartments contain:

Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$).
Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$).
Sodium chloride, USP, is chemically designated NaCl.
Potassium chloride, USP, is chemically designated KCl.
Sodium bicarbonate, USP, is chemically designated $NaHCO_3$.
Dextrose, USP, is chemically designated D-Glucose anhydrous ($C_6H_{12}O_6$) or D-Glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$).
Lactic acid, USP, is chemically designated $CH_3CH(OH)COOH$.
Dibasic sodium phosphate, USP, is chemically designated as disodium hydrogen phosphate, dihydrate ($Na_2HPO_4 \cdot 2H_2O$)

Table 2: Compartment Composition (Before Mixing)

	Compartment A (g/L)				Compartment B (g/L)			
	Calcium Chloride • $2H_2O$	Magnesium Chloride • $6H_2O$	Dextrose anhydrous (as monohydrate)	Lactic Acid	Sodium Chloride	Sodium bicarbonate	Potassium Chloride	Sodium Phosphate • $2H_2O$
PRISMASOL SOLUTIONS								
BGK 0/2.5	3.68	3.05	20 (22)	5.40	6.46	3.09	0	0
BGK 4/2.5	3.68	3.05	20 (22)	5.40	6.46	3.09	0.314	0
BGK 2/3.5	5.15	2.03	20 (22)	5.40	6.46	3.09	0.157	0
BGK 2/0	0	2.03	20 (22)	5.40	6.46	3.09	0.157	0
B22GK 4/0	0	3.05	20 (22)	5.40	7.07	2.21	0.314	0
BK 0/0/1.2	0	2.44	0 (0)	5.40	6.46	3.09	0	0
BGK 4/0/1.2	0	2.44	20 (22)	5.40	6.46	3.09	0.314	0
PHOXILLUM SOLUTIONS								
BK 4/2.5	3.68	3.05	0 (0)	0	6.34	3.09	0.314	0.187
B22K 4/0	0	3.05	0 (0)	0	6.95	2.21	0.314	0.187

The pH of the final solution is in the range of 7.0 to 8.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

PRISMASOL and PHOXILLUM solutions are pharmacologically inactive. The electrolyte concentrations in the solutions are chosen to restore plasma levels to clinically desired concentrations or maintain plasma levels at the desired concentrations.

PRISMASOL and PHOXILLUM solutions are used as replacement solution to replace water and electrolytes removed during hemofiltration and hemodiafiltration. Bicarbonate (or precursor lactate) in the solution is used as an alkalinizing buffer to restore acid-base balance to a clinically desirable level.

12.3 Pharmacokinetics

The distribution of electrolytes, bicarbonate, and dextrose is determined by the patient's clinical condition, metabolic status, and residual renal function.

The elimination and replacement of water, electrolytes and buffer depend on the patient's electrolyte and acid-base balance, metabolic status, residual renal function and ongoing physiologic losses through intestinal, respiratory and cutaneous routes.

16 HOW SUPPLIED/STORAGE AND HANDLING

PRISMASOL and PHOXILLUM solutions are supplied in a two-compartment bag made of polyolefin. The 5000 mL bag is composed of a small compartment (250 mL) and a large compartment (4750 mL). The two compartments are separated by a peel seal.

The bag is overwrapped with a transparent overwrap. See **Table 2** for the concentrations of the active ingredients in each compartment for each product *[see Description (11)]*.

Container	Fill Volume	NDC
PRISMASOL Solutions		
PRISMASOL BGK0/2.5	5000 mL	24571-108-06
PRISMASOL BGK4/2.5	5000 mL	24571-105-06
PRISMASOL BGK2/3.5	5000 mL	24571-103-06
PRISMASOL BGK2/0	5000 mL	24571-102-06
PRISMASOL B22GK4/0	5000 mL	24571-111-06
PRISMASOL BK0/0/1.2	5000 mL	24571-113-06
PRISMASOL BGK4/0/1.2	5000 mL	24571-114-06
PHOXILLUM Solutions		
PHOXILLUM BK4/2.5	5000 mL	24571-116-06
PHOXILLUM B22K4/0	5000 mL	24571-117-06

Not all formulations may be marketed.

Storage conditions
Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). *[See USP Controlled Room Temperature]*

Do not freeze or expose to excessive heat. Do not use if precipitate has formed or if container seals have been damaged.

Manufactured for:
Vantive US Healthcare LLC
One Baxter Parkway
Deerfield, Illinois 60015

07-19-00-6103

IFU Label

HIGHLIGHTS OF PRESCRIBING INFORMATION **These highlights do not include all the information needed to use PRISMASOL and PHOXILLUM safely and effectively.** **See full prescribing information for PRISMASOL and PHOXILLUM.** **PRISMASOL renal replacement solution PRISMASOL Initial U.S. Approval: 2006** **PHOXILLUM renal replacement solution PHOXILLUM Initial U.S. Approval: 2015** **----------INDICATIONS AND USAGE----------** PRISMASOL and PHOXILLUM solutions are indicated:	---------- **DOSAGE FORMS AND STRENGTHS**---------- PRISMASOL and PHOXILLUM are available in multiple combinations of ingredients and in multiple variations of strengths. See full Prescribing Information for detailed descriptions of each formulation. (2, 3, 11) ---------- **CONTRAINDICATIONS**---------- • Known hypersensitivities to PRISMASOL and PHOXILLUM solutions (4) --------- **WARNINGS AND PRECAUTIONS**---------- • Monitor hemodynamic status and fluid inputs and outputs, potassium, phosphorus, other electrolytes and acid-base balance. Abnormalities may be corrected by the use of appropriate formulations and dosage of PRISMASOL and PHOXILLUM solutions (5.1) • Treatment may affect glucose levels.

• As a replacement solution in Continuous Renal Replacement Therapy (CRRT) and in case of drug poisoning when CRRT is used to remove dialyzable substances (1) **---------DOSAGE AND ADMINISTRATION---------** • Therapy must be individualized based on the patient's clinical condition, fluid, electrolyte, acid-base and glucose balance (2.2) • Solution must be mixed prior to use (2.2) • Use only with extracorporeal dialysis equipment appropriate for CRRT (2.3)	Monitor blood glucose levels. Antidiabetic therapy adjustment or other corrective measures may be required during treatment (5.2) **To report SUSPECTED ADVERSE REACTIONS, contact Vantive US Healthcare LLC at 1-855-857-0003 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch** **Revised: 10/2024**

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

PRISMASOL and PHOXILLUM solutions are indicated in pediatric and adult patients for use as a replacement solution in Continuous Renal Replacement Therapy (CRRT) to replace plasma volume removed by ultrafiltration and to correct electrolyte and acid-base imbalances. They may also be used in case of drug poisoning when CRRT is used to remove dialyzable substances.

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

Visually inspect PRISMASOL and PHOXILLUM for particulate matter and discoloration prior to administration. Administration should only be under the direction of a physician competent in intensive care treatment including CRRT. Use only with extracorporeal dialysis equipment appropriate for CRRT. The prepared solution is for single patient use only. Aseptic technique should be used throughout administration to the patient. Discard any unused solution.

2.2 Dosing Considerations

PRISMASOL replacement solutions contain 4 different combinations of active ingredients (7 different products with varying ingredient amounts). PHOXILLUM replacement solutions contain 2 different combinations of active ingredients (2 different products with varying ingredient amounts). PRISMASOL and PHOXILLUM are supplied in a two-compartment bag that must be mixed immediately prior to use *[see Dosage and Administration (2.3)]:*

- Small compartment A (250 mL) containing an electrolyte solution, and
- Large compartment B (4750 mL) containing the buffer solution.

See **Table 1**for the concentrations of the active ingredients (after mixing) in these 9 different replacement solutions (total volume is 5 Liters).

Table 1: Concentrations of Active Ingredients in the 7 PRISMASOL and 2 PHOXILLUM Replacement Solutions after Mixing

	Ca^{2+} mEq/L	HCO_3^- mEq/L	K^+ mEq/L	Mg^{2+} mEq/L	Na^+ mEq/L	HPO_4^{2-} mmol/L	Cl^- mEq/L	Lactate mEq/L	Dextrose mg/dL	Osmolarity mOsm/L
PRISMASOL Replacement Solutions										
BGK0/2.5	2.5	32	0	1.5	140	0	109	3	100	292
BGK4/2.5	2.5	32	4	1.5	140	0	113	3	100	300
BGK2/3.5	3.5	32	2	1	140	0	111.5	3	100	296
BGK2/0	0	32	2	1	140	0	108	3	100	291
B22GK4/0	0	22	4	1.5	140	0	120.5	3	100	296
BGK4/0/1.2	0	32	4	1.2	140	0	110.2	3	100	295
BK0/0/1.2	0	32	0	1.2	140	0	106.2	3	0	282
PHOXILLUM Replacement Solutions										
BK4/2.5	2.5	32	4	1.5	140	1	114.5	0	0	294
B22K4/0	0	22	4	1.5	140	1	122	0	0	290

Ca^{2+} = calcium, HCO_3^- = bicarbonate, K^+ = potassium, Mg^{2+} = magnesium, Na^+ = sodium, HPO_4^{2-} = phosphate, Cl^- = chloride; osmolarity is estimated

The mode of therapy, solute formulation, flow rates, and length of PRISMASOL and PHOXILLUM replacement therapy in CRRT should be established by a physician based on the patient's clinical condition, blood concentration of phosphate and other electrolytes, acid-base and glucose balance. Administer either PRISMASOL or PHOXILLUM into the extracorporeal circuit:

- Before (pre-dilution) the hemofilter or hemodiafilter,
- After (post-dilution) the hemofilter or hemodiafilter, or
- Before and after the hemofilter or hemodiafilter.

2.3 Preparing the Solution

Use only if the overwrap is not damaged, all seals are intact, peel seal is not broken, and the solution is clear. The solution may be warmed to 37°C/98.6°F prior to removing the overwrap to enhance patient comfort. However, only dry heat should be used. Solutions should not be heated in water or in a microwave oven. After heating, verify that the solution remains clear and contains no particulate matter.

The solutions are supplied in two different two-compartment bags made of polyolefin with a peel seal separating compartment A and B (**see Figure 1**).

Follow the instructions below when connecting the solution bags for correct use of the

access ports.

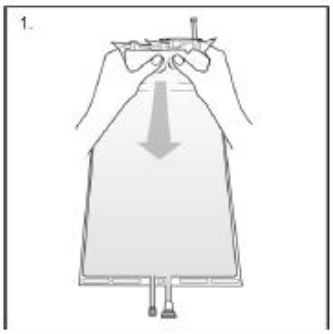
Figure 2	
	**Step 1** Immediately before use, remove the overwrap from the bag and mix the solutions in the two different compartments. After removing the overwrap, inspect the bag for leakage by pressing firmly on the bag. Discard the bag if any leakage is detected since sterility cannot be assured. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the mixed solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Hold the small compartment with both hands and squeeze it until an opening is created in the peel seal. (See **Figure 2** beside)

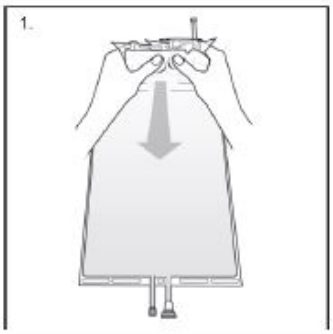
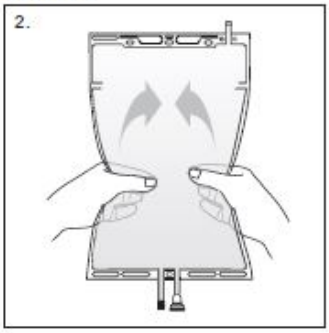
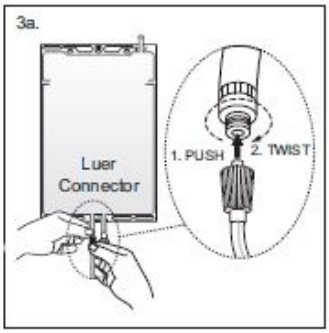
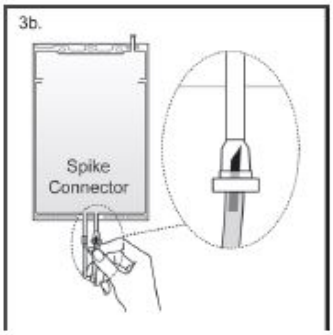
Figure 2	
	**Step 1** Immediately before use, remove the overwrap from the bag and mix the solutions in the two different compartments. After removing the overwrap, inspect the bag for leakage by pressing firmly on the bag. Discard the bag if any leakage is detected since sterility cannot be assured. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the mixed solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Hold the small compartment with both hands and squeeze it until an opening is created in the peel seal. (See **Figure 2** beside)

Figure 3 	**Step 2** Squeeze with both hands on the large compartment until the peel seal between the two compartments is entirely open. Shake gently to mix. (See **Figure 3** beside) The solution is now ready to use and the bag can be hung on the equipment.
Figure 4a 	**Step 3** The replacement line may be connected to the bag through either of the luer connector or the injection connector (spike connector). **Step 3a** The luer connector is a needle-less and swabbable connector. Remove the cap with a twist and pull motion, and connect the male luer lock on the replacement line to the female luer receptor on the bag. (See **Figure 4a** beside) Ensure that the connection is fully seated and tighten. The connector is now open. Verify that the fluid is flowing freely during use. When the replacement line is disconnected from the luer connector, the connector will close and the flow of the solution will stop.
Figure 4b 	**Step 3b** If the injection connector (spike connector) is used, first remove the snap-off cap. Then introduce the replacement line spike through the swabbable rubber septum of the bag connector. (See **Figure 4b** beside) Ensure that the spike is fully inserted and verify that the fluid is flowing freely during use.

2.4 Adding Drugs to the Solutions

After mixing, additional drugs may be added to the bag via injection connector (spike connector) in large compartment B. In general, administer drugs other than phosphate through a different access line.

When introducing drugs, use aseptic techniques and mix thoroughly prior to connecting the solution bag to the extracorporeal circuit.

Do not use if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals after addition of medication.

Phosphate:Up to 1.2 mmol/L of phosphate can be added to the bag as potassium phosphate or sodium phosphate. The total potassium concentration of PRISMASOL solution should not exceed 4 mEq/L.
Use sodium phosphate to add phosphate if the total potassium concentration in PRISMASOL solution is 4 mEq/L.

PHOXILLUM Solutions:
*Phosphate:*Phosphate up to 0.2 mmol/L may be added to the solution. Use sodium phosphate if adding phosphate to bag. The total phosphate concentration should not

exceed 1.2 mmol/L.

3 DOSAGE FORMS AND STRENGTHS

See **Table 1**for the concentrations of the active ingredients (after mixing) in these 9 different replacement solutions *[see Dosage and Administration (2.2)].*

4 CONTRAINDICATIONS

PHOXILLUM and PRISMASOL replacement solutions are contraindicated in patients with known hypersensitivities to these products.

5 WARNINGS AND PRECAUTIONS

5.1 Electrolyte and Volume Abnormalities

PHOXILLUM and PRISMASOL solutions can affect electrolytes and volume and may result in hyperkalemia or hyperphosphatemia. Monitor hemodynamic status and fluid inputs and outputs, potassium, phosphorous, calcium, other electrolytes and acid-base balance throughout the procedure. Abnormalities may be corrected by changing the formulation of replacement solution and/or dialysate, supplementation, or adjusting flow rates appropriately *[see Dosage and Administration (2)].*

PHOXILLUM replacement solutions contain hydrogen phosphate, a weak acid that may increase the risk of metabolic acidosis.

5.2 Blood Glucose Abnormalities

The use of PRISMASOL and PHOXILLUM replacement solutions can affect blood glucose levels resulting in hypo- or hyper-glycemia depending upon the dextrose content of the replacement solution. Monitor blood glucose levels regularly. Patients may require initiation of or modification of antidiabetic therapy or othercorrective measures during treatment.

6 ADVERSE REACTIONS

The following adverse reactions have been identified during postapproval use with these or other similar products and therefore may occur with use of PHOXILLUM or PRISMASOL. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Metabolic acidosis
- Hypotension
- Acid-base disorders
- Electrolyte imbalance including calcium ionized increased (reported in PRISMASOL solutions containing calcium), hyperphosphatemia, and hypophosphatemia
- Fluid imbalance

7 DRUG INTERACTIONS

As with the use of other replacement solutions, blood concentrations of dialyzable drugs may be reduced by CRRT due to their removal by the hemofilter or hemodiafilter. The blood concentrations of certain drugs may need to be monitored and appropriate therapy implemented to correct for removal during treatment.

7.1 Citrate

When used as an anticoagulant, citrate contributes to the overall buffer load and can reduce plasma calcium levels. Select the PRISMASOL/PHOXILLUM formulation(s) accordingly.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

PRISMASOL and PHOXILLUM are pharmacologically inactive solutions. While there are no adequate and well controlled studies in pregnant women, appropriate administration of PRISMASOL and PHOXILLUM solutions 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 PRISMASOL and PHOXILLUM solutions.

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.

Clinical Considerations
Maintenance of normal acid-base balance is important for fetal well-being.

8.2 Lactation
Risk Summary
The components of PRISMASOL and PHOXILLUM solutions are excreted in human milk. Appropriate administration of PRISMASOL and PHOXILLUM 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 have been established based on published clinical data of CRRT replacement solutions with compositions similar to PRISMASOL and PHOXILLUM used in adults and two hemofiltration studies in pediatric patients, including a study of newborns to 17 years old.

8.5 Geriatric Use
The experience with PRISMASOL and PHOXILLUM solutions in geriatric patients has not identified novel concerns.

11 DESCRIPTION
PRISMASOL and PHOXILLUM solutions are clear, sterile, free of bacterial endotoxins and contain no bacteriostatic or antimicrobial agents. These solutions are used in Continuous Renal Replacement Therapies (CRRT) as a replacement solution in hemofiltration and hemodiafiltration. Depending on the product (see **Table 2**), the two compartments contain:

Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$).
Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$).
Sodium chloride, USP, is chemically designated NaCl.
Potassium chloride, USP, is chemically designated KCl.
Sodium bicarbonate, USP, is chemically designated $NaHCO_3$.
Dextrose, USP, is chemically designated D-Glucose anhydrous ($C_6H_{12}O_6$) or D-Glucose monohydrate ($C_6H_{12}O6 \cdot H_2O$).
Lactic acid, USP, is chemically designated $CH_3CH(OH)COOH$.
Dibasic sodium phosphate, USP, is chemically designated as disodium hydrogen phosphate, dihydrate ($Na_2HPO_4 \cdot 2H_2O$)

Table 2: Compartment Composition (Before Mixing)

	Compartment A (g/L)				Compartment B (g/L)			
	Calcium Chloride • $2H_2O$	Magnesium Chloride • $6H_2O$	Dextrose anhydrous (as monohydrate)	Lactic Acid	Sodium Chloride	Sodium bicarbonate	Potassium Chloride	Sodium Phosphate • $2H_2O$
PRISMASOL SOLUTIONS								
BGK 0/2.5	3.68	3.05	20 (22)	5.40	6.46	3.09	0	0
BGK 4/2.5	3.68	3.05	20 (22)	5.40	6.46	3.09	0.314	0
BGK 2/3.5	5.15	2.03	20 (22)	5.40	6.46	3.09	0.157	0
BGK 2/0	0	2.03	20 (22)	5.40	6.46	3.09	0.157	0
B22GK 4/0	0	3.05	20 (22)	5.40	7.07	2.21	0.314	0
BK 0/0/1.2	0	2.44	0 (0)	5.40	6.46	3.09	0	0
BGK 4/0/1.2	0	2.44	20 (22)	5.40	6.46	3.09	0.314	0
PHOXILLUM SOLUTIONS								
BK 4/2.5	3.68	3.05	0 (0)	0	6.34	3.09	0.314	0.187
B22K 4/0	0	3.05	0 (0)	0	6.95	2.21	0.314	0.187

The pH of the final solution is in the range of 7.0 to 8.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

PRISMASOL and PHOXILLUM solutions are pharmacologically inactive. The electrolyte concentrations in the solutions are chosen to restore plasma levels to clinically desired concentrations or maintain plasma levels at the desired concentrations.

PRISMASOL and PHOXILLUM solutions are used as replacement solution to replace water and electrolytes removed during hemofiltration and hemodiafiltration. Bicarbonate (or precursor lactate) in the solution is used as an alkalinizing buffer to restore acid-base balance to a clinically desirable level.

12.3 Pharmacokinetics

The distribution of electrolytes, bicarbonate, and dextrose is determined by the patient's clinical condition, metabolic status, and residual renal function.

The elimination and replacement of water, electrolytes and buffer depend on the patient's electrolyte and acid-base balance, metabolic status, residual renal function and ongoing physiologic losses through intestinal, respiratory and cutaneous routes.

16 HOW SUPPLIED/STORAGE AND HANDLING

PRISMASOL and PHOXILLUM solutions are supplied in a two-compartment bag made of polyolefin. The 5000 mL bag is composed of a small compartment (250 mL) and a large compartment (4750 mL). The two compartments are separated by a peel seal.

The bag is overwrapped with a transparent overwrap. See **Table 2** for the concentrations of the active ingredients in each compartment for each product *[see Description (11)]*.

The pH of the final solution is in the range of 7.0 to 8.5.

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Container	Fill Volume	NDC
PRISMASOL Solutions		
PRISMASOL BGK0/2.5	5000 mL	24571-108-06
PRISMASOL BGK4/2.5	5000 mL	24571-105-06
PRISMASOL BGK2/3.5	5000 mL	24571-103-06
PRISMASOL BGK2/0	5000 mL	24571-102-06
PRISMASOL B22GK4/0	5000 mL	24571-111-06
PRISMASOL BK0/0/1.2	5000 mL	24571-113-06
PRISMASOL BGK4/0/1.2	5000 mL	24571-114-06
PHOXILLUM Solutions		
PHOXILLUM BK4/2.5	5000 mL	24571-116-06
PHOXILLUM B22K4/0	5000 mL	24571-117-06

Not all formulations may be marketed.

Storage conditions

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15ºC to 30ºC (59ºF to 86ºF). *[See USP Controlled Room Temperature]*

Do not freeze or expose to excessive heat. Do not use if precipitate has formed or if container seals have been damaged.

Manufactured for:

Vantive US Healthcare LLC
One Baxter Parkway
Deerfield, Illinois 60015

07-19-00-6103

PRISMASOL BGK0/2.5

calcium chloride, magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, and sodium bicarbonate injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-108
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	3.68 g in 1 L
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	3.05 g in 1 L
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	ANHYDROUS DEXTROSE	20 g in 1 L
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	5.4 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:24571-108-06	2 in 1 CASE	10/25/2006	
1		5 L 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	NDA021703	10/25/2006	

PRISMASOL BGK4/2.5

calcium chloride, magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-105
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	3.68 g in 1 L
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	3.05 g in 1 L

ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	ANHYDROUS DEXTROSE	20 g in 1 L
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	5.4 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24571-105-06	2 in 1 CASE	10/25/2006	
1		5 L 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	NDA021703	10/25/2006	

PRISMASOL BGK2/3.5

calcium chloride, magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-103
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	5.15 g in 1 L
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	2.03 g in 1 L
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	ANHYDROUS DEXTROSE	20 g in 1 L
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	5.4 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L

POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.157 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24571-103-06	2 in 1 CASE	10/25/2006	
1		5 L 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	NDA021703	10/25/2006	

PRISMASOL BGK2/0

magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-102
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	2.03 g in 1 L
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	ANHYDROUS DEXTROSE	20 g in 1 L
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	5.4 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.157 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24571-102-06	2 in 1 CASE	10/25/2006	
1		5 L 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	NDA021703	10/25/2006	

PRISMASOL B22GK4/0

magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-111
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	3.05 g in 1 L
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	ANHYDROUS DEXTROSE	20 g in 1 L
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	5.4 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	7.07 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	2.21 g in 1 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24571-111-06	2 in 1 CASE	10/10/2008	
1		5 L 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	NDA021703	10/25/2006	

PRISMASOL BK0/0/1.2

magnesium chloride, lactic acid, sodium chloride, and sodium bicarbonate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-113
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	2.44 g in 1 L
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	5.4 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24571-113-06	2 in 1 CASE	10/10/2008	
1		5 L 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	NDA021703	10/25/2006	

PRISMASOL BGK4/0/1.2

magnesium chloride, dextrose anhydrous, lactic acid, sodium chloride, sodium bicarbonate, and potassium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-114
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	2.44 g in 1 L
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	ANHYDROUS DEXTROSE	20 g in 1 L
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	5.4 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:24571-114-06	2 in 1 CASE	10/10/2008	
1		5 L 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	NDA021703	10/25/2006	

PHOXILLUM BK4/2.5

calcium chloride, magnesium chloride, sodium chloride, sodium bicarbonate, potassium chloride, and sodium phosphate dibasic dihydrate injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-116
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	3.68 g in 1 L
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	3.05 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.34 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC	0.187 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24571-116-06	2 in 1 CASE	01/13/2015	
1		5 L 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	NDA207026	01/13/2015	

PHOXILLUM B22K4/0

magnesium chloride, sodium chloride, sodium bicarbonate, potassium chloride, and sodium phosphate dibasic dihydrate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24571-117
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	3.05 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.95 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	2.21 g in 1 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L

SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC	0.187 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBON DIOXIDE (UNII: 142M471B3J)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24571-117-06	2 in 1 CASE	01/13/2015	
1		5 L 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	NDA207026	01/13/2015	

Labeler - Vantive US Healthcare LLC (119181963)

Registrant - Vantive US Healthcare LLC (119181963)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter, S.A. de C.V.		810432484	analysis(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117) , label(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117) , manufacture(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117) , pack(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117) , sterilize(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117)

Establishment

Name	Address	ID/FEI	Business Operations
Bieffe Medital S.p.A.		437668413	analysis(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117) , manufacture(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117) , label(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117) , pack(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117) , sterilize(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117)