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 monohydrate, 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

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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) • Monitor hemodynamic status and fluid inputs and outputs, potassium, phosphorus, other electrolytes

 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 Baxter Healthcare Corporation at 1-866-888-2472 or FDA at 1-800-FDA-1088 or <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a>

#### **FULL PRESCRIBING INFORMATION: CONTENTS\***

### **1 INDICATIONS AND USAGE**

### **2 DOSAGE AND ADMINISTRATION**

- 2.1 Administration Instructions
- 2.2 Dosing Considerations
- 2.3 Preparing the Solution
- 2.4 Adding Drugs to the Solutions

#### **3 DOSAGE FORMS AND STRENGTHS**

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# **11 DESCRIPTION**

#### **12 CLINICAL PHARMACOLOGY**

- 12.1 Mechanism of Action
- 12.3 Pharmacokinetics

#### **16 HOW SUPPLIED/STORAGE AND HANDLING**

\* 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 acidbase 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).

				•						
	Ca 2+ mEq/L	HCO 3 <sup>-</sup> mEq/L	K <sup>+</sup> mEq/L		Na + mEq/L	HPO 4 <sup>2-</sup> mmol/L	mEq/L		Dextrose mg/dL	Osmolarity mOsm/L
PRISMASC	)L Re	placer	nent	Soluti	ons	1			I	L
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
PHOXILLUN	1 Repla	aceme	nt Solı	utions						
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
$C_2 2 + - c_2 k$	-ium L	- 021	- hica	rhono	$+ $ $\vee +$	- noto	ccium	$M_{\alpha} 2 + -$	magnociur	n N n + -

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

Ca <sup>2+</sup> = calcium, HCO  $_3^-$  = bicarbonate, K <sup>+</sup> = potassium, Mg <sup>2+</sup> = magnesium, Na <sup>+</sup> = 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:

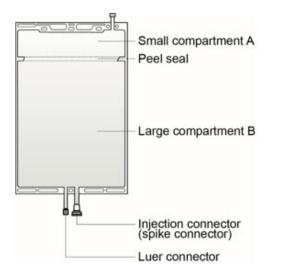
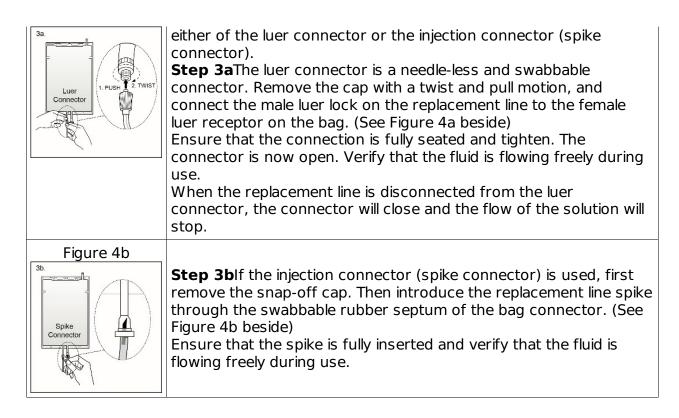


Figure 2	<b>Step 1</b> Immediately before use, remove the overwrap from the bag and mix the solutions in the two different compartments. After removing the overwrap, inspect the bag for leakage by pressing firmly on the bag. Discard the bag if any leakage is detected since sterility cannot be assured. 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
Figure 3	an opening is created in the peel seal. (See Figure 2beside)  Step 2Squeeze 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	<b>Step 3</b> The replacement line may be connected to the bag through



#### 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 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  $_2$ • 2H  $_2$ O).

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate (MgCl  $_2$ • 6H  $_2$ O).

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  $_6$ H  $_{12}$ O  $_6$ ) or D-Glucose monohydrate (C  $_6$ H  $_{12}$ O  $_6$ • H  $_2$ O).

Lactic acid, USP, is chemically designated CH <sub>3</sub>CH(OH)COOH.

Dibasic sodium phosphate, USP, is chemically designated as disodium hydrogen phosphate, dihydrate (Na  $_2$ HPO  $_4$ • 2H  $_2$ O)

		Compartm	ent A (g/L)		Compartment B (g/L)				
		Magnesium Chloride 6H <sub>2</sub> O	annyarous	Acid	Sodium Chloride	Sodium bicarbonate	Potassium Chloride	Sodium Phosphate · 2H <sub>2</sub> 0	
PRISM	ASOL SO	LUTIONS		1		1	I	<u>I</u>	
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	
PHOXI	LLUM SO	LUTIONS							
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	

Table 2 - Compartment Composition (Before Mixing)

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 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]

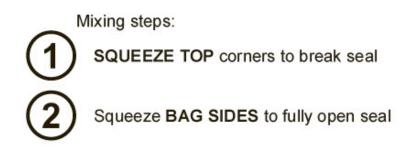
Do not freeze or expose to excessive heat. Do not use if precipitate has formed or if container seals have been damaged.

Manufactured for: Baxter Healthcare Corporation One Baxter Parkway Deerfield, Illinois 60015

07-19-00-6103

Baxter, Gambro, Phoxillum and PrismaSol are trademarks of Baxter International Inc., or its subsidiaries

#### Package/Label Display Panel







2 EC-2+
2.5Ca
mEq/L
 10 Bill

07-25-00-0110



PrismaSol BG Replacement Solution for Continuous Renal	-	_		
Before reconstitution each 1000 mL contains (g)	A	в		
Calcium chloride • 2 H <sub>2</sub> O	3.68		A 250 mL	-
Magnesium chloride • 6 H,O	3.05		200 mL	
Dextrose anhydrous	20.0		D	
(as dextrose monohydrate)	22.0		Б	
Sodium chloride		6.46	4750 mL	
Lactic acid	5.40			
Sodium bicarbonate		3.09		

	De	xtrose anhydr	ous			20.0		В
		dextrose mor	nohydrate	э)		22.0		
		dium chloride					6.46	4750 mL
		ctic acid				5.40		
		dium bicarbon		(1) / (2)		annen komm	3.09	
	Wa	ster for injectio	nsqs,Ca	arbon diox	ide for pH	adjustment		
	1.2						0	
After re	constituti							
	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na <sup>+</sup>	Chloride CI	Lactate C <sub>3</sub> H <sub>6</sub> O <sub>3</sub>	Bicarbonate HCO3	Potassium K*	Dextrose
mmo⊮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)
-								
Mix bot	th compar	tments before	use.		Do not free	ze or expose to		
Mix bot See pac further in Sterile a Confirm solution DISCAF Store at cursions	th compar ckage inse instructions and free fro the integri is clear. F RD ANY UI t +20°C to s permitted	tments before rt for dosage in	e use. formation dotoxins. aging. Use nly. TION. to +77°F); 30°C (+59	e only if e only if ex- PF to	Do not free As soon as stitution of and the rec mediately. / tion is stabl the treatme this bag to 1 for further ii	ze or expose to the overwrap compartments onstituted solu After removal o e for 24 hours nt. Mix additive the extracorpoin formation.) Th i rubber latex.	is removed, t A and B should b f the overwas including the es BEFORE real circuit. (6	the recon- uld be done be used im- ap, the solu- a duration of connecting See insert

Mixing steps

SQUEEZE TOP corners to break seal

Squeeze BAG SIDES to fully open seal

Barcode NDC# 24571-108-06

# OK <sup>+</sup> mEq/L

# 2.5 Ca <sup>2+</sup> mEq/L

# PrismaSolBGK0/2.5

Rx only Barcode

Barcode Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	A	В
Calcium chloride • 2H <sub>2</sub> O	3.68	
Magnesium chloride • 6H <sub>2</sub> O	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 p	H adjustment	

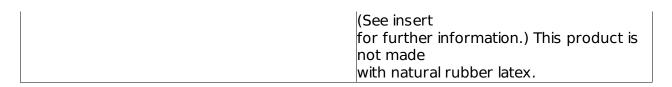
#### A 250 mL

# B

4750 mL

	Calcium	Magnesium	Sodium	Chloride	Lactate	Bicarbonate	Potassium	Dextros
	Ca <sup>2+</sup>	M̃g <sup>2+</sup>	Na +	CI -	C <sub>3</sub> H <sub>5</sub> O 3 <sup>-</sup>	HCO 3 <sup>-</sup>	К +	
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)

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



#### 5000 mL EAN-14: 07332414091613 Product # 110240

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

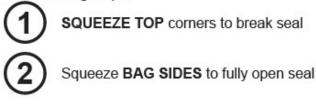
#### GAMBRO Logo

#### REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0110

Mixing steps:

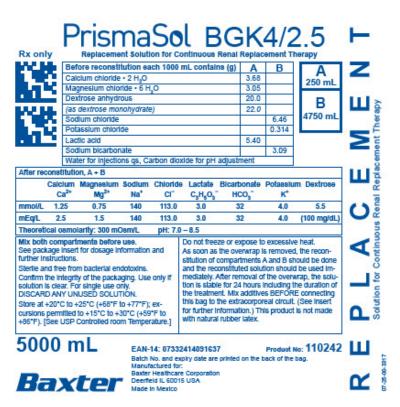




NDC# 24571-105-08







Mixing steps

SQUEEZE TOPcorners to break seal

Squeeze BAG SIDES to fully open seal

Barcode NDC# 24571-105-06

4K <sup>+</sup> mEq/L

2.5 Ca <sup>2+</sup> mEq/L

PrismaSol BGK4/2.5 Rx only

# Barcode Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	Α	В
Calcium chloride • 2H <sub>2</sub> O	3.68	
Magnesium chloride • 6H <sub>2</sub> O	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

#### В 4750 mL

After reconstitution, A + B

					Lactate	Bicarbonate	Potassium	Dextrose
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na +	CI -	C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> -	HCO 3 <sup>-</sup>	К +	
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)

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

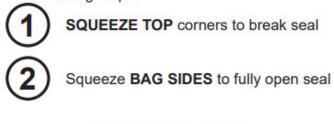
Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Mexico

# Baxter Logo

REPLACEMENT

Solution for Continuous Renal Replacement Therapy 07-25-00-3317

Mixing steps:









10.2	Before reconsti	tution each 1000	mL contain	s (g) A	В	Α
2.2.0	Calcium chloride	• 2 H,O		5.15		250 mL
	Magnesium chlo	ride • 6 H <sub>2</sub> O		2.03		200 ML
and the second second	Dextrose anhydr	ous		20.0		B
007.5	(as dextrose mo	nohydrate)		22.0		4750 mL
2.0	Sodium chloride				6.46	4/50 ML
6 m C	Potassium chlori	de		- 2 Sec. 2	0.157	
-	Lactic acid			5.40		
	Sodium bicarbor	ate	100-10-00	and the set	3.09	3
	Water for injection	ns qs, Carbon dio	ixide for pH a	djustment		
nEg/L 3	.75 0.5	140 111.5	3.0			
	and the second se	140 111.0	3.0	32	2.0	(100 mg/dL)
Contractor of the local division of the loca	osmolarity: 296 m0	Dsm/L pH: 7.0	0 - 8.5			
Mix both co See package further instru Sterile and fr Confirm the i solution is ck DISCARD AI Store at +20' cursions per	mpartments before insert for dosage in	sm/L         pH: 7.           use.         formation and           dotoxins.         ging. Use only if nly.           riON.         riON.           vor +77°F); ex-         so*C (+59°F to	0 – 8.5 Do not freez As soon as stitution of c and the reco- mediately. A tion is stable the treatmen this bag to the for further in	32 e or expose to he overwrap is ompartments A nstituted solut fter removal of for 24 hours i d. Mix additive te extracorpor formation.) Thi rubber latex.	excessive removed and B sh ion shouk the overvincluding to s BEFOR sal circuit.	e heat. I, the recon- iould be done t be used im- vrap, the solu- he duration of E connecting (See insert

Mixing steps

SQUEEZE TOPcorners to break seal

Squeeze BAG SIDES to fully open seal

Barcode NDC# 24571-103-06

2K <sup>+</sup> mEq/L

3.5 Ca <sup>2+</sup> mEq/L

# PrismaSolBGK2/3.5

Rx only Barcode Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	Α	В
Calcium chloride • 2H <sub>2</sub> O	5.15	
Magnesium chloride • 6H <sub>2</sub> O	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 p	H adjustment	

### Rx only A 250 mL B

#### ь 4750 mL

	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>		Chloride Cl <sup>-</sup>	C <sub>3</sub> H	Bicarbonate HCO 3 <sup>-</sup>	Potassium K <sup>+</sup>	Dextrose
mmol/L	1.75	0.5	140	111.5	<sub>5</sub> O <sub>3</sub> - 3.0	32	2.0	5.5
mEq/L	3.5	1.0	140	111.5	3.0	32	2.0	(100 mg/dL)

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

Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Mexico

### Baxter Logo

REPLACEMENT

Solution for Continuous Renal Replacement Therapy 07-25-00-4423

Mixing steps:





PrismaSol BGK2/0







2276 232		151		_		Gn		
Rx only		Replaceme	nt Soluti	on for C	ontinuous R	tenal Repla	cement T	herapy
PR - 2	Befo	re reconsti	tution ea	ch 1000	mL contains		В	A
	Magn	esium chlo	ride • 6 H	20		2.03		250 mL
	Dext	ose anhydr	ous	2		20.0		200 1112
	(as d	extrose moi	nohydrate	9)		22.0	1	в
	Sodiu	um chloride					6.46	
		sium chlori	de				0.157	4750 mL
		cacid	-			5.40	1	
		um bicarbon					3.09	
	Wate	r for injectio	ins qs, Ca	rbon dio	xide for pH a	djustment		
After recor	nstitution	, A + B						
Ca		/agnesium		Chlorid	e Lactate I	Bicarbonate		m Dextrose
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na*	СГ	C3H603	HCO3	К*	
mmoVL	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)
Theoretica	l osmola	rity: 291 m0	Osm/L	pH: 7.0	) - 8.5			
Mix both c	ompartm	ents before	use.		Do not freeze	e or expose t	o excessiv	ve heat.
		or dosage in	formation	and	As soon as t			
further instr								hould be done
		bacterial en		and a M				d be used im- wrap, the solu-
		of the packa single use o		only if				the duration of
		SED SOLU						E connecting
Store at +2	0°C to +2	5°C (+68°F	to +77°F);	ex-	this bag to th			
		+15°C to +			for further inf with natural in		his product	t is not made
+86°F). [Se	e USP C	ontrolled roo	m Temper	ature.]	with natural l	upper latex.		
500	0 m		FAN	14.0733	2414091651		Product	No: 110244
					coiry date are p	ninted on the		
				actured for				and a
GA			Baxter		e Corporation			

Mixing steps

SQUEEZE TOPcorners to break seal

Squeeze BAG SIDES to fully open seal

Barcode NDC# 24571-102-06

# 2K <sup>+</sup> mEq/L

# 0Ca <sup>2+</sup> mEq/L

# PrismaSol BGK2/0

Rx only Barcode

Barcode Replacement Solution for Continuous Renal Replacement Therapy

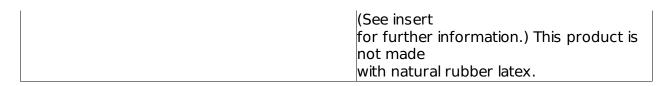
Before reconstitution each 1000 mL contains (g)	A	В
Magnesium chloride • 6H <sub>2</sub> O	2.03	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	22.0	
Sodium chloride		6.46
Potassium chloride		0.157
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for p	H adjustment	

# A 250 mL

#### B 4750 mL

After rec	constituti	on, A + B						
	Calcium	Magnesium	Sodium	Chloride	Lactate	Bicarbonate	Potassium	Dextrose
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na +	Cl -	C 3H 5O	HCO 3 <sup>-</sup>	K +	
					3			
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)
Theorem	retical osi	molarity: 29	1 mOsm/	′L pH: 7.0	- 8.5			
		2		•				

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



#### 5000 mL EAN-14: 07332414091651 Product # 110244

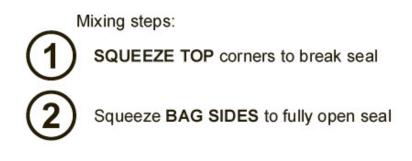
Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

#### **GAMBRO** Logo

#### REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0114







c prá					ontinuous Rer mL contains (		В		7
6583	Magn	esium chlo	ride • 6 H	0		3.05		250 mL	
- C. Statel	Dextro	ose anh ydi	rous			20.0		200 1112	
	(as de	xtrose mo	nohydrate	)		22.0		в	111
	Sodiu	m chloride				_	7.07	_	
C Los e	Potas	sium chlor	ide				0.314	4750 mL	
	Lactic	acid				5.40			
	Sodiu	m bicarbor	nate			_	2.21		>
	Water	for injection	ons qs, Ca	rbon dio	xide for pH adju	ustment			
		12					5.0		
	0	0.75	140	120.5	3.0				
	*								
nEq/L	0	1.5	140	120.5	3.0	22	4.0	(100 mg/dL)	0
nEq/L Theoretical	0 osmolar	1.5 ity: 296 m	140 Osm/L		3.0 0 8.5				0
mmoVL mEq/L Theoretical Mix both co See package urther instru Starile and fr Confirm the i solution is clu DISCARD AN Store at +20° zursions perr +86°F). [See	0 osmolar insert fo ctions. ee from I ntegrity o ear. For s VY UNUS C to +25 mitted to	1.5 ity: 296 mil- ents before r dosage in bacterial en of the packa- ingle use o SED SOLU °C (+68°F +15°C to +	140 Osm/L e use. Information Indotoxins. aging. Use nly. TION. to +77°F); 30°C (+59	120.5 pH:7.0 and only if ex- °F to	3.0	or expose to overwrap is partments A fituted soluti r removal of r 24 hours ir Mix additive extracorpore mation.) This	excessive s removed and B sh ion should the overv noluding t s BEFOR eal circuit	e heat. i, the recon- tould be done d be used im- wrap, the solu- he duration of E connecting (See insert	PLAC

Mixing steps

SQUEEZE TOPcorners to break seal

Squeeze BAG SIDES to fully open seal

Barcode NDC# 24571-111-06

#### 4K <sup>+</sup> mEq/L

#### **Bicarbonate 22**

0Ca <sup>2+</sup> mEq/L

# PrismaSol B22GK4/0

Rx only

Barcode

Replacement Solution for Continuous Renal Replacement Therapy

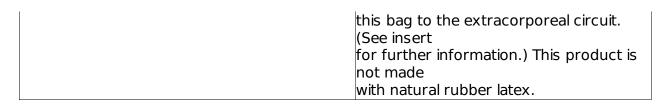
Before reconstitution each 1000 mL contains (g)	Α	В
Magnesium chloride • 6H <sub>2</sub> O	3.05	
Dextrose anhydrous	20.0	
(as dextrose monohydrate)	22.0	
Sodium chloride		7.07
Potassium chloride		0.314
Lactic acid	5.40	
Sodium bicarbonate		2.21
Water for injections q.s, Carbon dioxide for pH	adjustment	

# A 250 mL B

4750 mL

	Calcium	Magnesium	Sodium	Chloride	Lactate	Bicarbonate	Potassium	mDextrose	
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na +	CI -	C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> -	HCO 3 <sup>-</sup>	К +		
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)	

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



#### 5000 mL EAN-14: 07332414116781 Product # 115001

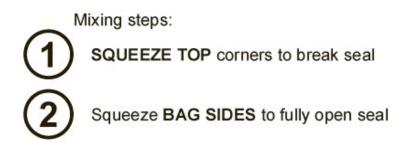
Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

#### GAMBRO Logo

# REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0115











		sma	_			-		E.
Rx only	Before reco Magnesium Sodium chlo	ement Solution nstitution each chloride • 6 H <sub>2</sub> O ride	1000		(g) A 2.44	B 6.46	A 250 mL B	Z
17	Sodium bica	Lactic acid     5.40       Sodium bicarbonate     3.09       Water for injections qs, Carbon dioxide for pH adjustment						
Ca	Ca <sup>2+</sup> Mg <sup>2</sup>		сг	C3H803	HCO3	К*	C.A.H.A.H.A.H.A.H.A.H.A.H.A.H.A.H.A.H.A.	
mmol/L mEg/L	0 0.6	140	106.2	3.0	32	0	0 (0 mg/dL)	C
Theoretical Mix both co See package further instru Sterile and fi Confirm the solution is cl DISCARD A Store at +20 cursions per	ctions. ree from bacteri integrity of the p ear. For single u NY UNUSED St °C to +25°C (+6 mitted to +15°C	fore use. ge information an al endotoxins. ackaging. Use or se only.	nd niy if (- to	As soon as the stitution of co- and the recom- mediately. Aft tion is stable the treatment this bag to the	or expose to the overwrap is mpartments A istituted soluti- er removal of to for 24 hours in . Mix additives e extracorpore primation.) This ubber latex.	removed, and B sho on should the overw cluding the BEFORE al circuit.	heat. the recon- build be done be used im- rap, the solu- ie duration of connecting (See insert	PLA Solution for Continuous
5000 GA	) mL MBR	Batch No Manufact	and en ured for althcar IL 600	re Corporation			o: 110239	<b>R E</b>

Mixing steps

SQUEEZE TOP corners to break seal

Squeeze BAG SIDES to fully open seal

Barcode NDC# 24571-113-06

#### 0K <sup>+</sup> mEq/L

0Ca <sup>2+</sup> mEq/L

#### PrismaSol BK0/0/1.2

Rx only Barcode Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g)	Α	В
Magnesium chloride • 6H <sub>2</sub> O	2.44	
Sodium chloride		6.46
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for p	H adjustment	

#### A 250 mL

# B 4750 mL

	Calcium		Sodium	Chloride	Lactate	Bicarbonate	Potassium	Dextros
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na +	CI -	C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> -	HCO 3 <sup>-</sup>	К +	
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)

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

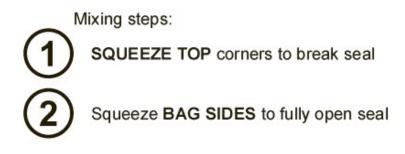
Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

# GAMBRO Logo

#### REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0109









07-25-00-0111



PrismaSol BG				H
Before reconstitution each 1000 mL contains (g)	A	В		Z
Magnesium chloride + 6 H,O	2.44	1	250 mL	
Dextrose anhydrous	20.0		200 mL	
(as dextrose monohydrate)	22.0	1	Б	11
Sodium chloride		6.46	Б	
Potassium chloride		0.314	4750 mL	
Lactic acid	5.40			
Sodium bicarbonate		3.09		5
Water for injections qs, Carbon dioxide for pH adjustn	nent			-

	(as	dextrose mor	ohydrate	)		22.0		в
	So	dium chloride					6.46	
	Po	tassium chlorid	le				0.314	4750 mL
		ctic acid				5.40		
		dium bicarbon					3.09	
	Wa	ter for injectio	ns qs, Ca	arbon dio	xide for pH	adjustment		
After rec		on, A + B						
		Magnesium		Chlorid		Bicarbonate		m Dextrose
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na*	CI	C3H603	HCO3	К*	
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)
Theoret	ical osmo	larity: 295 mC	sm/L	pH:7.0	0 - 8.5			
Mix both	compart	tments before	use.		Do not free	ze or expose to	excessive	e heat.
		t for dosage inf	formation	and		the overwrap is		
	structions	m bacterial end	Interior			compartments / constituted solut		
		ty of the packa		only if		After removal of		
		or single use or		only in	tion is stabl	e for 24 hours i	ncluding t	he duration of
		USED SOLUT				nt. Mix additive		
		+25°C (+68°F t				the extracorpor nformation.) Thi		
		to +15°C to +3 Controlled roor				rubber latex.	e product	IS NOT MODE
400 F).[	aee Uar	Controlleu Tool	ii reiiipei	ature.j	-			
	)0 n		122244					
500			EAN-	14: 0733	241409162	0	Product N	Io: 110241
				No, and ex actured for		printed on the b	ack of the	bag.
5					r: re Corporation	n		
G	AM	BRO.	Deerfie	eld IL 6001				
0		DICO.	Made	in Italy				

Mixing steps

① SQUEEZE TOPcorners to break seal

Squeeze BAG SIDES to fully open seal

Barcode NDC# 24571-114-06

# 4K <sup>+</sup> mEq/L

# 0Ca <sup>2+</sup> 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	В
Magnesium chloride • 6H <sub>2</sub> O	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 p	H adjustment	

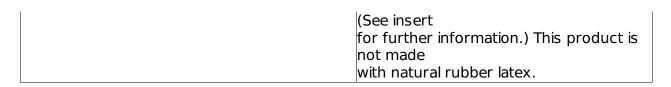
#### A 250 mL

# B

4750 mL

			Sodium	Chloride	Lactate	Bicarbonate	Potassium	Dextrose
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na +	CI -	C <sub>3</sub> H <sub>5</sub> O 3 <sup>-</sup>	HCO 3 <sup>-</sup>	К +	
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)

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



#### 5000 mL EAN-14: 07332414091620 Product # 110241

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

#### **GAMBRO** Logo

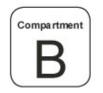
#### REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0111

Mixing steps

SQUEEZE TOP corners to break seal



Squeeze BAG SIDES to fully open seal



NDC# 24571-116-06



# Phoxillum BK4/2.5 Replacement Solution for Continuous Renal Replacement Therapy



Before reconstitution, each 1000 mL contains (g):	A	В	Rx only
Calcium chloride • 2H <sub>2</sub> O	3.68		10 M
Magnesium chloride • 6H <sub>2</sub> O	3.05		Α
Sodium chloride		6.34	250 mL
Potassium chloride		0.314	
Sodium bicarbonate		3.09	B
Dibasic sodium phosphate • 2H <sub>2</sub> O		0.187	4750 ml
Water for injections q.s			

After reconstitution, A + B

	Calcium Ca2+	Magnesium Mg <sup>2+</sup>	Sodium Na*	Chloride Cl <sup>-</sup>	Bicarbonate HCO3 <sup>-</sup>	Potassium K*	Phosphate HPO <sub>4</sub> <sup>2-</sup>	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)
Theore	Theoretical osmolarity: 294 mOsm/L				- 8.5		iii da	- 10

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 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 extra corporeal 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

GAMBRO

5

EAN-14: 07332414116040 Product# 114905 Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

REPLACEMENT Solution for Continuous Renal Replacement Therapy

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

Squeeze BAG SIDES to fully open seal

Compartment B

#### Barcode NDC# 24571-116-06

#### 4K <sup>+</sup> mEq/L

#### 1 Phosphate mmol/L

#### 2.5 Ca <sup>2+</sup> mEq/L

#### Phoxillum BK4/2.5

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution, each 1000 mL contains (g):	А	В
Calcium chloride • 2H <sub>2</sub> O	3.68	
Magnesium chloride • 6H <sub>2</sub> O	3.05	
Sodium chloride		6.34
Potassium chloride		0.314
Sodium bicarbonate		3.09
Dibasic sodium phosphate • 2H <sub>2</sub> O		0.187
Water for injections q.s		

# Rx only

#### A 250 mL

# B

4750 mL

After reconstitution, A + B

	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na +	Chloride Cl <sup>-</sup>	Bicarbonate HCO 3 <sup>-</sup>	Potassium K <sup>+</sup>	Phosphate HPO 4 <sup>2-</sup>	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	(0
							mmol/L)	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 +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C - +30°C (+59°F

to  $+86^{\circ}$ 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: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

#### GAMBRO Logo

#### REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0107

Mixing steps



SQUEEZE TOP corners to break seal



Squeeze BAG SIDES to fully open seal



NDC# 24571-117-06



# Phoxillum B22K4/0

Replacement Solution for Continuous Renal Replacement Therapy



Before reconstitution, each 1000 mL contains (g):	A	В	Rx only
Magnesium chloride • 6H2O	3.05		•
Sodium chloride		6.95	250 mL
Potassium chloride		0.314	200 IIIL
Sodium bicarbonate		221	B
Dibasic sodi um phosphate • 2H <sub>2</sub> O		0.187	4750 mL
Water for injections q.s		10	

After reconstitution, A + B

1	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na*	Chloride Cl <sup>-</sup>	Bicarbonate HCO3 <sup>-</sup>	Potassium K*	Phosphate HPO <sub>2</sub> <sup>2+</sup>	Dextrose
mm ol/L	0	0.75	140	122.0	22	4.0	1	0
mEq/L	0	1.5	140	122.0	22	4.0	(1 m mol/L)	(0 mg/dL)
Theoret	tical osmo	larity: 290 mOs	sm/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 +76°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: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy REPLACEMEN Solution for Continuous Renal Replacement Therapy

07-25-00-0108

Mixing steps

SQUEEZE TOPcorners to break seal

Squeeze BAG SIDES to fully open seal

Compartment B

Barcode NDC# 24571-117-06

### 4K <sup>+</sup> mEq/L

#### 0 Ca <sup>2+</sup> 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):	А	В
Magnesium chloride • 6H <sub>2</sub> O	3.05	
Sodium chloride		6.95
Potassium chloride		0.314
Sodium bicarbonate		2.21
Dibasic sodium phosphate • 2H <sub>2</sub> O		0.187
Water for injections q.s		

# Rx only A

# 250 mL

#### B 4750 mL

After reconstitution, A + B

	Calcium Ca <sup>2+</sup>	Magnesium Ma <sup>2+</sup>	Sodium Na <sup>+</sup>	Chloride	Bicarbonate HCO 3 <sup>-</sup>	Potassium ĸ +	Phosphate HPO ⊿ <sup>2-</sup>	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

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: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

#### **GAMBRO** Logo

#### REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0108

#### 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			
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	3.05 g in 1 L			
<b>ANHYDROUS DEXTROSE</b> (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			
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L			
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L			
Inactive Ingredients					
Ingredient Name	Stren	gth			
WATER (UNII: 059QF0KO0R)					
CARBON DIOXIDE (UNII: 142M471B3J)					
De alcavin v					

Packaging								
# Item Code	Package Description	Marketing Start Date	Marketing End Date					
NDC-24571 100								

1	NDC:24571-108- 06	2 in 1 CASE	10/25/2006			
1		5 L in 1 BAG; Type 0: Not a Combination Product				
Μ	Marketing Information					
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NC	A	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				
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	3.05 g in 1 L				
<b>ANHYDROUS DEXTROSE</b> (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				
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L				
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L				
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32ZN48698)	POTAS SIUM CHLORIDE	0.314 g in 1 L				

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

Pa	Packaging				
#	ltem 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			
Μ	Marketing Information				

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	2.03 g in 1 L
<b>ANHYDROUS DEXTROSE</b> (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
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.46 g in 1 L
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32ZN48698)	POTAS SIUM CHLORIDE	0.157 g in 1 L

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

P	Packaging				
#	ltem 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			
M	Marketing Information				

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
NDA	NDA021703	10/25/2006	

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

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

Active Ingredient/Active Moiety			
Basis of Strength	Strength		
MAGNESIUM CHLORIDE	2.03 g in 1 L		
ANHYDROUS DEXTROSE	20 g in 1 L		
LACTIC ACID	5.4 g in 1 L		
SODIUM CHLORIDE	6.46 g in 1 L		
SODIUM BICARBONATE	3.09 g in 1 L		
POTAS SIUM CHLORIDE	0.157 g in 1 L		
	Strength       MAGNESIUM CHLORIDE       ANHYDROUS DEXTROSE       LACTIC ACID       SODIUM CHLORIDE       SODIUM BICARBONATE       POTASSIUM		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0K00R)			
CARBON DIOXIDE (UNII: 142M471B3J)			

P	Packaging				
#	ltem 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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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 Ingredie	ent/Active Moiety					
	Ingredient Name				asis of rength	Strengt
MAGNESIUM CHLO CHLORIDE ION - UNII	<b>RIDE</b> (UNII: 02F3473H9O) (MAGNESIUM CATIO :Q32Z N48698)	N - UI	NII:T6V3LHY838,	MAGN CHLO	ESIUM RIDE	3.05 g in 1 L
ANHYDROUS DEXT UNII:5SL0G7R0OK)	ANHYI DEXTF	OROUS ROSE	20 g in 1			
LACTIC ACID (UNII:	LACTI	C ACID	5.4 g in 1 L			
SODIUM CHLORIDE CHLORIDE ION - UNII	JM RIDE	7.07 g in 1 L				
SODIUM BICARBOI BICARBONATE ION -	NATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:HN1Z RA3Q20)	UNII:L	_YR4M0NH37,	SODIL BICAR	JM BONATE	2.21 g in 1 L
POTASSIUM CHLO CHLORIDE ION - UNII	RIDE (UNII: 660YQ98I10) (POTASSIUM CATION :Q32ZN48698)	- UNI	I:295053K152,	POTAS CHLO	SSIUM RIDE	0.314 g in 1 L
Inactive Ingredients						
Ingredient Name Strength						
WATER (UNII: 059Q)						
CARBON DIOXIDE	(UNII: 142M471B3J)					
Packaging						
# Item Code	Package Description	ſ	Marketing Sta Date	rt		ting End ate
<b>1</b> NDC:24571-111- 06	2 in 1 CASE	10/	10/2008			
1	5 L in 1 BAG; Type 0: Not a Combination Product					
Marketing I	Information					
Marketing I Marketing Category	Application Number or Monogra Citation	bh	Marketing S Date	tart		eting End Date
Marketing	Application Number or Monogra	bh		tart		

PRISMASOL BK0/0/ magnesium chloride, lactic ac		ium bicarbonate	injection	1	
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	ltem Code (Sou	rce)	NDC:2	4571-113
Route of Administration	INTRAVENOUS				
	N# - <sup>1</sup> - 1				
Active Ingredient/Active	мојету				
h	ngredient Name		Basis Stren		Strength
MAGNESIUM CHLORIDE (UNII: 02 CHLORIDE ION - UNII:Q32Z N48698)	F3473H9O) (MAGNESIUM CATION -	UNII:T6V3LHY838,	MAGNESI CHLORIDI		2.44 g in 1 L
LACTIC ACID (UNII: 33X04XA5AT) (	LACTIC ACID - UNII:33X04XA5AT)		LACTIC A	CID	5.4 g in 1 L
SODIUM CHLORIDE (UNII: 451W47 ION - UNII:Q32ZN48698)	IQ8X) (SODIUM CATION - UNII:LYR4	M0NH37, CHLORIDE	SODIUM CHLORIDI	E	6.46 g in 1 L
SODIUM BICARBONATE (UNII: 8M	DF5V39QO) (SODIUM CATION - UNI	I:LYR4M0NH37,	SODIUM		3.09 g

In	active Ingree	dients					
		Ingredient Name			Strength		
w	ATER (UNII: 059QF	FOKOOR)					
CA	RBON DIOXIDE (	UNII: 142M471B3J)					
Pa	Packaging						
#	ltem Code	Package Description	ſ	Aarketing 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					
Μ	larketing I	nformation					
	Marketing Category	Application Number or Monograp Citation	h	Marketing Start Date	Marketing End Date		
	Α	NDA021703		10/25/2006			

# PRISMASOL BGK4/0/1.2

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

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

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32Z N48698)	MAGNESIUM CHLORIDE	2.44 g in 1 L			
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	22 g in 1 L			
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	5.4 g in 1 L			
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32Z N48698)	SODIUM CHLORIDE	6.46 g in 1 L			
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L			
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32Z N48698)	POTAS SIUM CHLORIDE	0.314 g in 1 L			

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

Pa	Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:24571-114- 06	2 in 1 CASE	10/10/2008			
1		5 L in 1 BAG; Type 0: Not a Combination Product				
Μ	Marketing Information					
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	category	Citation	Dutt	Dutt		

# PHOXILLUM BK4/2.5

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

Ρ	roduct Inform	nation					
P	roduct Type		HUMAN PRESCRIPTION DRUG	ltem Code (So	urce)	NDC:24	4571-116
R	oute of Adminis	stration	INTRAVENOUS				
A	ctive Ingredie	ent/Active	Moiety				
		In	gredient Name		_	asis of rength	Strength
	ALCIUM CHLORID ILORIDE ION - UNII:		6VV5M) (CALCIUM CATION - UNII:	2M83C4R6ZB,	CALC CHLO		3.68 g in 1 L
	AGNESIUM CHLO ILORIDE ION - UNII:		F3473H9O) (MAGNESIUM CATION	I - UNII:T6V3LHY838,	MAGN CHLO	IESIUM RIDE	3.05 g in 1 L
	DDIUM CHLORIDE ILORIDE ION - UNII:	•	(IQ8X) (SODIUM CATION - UNII:LY	′R4M0NH37,	SODII CHLO	•••	6.34 g in 1 L
	DDIUM BICARBON CARBONATE ION - U	· · · ·	DF5V39QO) (SODIUM CATION - L 220)	JNII:LYR4M0NH37,	SODII BICAF	UM RBONATE	3.09 g in 1 L
	TASSIUM CHLOF ILORIDE ION - UNII:	•	YQ98I10) (POTASSIUM CATION -	UNII:295053K152,	POTA CHLO	S S IUM RIDE	0.314 g in 1 L
			O181101B5G) (PHOSPHATE ION - UNII:LYR4M0NH37)	I P-32 -	SODII PHOS	UM PHATE P-32	0.187 g in 1 L
In	active Ingree	dients					
			Ingredient Name			Strei	ngth
w	ATER (UNII: 059QF	OKOOR)					
	ARBON DIOXIDE (						
H	DROCHLORIC AC	CID (UNII: QTT1	17582CB)				
Pa	ackaging						
#	ltem Code	Рас	kage Description	Marketing Sta Date	art	Marketi Da	
1	NDC:24571-116- 06	2 in 1 CASE		01/13/2015			
1		5 L in 1 BAG; Product	Type 0: Not a Combination				

Marketing Information						
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
NDA207026	01/13/2015					
	Application Number or Monograph Citation	Application Number or Monograph Citation Date				

### 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		
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	3.05 g in 1 L		
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.95 g in 1 L		
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	2.21 g in 1 L		
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L		
SODIUM PHOSPHATE P-32 (UNII: 0181101B5G) (PHOSPHATE ION P-32 - UNII:N27ADP50ER, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE P-32	0.187 g in 1 L		

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

Pa	Packaging			
#	ltem Code	Package Description		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	Application Number or Monograp	h Marketing Start	Marketing End

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
NDA	NDA207026	01/13/2015	

# Registrant - Vantive US Healthcare LLC (119181963)

LSLA			
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, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-105, 24571-103,

# Establishment

# Establishment

Name	Address	ID/FEI	Business Operations
Bieffe Medital S.p.A.		437668413	label(24571-103, 24571-102, 24571-111, 24571-113, 24571-114, 24571-116, 24571-117, 24571-105, 24571-108) , pack(24571-108, 24571-105, 24571-103, 24571-102, 24571-114, 24571-116, 24571-105, 24571-103, 24571-102, 24571-104, 24571-117) , sterilize(24571-108, 24571-105, 24571-103, 24571-102, 24571-102, 24571-113, 24571-114, 24571-114, 24571-116, 24571-117) , analysis(24571-108, 24571-105, 24571-103, 24571-102, 24571-103, 24571-103, 24571-103, 24571-114, 24571-116, 24571-113, 24571-114, 24571-116, 24571-113, 24571-102, 24571-114, 24571-116, 24571-113, 24571-102, 24571-103, 24571-102, 24571-113, 24571-102, 24571-113, 24571-102, 24571-113, 24571-102, 24571-113, 24571-102, 24571-113, 24571-102, 24571-113, 24571-102, 24571-103, 24571-102, 24571-113, 24571-102, 24571-103, 24571-102, 24571-113, 24571-103, 24571-102, 24571-114, 24571-116, 24571-103, 24571-102, 24571-114, 24571-116, 24571-117)

Revised: 5/2023

Vantive US Healthcare LLC