PRISMASOL BGK0/2.5- calcium chloride, magnesium chloride, dextrose monohydrate, lactic acid, sodium chloride and sodium bicarbonate injection PRISMASOL BGK4/2.5- calcium chloride, magnesium chloride, dextrose monohydrate, lactic acid, sodium chloride, sodium bicarbonate and potassium chloride injection

PRISMASOL BGK2/3.5- calcium chloride, magnesium chloride, dextrose monohydrate, lactic acid, sodium chloride, sodium bicarbonate and potassium chloride injection

PRISMASOL BGK2/0- magnesium chloride, dextrose monohydrate, lactic acid, sodium chloride, sodium bicarbonate and potassium chloride injection PRISMASOL B22GK4/0- magnesium chloride, dextrose monohydrate, 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 Baxter Healthcare Corporation

Reference Label Set Id: 25c4d41f-bdcc-479e-a49f-96d7a2d46fc1

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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

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)

#### 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**

#### **4 CONTRAINDICATIONS**

#### **5 WARNINGS AND PRECAUTIONS**

- 5.1 Electrolyte and Volume Abnormalities
- 5.2 Blood Glucose Abnormalities

#### 6 ADVERSE REACTIONS

#### **7 DRUG INTERACTIONS**

7.1 Citrate

#### **8 USE IN SPECIFIC POPULATIONS**

- 8.1 Pregnancy
- 8.2 Lactation
- 8.4 Pediatric Use
- 8.5 Geriatric Use

#### **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 <sup>2+</sup> mEq/L	HCO3 <sup>-</sup> mEq/L	K <sup>+</sup> mEq/L	Mg <sup>2+</sup> mEq/L	Na+ mEq/L	HPO4 <sup>2-</sup> mmol/L	Ċ Cŀ 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
PHOXILLUN	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

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

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

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:

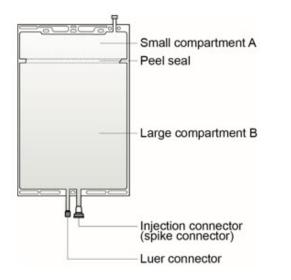


Figure 1

Figure 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 an opening is created in the peel seal. (See Figure 2 beside)
Figure 3	<b>Step 2</b> 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	<ul> <li>Step 3 The replacement line may be connected to the bag through either of the luer connector or the injection connector (spike connector).</li> <li>Step 3a The luer connector is a needle-less and swabbable</li> </ul>

Luer Connector	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	<b>Step 3b</b> 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 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<sub>2</sub>  $\cdot$  2H<sub>2</sub>O).

Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate (MgCl<sub>2</sub>  $\cdot$  6H<sub>2</sub>O).

Sodium chloride, USP, is chemically designated NaCl.

Potassium chloride, USP, is chemically designated KCl.

Sodium bicarbonate, USP, is chemically designated NaHCO<sub>3</sub>.

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<sub>3</sub>CH(OH)COOH.

Dibasic sodium phosphate, USP, is chemically designated as disodium hydrogen phosphate, dihydrate (Na<sub>2</sub>HPO<sub>4</sub>  $\cdot$  2H<sub>2</sub>O)

		Compartm	ent A (g/L)			Compartm	nent B (g/L	)
	Chloride	Magnesium Chloride · 6H <sub>2</sub> O	-	Acid	Sodium Chloride	Sodium bicarbonate	Potassium Chloride	Sodium Phosphate · 2H <sub>2</sub> O
PRISM	ASOL SO	LUTIONS	-	I.	1		1	
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
PHOXII	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

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	I	
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]

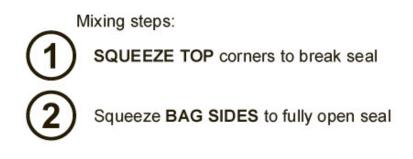
Do not freeze or expose to excessive heat. Do not use if precipitate has formed or if container seals have been damaged.

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



.....

Before reconstitution each 1000 mL contains (g)	A	В		Z
Calcium chloride • 2 H <sub>2</sub> O	3.68		250 mL	
Magnesium chloride • 6 H,O	3.05		200 mL	
Dextrose anhydrous	20.0		D	L
(as dextrose monohydrate)	22.0		Б	
Sodium chloride		6.46	4750 mL	
Lactic acid	5.40			
Sodium bicarbonate		3.09		
Water for injections gs, Carbon dioxide for pH adjustn	nent			

	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na*	Chloride CГ	Lactate C <sub>3</sub> H <sub>6</sub> O <sub>3</sub>	Bicarbonate HCO3	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)
Theoret	ical osmo	larity: 292 mG	Osm/L	pH: 7.0	- 8.5			
further in Sterile a Confirm solution DISCAR Store at cursions	nd free from the integrit is clear. For DANY UN +20°C to + permitted	t for dosage in m bacterial en y of the packs r single use o IUSED SOLU 25°C (+68°F + to +15°C to + Controlled roo	dotoxins. aging. Use nly. TION. to +77°F); 30°C (+55	ex- PF to	stitution of and the rec mediately. tion is stabl the treatme this bag to for further i	the overwrap compartments onstituted solu After removal o le for 24 hours int. Mix additiv the extracorpo nformation.) Th I rubber latex.	A and B sho tion should b f the overwra including the es BEFORE real circuit. (	uld be done be used im- ap, the solu- e duration of connecting See insert
	)0 n AM	nL BRO,	Batch Manuf	No. and exp actured for:	Corporatio	printed on the		x <b>110240</b> %

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)	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
Lactic acid	5.40	
Sodium bicarbonate		3.09
Water for injections q.s, Carbon dioxide for pH	adjustment	

### A 250 mL

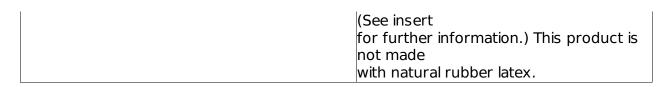
#### B 4750

4750 mL

	Calcium	Magnesium	Sodium	Chloride	Lactate	Bicarbonate	Potassium	Dextros
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na <sup>+</sup>		C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> <sup>-</sup>		K <sup>+</sup>	
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.	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.



#### 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

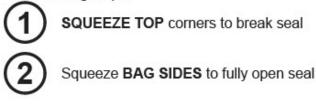
#### GAMBRO Logo

#### REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0110

Mixing steps:

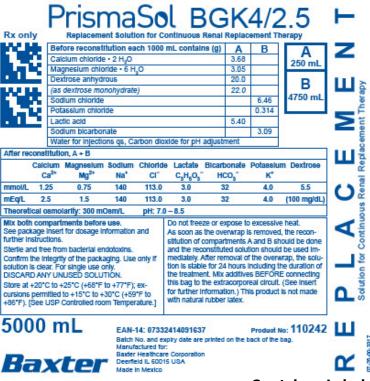




NDC# 24571-105-08







**Container Label** 

Mixing steps

SQUEEZE TOP corners 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

#### B 4750 mL

After reconstitution, A + B

After r	econstit	ution, A + I	В					
	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na <sup>+</sup>		Lactate C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> -	Bicarbonate HCO3 <sup>-</sup>	Potassium K <sup>+</sup>	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

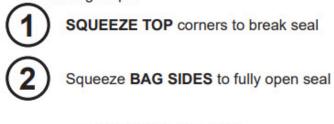
Mix both compartments before use.	Do not freeze or expose to excessive
See package insert for dosage information an	dheat.
further instructions.	As soon as the overwrap is removed, the
Sterile and free from bacterial endotoxins.	reconstitution
Confirm the integrity of the packaging. Use only if	of compartments 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: 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 reconst	itution each 1000	mL contains	s (g) A	В	A
120	Calcium chloride	• 2 H,O		5.15		250 mL
87 Y 6	Magnesium chlo	ride • 6 H <sub>2</sub> O		2.03		200 IIIL
Sec.	Dextrose anhyd	rous		20.0		B
000.0	(as dextrose mo	nohydrate)		22.0		_
	Sodium chloride				6.46	4750 mL
	Potassium chlor	ide		1.0	0.157	
-	Lactic acid			5.40		
	Sodium bicarbo		100-00-00	and the second	3.09	10
	Water for injecti	ons qs, Carbon die	oxide for pH a	djustment		1
nmol/L 1	1.75 0.5	140 111.5	C3H5O3	2		
			3.0	32	2.0	5.5
	3.5 1.0	140 111.5	3.0	32 32	2.0 2.0	5.5 (100 mg/dL)
heoretical	osmolarity: 296 m	140 111.5 Osm/L pH: 7.	3.0 0 - 8.5	32	2.0	(100 mg/dL)
Theoretical Mix both co See package further instru- Sterile and fi Confirm the solution is cl DISCARD A Store at +20 cursions per	osmolarity: 296 m mpartments before e insert for dosage in	140         111.5           Dsm/L         pH: 7.2           use.         information and           idotoxins.         aging. Use only if only.           TION.         to +77°F); ex-30°C (+59°F to	3.0 0 - 8.5 Do not freeze As soon as the stitution of co and the recom- mediately. At tion is stable the treatment this bag to the the stage of th	32 e or expose to he overwrap is mpartments A instituted soluti ter removal of for 24 hours in t. Mix additive: e extracorpore formation.) Thi	2.0 excessive and B sh on should the overwinduding the s BEFORI sal circuit.	(100 mg/dL) e heat. I, the recon- iould be done I be used im- wrap, the solu- he duration of E connecting (See insert

Mixing steps

SQUEEZE TOP corners 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

After re	econstit	ution, A + E	3					
	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na <sup>+</sup>		Lactate C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> -	Bicarbonate HCO3 <sup>-</sup>	Potassium K <sup>+</sup>	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

Min both commenter bofers and	
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.
	(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







- 18 A				30		GU	_		
Rx only	F	eplaceme	nt Soluti	on for C	ontinuous R	enal Replac	ement T	herapy	
PM 12-	Befor	e reconstit	tution ea	ch 1000	mL contains		В	A	7
	Magn	esium chlor	ride • 6 H.	,0		2.03		250 mL	
7 A B	Dextro	ose anhydr	ous			20.0	1	200 1112	
		xtrose mor	nohydrate	)		22.0		В	111:
10112		m chloride					6.46	4750 mL	
1.10	Potas	sium chlori	de				0.157	4750 mL	
	Lactic		-			5.40			Final Provide
		m bicarbon					3.09		2
	Water	for injectio	ns qs, Ca	rbon dio	xide for pH as	djustment	12. ()		
2 - · · · · · · · · · · · · · · · · · ·									2
After recons	titution,	A+B							
		agnesium		Chlorid	e Lactate E	Bicarbonate		m Dextrose	
C	2a <sup>2+</sup>	Mg <sup>2+</sup>	Na <sup>*</sup>	СГ	C3H803	HCO3	К*		-
mmol/L (	0	0.5	140	108.0	3.0	32	2.0	5.5	C
mEq/L	0	1.0	140	108.0	3.0	32	2.0	(100 mg/dL)	
Theoretical of	osmolar	ity: 291 mC	)sm/L	pH: 7.0	) - 8.5				
Mix both con	mpartme	ents before	use.		Do not freeze	e or expose to	excessiv	e heat.	۲
See package		r dosage in	formation	and	As soon as th	he overwrap i	sremove	d, the recon-	
further instruc								hould be done	1
Sterile and fre								d be used im- wrap, the solu-	
Confirm the in solution is cle				only if				the duration of	
DISCARDAN								Econnecting	
Store at +20°				ex-	this bag to th				
cursions pern					for further inf		is product	t is not made	0
+86°F). [See	USP Co	ntrolled roo	m Temper	ature.]	with natural r	ubber latex.			
5000	m	122	FAN	14.0733	2414091651		Product	No: 110244	111
					piry date are p	inted on the			and the second
				actured for			ALC: 10 10 10	and a	
9		BRO.	Bayter		e Corporation				~

Mixing steps

SQUEEZE TOP corners 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	

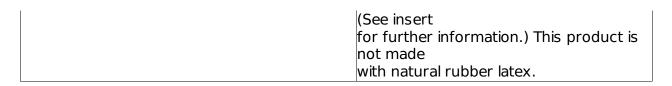
# A 250 mL

#### B 4750 mL

	Calcium	Magnesium	Sodium	Chloride	Lactate	Bicarbonate	Potassium	Dextros
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na+	Cŀ	$C_{3}H_{5}O_{3}^{-}$	HCO <sub>3</sub> -	K+	
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.	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

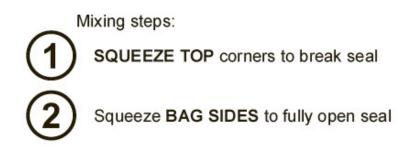
Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

#### **GAMBRO** Logo

#### REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0114







Rx only			tion eac	ch 1000	mL contains (		в	herapy	7
	Magnesiu					3.05	-	A 250 mL	
	Dextrose a	anhydrou	IS			20.0		200 ML	
	(as dextro	se mond	hydrate,	)		22.0		в	111
C 1006	Sodium ch	hloride					7.07	_	
	Potassium	n chloride	1) 				0.314	4750 mL	
<b>100 10</b>	Lactic ack	d				5.40			
	Sodium bi	ica rbon a	te				2.21		>
	Water for	injection	s qs, Ca	rbon dio	xide for pH adj	ustment			
	titution, A +								
nEq/L	0 1	.5	140	120.5	3.0	22	4.0	(100 mg/dL)	-
		20.6 m.O.e	lion	pH:7.0	0.5				
	osmolarity:			prices					
Vix both con See package urther instruct Sterile and fro Confirm the in colution is cle DISCARD AN	npartments insert for do	before u sage info erial endo e packagi e use only SOLUTIO	se. rmation toxins. ng. Use y. DN.	and only if	Do not freeze of As soon as the stitution of com and the recons mediately. After tion is stable for the treatment. I this bag to the for further infor	overwrap is ipartments / fituted solut r removal of r 24 hours in Mix additive extracorpore	and B sh ion should the overvincluding t s BEFOR cal circuit.	d, the recon- tould be done d be used im- wrap, the solu- he duration of E connecting . (See insert	LA

Mixing steps

SQUEEZE TOP corners 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	

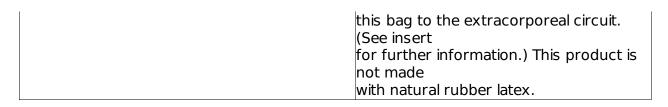
## A 250 mL B

4750 mL

After r	econstit	ution, A + E	3					
	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na <sup>+</sup>		Lactate C <sub>3</sub> H <sub>5</sub> O3 <sup>-</sup>	Bicarbonate HCO3 <sup>-</sup>	Potassium K <sup>+</sup>	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.	Do not freeze or expose to excessive
See package insert for dosage information and	dheat.
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



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

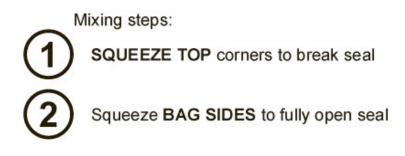
Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

#### GAMBRO Logo

## REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0115











Rx only	Befor	Replacementer reconstit	nt Solution ea	on for C ch 1000	ontinuous Re mL contains	enal Replac			⊢ z	
	Magnesium chloride • 6 H <sub>2</sub> O       2.44         Sodium chloride       6.46         Lactic acid       5.40         Sodium bicarbonate       3.09         Water for injections qs, Carbon dioxide for pH adjustment							8 4750 mL	Ш	nt Therapy
	Calcium M Ca <sup>2+</sup> 0		Sodium Na <sup>+</sup> 140	Chlorid CF 106.2	e Lactate B C <sub>3</sub> H <sub>6</sub> O <sub>3</sub> <sup></sup> 3.0	icarbonate HC 0 <sub>3</sub> 32	Potassiu K* 0	m Dextrose 0	ш U	Renal Replacement
mEq/L	0	1.2	140	106.2	3.0	32	0	(0 mg/dL)	U	
Mix both See packs further ins Sterile and Confirm th solution is DISCARD Store at +: cursions p	compartm age insert fr tructions. d free from the integrity clear. For: ANY UNU 20°C to +2: cermitted to	rity: 282 mO ents before or dosage inf bacterial end of the packas single use or SED SOLUT 5°C (+68°F to +15°C to +3 ontrolled roor	use. ormation lotoxins. ging. Use hly. ION. o +77°F); 0°C (+59	only if ex- °F to	Do not freeze As soon as th stitution of co and the recor mediately. Aft	e overwrap is mpartments / istituted solut er removal of for 24 hours i Mix additive e extracorpor prination.) Thi	s removed A and B sh ion should the overwincluding to s BEFORI eal circuit.	, the recon- ould be done be used im- rap, the solu- ne duration of connecting (See insert	PLA	Solution for Continuous
500 • G/		L BRO.	Batch I Manufa	No. and ex actured for Healthcar Id IL 600	re Corporation	inted on the b		lo: <b>110239</b> bag.	ш Ж	07-25-00-0109

Mixing steps

SQUEEZE TOP corners to break seal

Squeeze BAG SIDES to fully open seal

Barcode NDC# 24571-113-06

#### 0K+ 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)	A	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	Water for injections q.s, Carbon dioxide for pH adjustment						

#### Α 250 mL

## В 4750 mL

	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na <sup>+</sup>		Lactate C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> -	Bicarbonate HCO3 <sup>-</sup>	Potassium K <sup>+</sup>	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)

i neoretical osmolarity: 282 mOsm/L pH: 7.0 - 8.5

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

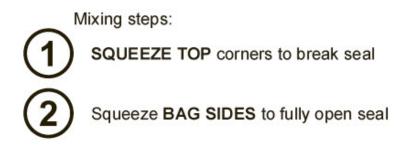
Batch No. and expiry date are printed on the back of the bag. Manufactured for: Baxter Healthcare Corporation Deerfield IL 60015 USA Made in Italy

## GAMBRO Logo

REPLACEMENT

Solution for Continuous Renal Replacement Therapy

07-25-00-0109









07-25-00-0111



efore reconstitution each 1000 mL contains (g)	A	B B	
Agnesium chloride + 6 H.O	2.44		A
Dextrose anhydrous	20.0		250 m L
as dextrose monohydrate)	22.0	-	в
odium chloride		6.46	В
Potassium chloride		0.314	4750 mL
actic acid	5.40	-	
odium bicarbonate		3.09	1

	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na*	Chloride Cl <sup>-</sup>	Lactate C <sub>3</sub> H <sub>6</sub> O <sub>3</sub>	Bicarbonate HCO3	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)
Theoret	ical osmo	larity: 295 m	Osm/L	pH: 7.0	- 8.5			
Sterile a Confirm solution DISCAR Store at cursions	the integrit is clear. Fo DANYUN +20°C to + permitted	m bacterial en ty of the packs or single use o IUSED SOLU +25°C (+68°F to +15°C to + Controlled roo	aging. Use nly. TION. to +77°F); 30°C (+59	ex- PF to	stitution of and the rec mediately. tion is stabl the treatme this bag to for further i	the overwrap compartments onstituted solu After removal o le for 24 hours ent. Mix additiv the extracorpo nformation.) Th I rubber latex.	A and B should b f the overwra including the es BEFORE real circuit. (5	uld be done be used im- ap, the solu- e duration of connecting See insert
500	)0 n	nL	Batch		41409162 biry date are	0 printed on the		: <b>11024</b> 1

Mixing steps

① SQUEEZE TOP corners 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)	Α	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 pH	adjustment	

#### A 250 mL

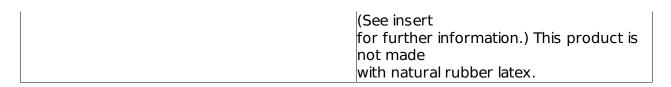
#### B 4750

4750 mL

	1	ution, A + E				1		n
	Calcium	Magnesium	Sodium	Chloride	Lactate	Bicarbonate	Potassium	Dextros
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na+	CL	C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> <sup>-</sup>	HCO <sub>3</sub> -	K+	
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.	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: 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

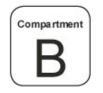
#### REPLACEMENT

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 onl
Calcium chloride • 2H <sub>2</sub> O	3.68		-
Magnesium chloride • 6H <sub>2</sub> O	3.05		Δ
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 m
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	tical osmo	larity: 294 mOs	sm/L	pH: 7.0	- 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

EA.N-14: 07332414116040 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



Product# 114905

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 <sup>+</sup>	Chloride Cl <sup>-</sup>	Bicarbonate HCO <sub>3</sub> -	Potassium K <sup>+</sup>	Phosphate HPO4 <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		A
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 R E P L A C E M E N Solution for Continuous Renal Replacement Therapy

07-25-00-0108

Mixing steps

SQUEEZE TOP corners 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	Magnesium	Sodium	Chloride	Bicarbonate	Potassium	Phosphate	Dextrose
	Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na+	Cŀ	HCO <sub>3</sub> -	K+	HPO <sub>4</sub> <sup>2-</sup>	
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	(0
							mmol/L)	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 monohydrate, 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
<b>CALCIUM CHLORIDE</b> (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIU	JM CHLORIDE	3.68 g in 1 L
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNE CHLOF		3.05 g in 1 L
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTR MONO	OSE HYDRATE	22 g in 1 L
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT) (LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)		C ACID, CIFIED FORM	5.4 g in 1 L
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32Z N48698)	SODIU	M CHLORIDE	6.46 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIU BICARE	M BONATE	3.09 g in 1 L
Inactive Ingredients			
Ingredient Name		Stren	gth
WATER (UNII: 059QF0KO0R)			

CARBON DIOXIDE (UNII: 142M471B3J)

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

Marketing End Date

## PRISMASOL BGK4/2.5

calcium chloride, magnesium chloride, dextrose monohydrate, 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			
<b>CALCIUM CHLORIDE</b> (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			
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	22 g in 1 L			
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT) (LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	LACTIC ACID, UNSPECIFIED FORM	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			
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:295053K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L			

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

#	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				
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 monohydrate, lactic acid, sodium chloride, sodium bicarbonate and potassium chloride injection

Product Infor	mation					
Product Type		HUMAN PRESCRIPTION DRUG	Item Code	(Source)	NDC:24	4571-103
Route of Admin	istration	INTRAVENOUS				
Active Ingred	ient/Active	Moiety			_	
	Ingi	redient Name		Basis ( Streng		Strengt
Calcium Chlori Chloride Ion - Uni		5VV5M) (CALCIUM CATION - UNII:2	2M83C4R6ZB,	CALCIUM CHLC	ORIDE	5.15 g in 1 L
<b>MAGNESIUM CHLO</b> UNII:T6V3LHY838, C	MAGNESIUM CHLORIDE		2.03 g in 1 L			
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)					E	22 g in 1
				LACTIC ACID, UNSPECIFIED F	FORM	5.4 g in 1 L
CHLORIDE ION - UNI	<b>DDIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, HLORIDE ION - UNII:Q32Z N48698)SODIUM CHLORIDE				RIDE	6.46 g in 1 L
UNII:LYR4M0NH37, I	BICARBONATE IO	DF5V39QO) (SODIUM CATION - N - UNII:HN1ZRA3Q20)		SODIUM BICARBONATE		3.09 g in 1 L
	POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - JNII:295053K152, CHLORIDE ION - UNII:Q32ZN48698) POTASSIUM CHLORIDE				HLORIDE	0.157 g in 1 L
Inactive Ingre	edients					
Inactive Ingre		ngredient Name			Stren	gth
WATER (UNII: 0590	F0KO0R)				Streng	gth
WATER (UNII: 0590	F0KO0R)				Stren	gth
WATER (UNII: 0590	F0KO0R)				Stren	gth
WATER (UNII: 0590 CARBON DIOXIDE	F0KO0R)					
WATER (UNII: 059C CARBON DIOXIDE Packaging	 )F0KO0R) (UNII: 142M4711		Marketing Date			ing End
WATER (UNII: 059C CARBON DIOXIDE Packaging	I PFOKOOR) (UNII: 142M4711 Pac	B3J)	-		1arketi	ng End
WATER (UNII: 059C CARBON DIOXIDE Packaging # Item Code 1 NDC:24571-103- 06	I PFOKOOR) (UNII: 142M471I Pac 2 in 1 CASE	B3J)	Date		1arketi	ng End
WATER (UNII: 059C CARBON DIOXIDE Packaging # Item Code 1 NDC:24571-103- 06	I SFOKOOR) (UNII: 142M471) 2 in 1 CASE 5 L in 1 BAG;	B3J) kage Description	Date		1arketi	ng End
WATER (UNII: 0590 CARBON DIOXIDE Packaging # Item Code 1 NDC:24571-103- 06 1	I PFOKOOR) (UNII: 142M471 2 in 1 CASE 5 L in 1 BAG; Product	B3J) <b>kage Description</b> Type 0: Not a Combination	Date		1arketi	ng End
WATER (UNII: 059C CARBON DIOXIDE Packaging # Item Code 1 NDC:24571-103-	I PFOKOOR) (UNII: 142M471I 2 in 1 CASE 2 in 1 CASE 5 L in 1 BAG; Product Informat	B3J) <b>kage Description</b> Type 0: Not a Combination	Date 10/25/2006		1arketi Da Marke	ing End

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

	mation					
Product Type		HUMAN PRESCRIPTION DRUG	Item Code	(Source)	NDC:24	4571-102
Route of Adminis	stration	INTRAVENOUS				
Active Ingredie	ent/Active	Moiety				
	Ing	redient Name			sis of ength	Strength
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION -MAGNEUNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)CHLOR					ЛМ	2.03 g in 1 L
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - DEXTRO UNII:5SL0G7R00K) DEXTROSE - DEXTRO						22 g in 1
ACTIC ACID, UNSI JNSPECIFIED FORM -		KM (UNII: 33X04XA5AT) (LACTIC / GAT)	ACID,	LACTIC AC		5.4 g in 1 L
CHLORIDE ION - UNII:	Q32ZN48698)	(IQ8X) (SODIUM CATION - UNII:L)	′R4M0NH37,		HLORIDE	6.46 g in 1 L
	· · ·	DF5V39QO) (SODIUM CATION - NN - UNII:HN1ZRA3Q20)		SODIUM BICARBON	IATE	3.09 g in 1 L
	SSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - POTASSIUM CHLORIDE ION - UNII:032ZN48698)			M CHLORIDE	0.157 g in 1 L	
nactive Ingree	dients					
	I	ngredient Name			Streng	gth
NATER (UNII: 059QF	F0KO0R)				Streng	gth
VATER (UNII: 059QF	F0KO0R)				Streng	gth
NATER (UNII: 059QF	F0KO0R)				Stren	gth
WATER (UNII: 059QF CARBON DIOXIDE ( Packaging	F0KO0R)					
VATER (UNII: 059QF CARBON DIOXIDE ( Packaging	F0KO0R) (UNII: 142M471		Marketing Date		Streng Marketi Da	ng End
VATER (UNII: 059QF CARBON DIOXIDE ( Packaging t Item Code	F0KO0R) (UNII: 142M471	B3J)	_		Marketi	ng End
ARBON DIOXIDE ( Packaging Item Code NDC:24571-102- 06	F0KO0R) (UNII: 142M471 <b>Pac</b> 2 in 1 CASE	B3J)	Date		Marketi	ng End
VATER (UNII: 059QF CARBON DIOXIDE ( Packaging t Item Code NDC:24571-102- 06	F0KO0R) (UNII: 142M471 Pac 2 in 1 CASE 5 L in 1 BAG;	B3J) kage Description	Date		Marketi	ng End
VATER (UNII: 059QF CARBON DIOXIDE ( Packaging Item Code NDC:24571-102- 06	F0KO0R) (UNII: 142M471 Pac 2 in 1 CASE 5 L in 1 BAG; Product	B3J) <b>kage Description</b> Type 0: Not a Combination	Date		Marketi	ng End
ATER (UNII: 059QF CARBON DIOXIDE ( Packaging Item Code NDC:24571-102-	FOKOOR) (UNII: 142M471 Pac 2 in 1 CASE 5 L in 1 BAG; Product <b>nformat</b>	B3J) <b>kage Description</b> Type 0: Not a Combination	Date 10/25/2006 h Marketi		Marketi Da Market	ng End

# PRISMASOL B22GK4/0

magnesium chloride, dextrose monohydrate, 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 Ingredi	ent/Active Moi	ety					
	Ingredi	ent Name			_	asis of trength	Strength
MAGNESIUM CHLO UNII:T6V3LHY838, CI	•	8H9O) (MAGNESIUM CATIO 232Z N48698)	N -		MAGNES CHLORII		3.05 g in 1 L
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - DEXTROSE - UNII:5SL0G7R00K) DEXTROSE							22 g in 1 L
LACTIC ACID, UNS UNSPECIFIED FORM		NII: 33X04XA5AT) (LACTIC	ACID,		LACTIC UNS PEC	ACID, CIFIED FORM	5.4 g in 1 L
SODIUM CHLORIDI CHLORIDE ION - UNII		) (SODIUM CATION - UNII:L	YR4M	IONH37,	SODIUM	I CHLORIDE	7.07 g in 1 L
SODIUM BICARBOI UNII:LYR4M0NH37, B		39QO) (SODIUM CATION - INII:HN1Z RA3Q20)			SODIUM BICARB		2.21 g in 1 L
POTASSIUM CHLO UNII:295053K152, C		8110) (POTASSIUM CATION Q32ZN48698)	-		POTASS	IUM CHLORIDE	0.314 g in 1 L
Inactive Ingre	dients						
	Ingre	edient Name				Stren	gth
WATER (UNII: 059Q							
CARBON DIOXIDE	(UNII: 142M471B3J)						
Packaging							
# Item Code	Packag	e Description	ſ	Marketing Date	Start	Marketi Da	ing End Ite
1 NDC:24571-111- 06	2 in 1 CASE		10/	10/2008			
1	5 L in 1 BAG; Type Product	0: Not a Combination					
Marketing I	nformation						
Marketing Category		Number or Monogra Citation	bh	Marketi Da	-		ting End ate
NDA	NDA021703			10/25/2006			

PRISMASOL BK0/0/ magnesium chloride, lactic ad	<b>1.2</b> cid, sodium chloride and sodi	um bicarbor	nate injection			
Product Information						
Product Type	HUMAN PRESCRIPTION DRUG	ltem Code	(Source)	NDC:24	NDC:24571-113	
Route of Administration	INTRAVENOUS					
Active Ingredient/Active	Mojety					
	redient Name		Basis o Strengt	-	Strength	
MAGNESIUM CHLORIDE (UNII: 02 UNII:T6V3LHY838, CHLORIDE ION -	2F3473H9O) (MAGNESIUM CATION - UNII:Q32ZN48698)		MAGNESIUM CHLORIDE		2.44 g in 1 L	
LACTIC ACID, UNSPECIFIED FO UNSPECIFIED FORM - UNII:33X04XA	<b>RM</b> (UNII: 33X04XA5AT) (LACTIC ACI 5AT)	D,	LACTIC ACID, UNSPECIFIED F	ORM	5.4 g in 1 L	
SODIUM CHLORIDE (UNII: 451W4 CHLORIDE ION - UNII:Q32ZN48698	7IQ8X) (SODIUM CATION - UNII:LYR4 )	MONH37,	SODIUM CHLOF	RIDE	6.46 g in 1 L	
SODIUM BICARBONATE (UNII: 8	MDE5V3900) (SODIUM CATION -		SODIUM		3.09 a	

Inactive Ingredients					
		Ingredient Name			Strength
w	ATER (UNII: 059QF				
CA	ARBON DIOXIDE (				
Pa	ackaging				
#	ltem Code	Package Description	larketing Start Date	Marketing End Date	
1	NDC:24571-113- 06	2 in 1 CASE	10/1	0/2008	
1		5 L in 1 BAG; Type 0: Not a Combination Product			
-					
Μ	larketing I	nformation			
Marketing Application Number or Monograph Marketing Sta Category Citation Date					Marketing End Date
ND	A	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	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		
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROS E MONOHYDRATE	22 g in 1 L		
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT) (LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	LACTIC ACID, UNSPECIFIED FORM	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		
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	3.09 g in 1 L		
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L		
Inactive Ingredients				

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

Pa	Packaging					
#	Item 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					
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 Inform	nation					
Product Type		HUMAN PRESCRIPTION DRUG	Item Coc	le (Source)	NDC:2	4571-116
Route of Adminis	tration	INTRAVENOUS				
Active Ingredie	ent/Active	Moiety				
		edient Name		Basis of	Strength	Strength
CALCIUM CHLORIDI CHLORIDE ION - UNII:		5VV5M) (CALCIUM CATION - UNII:	2M83C4R6ZB,	CALCIUM CH	ILORIDE	3.68 g in 1 L
MAGNESIUM CHLOP UNII:T6V3LHY838, CH	•	3473H9O) (MAGNESIUM CATION JNII:Q32ZN48698)	-	MAGNESIUM	CHLORIDE	3.05 g in 1 L
SODIUM CHLORIDE CHLORIDE ION - UNII:		IQ8X) (SODIUM CATION - UNII:LY	R4M0NH37,	SODIUM CHI	LORIDE	6.34 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20) SODIUM BIC			ARBONATE	3.09 g in 1 L		
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32ZN48698) POTASSIUM			CHLORIDE	0.314 g in 1 L		
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T) (SODIUMSODIUM PHOCATION - UNII:LYR4M0NH37, PHOSPHATE ION - UNII:NK08V8K8HR)DIBASIC, DIH			,	0.187 g in 1 L		
Inactive Ingred	lients					
Ingredient Name Strength					ngth	
	WATER (UNII: 059QF0KO0R)					
		•				
HYDROCHLORIC AC		7562CB)				
Packaging						
# Item Code	Pac	kage Description	Marketir Da	-		ing End ate
<b>1</b> NDC:24571-116- 06	2 in 1 CASE		01/13/2015			
1	5 L in 1 BAG; <sup>-</sup> Product	Type 0: Not a Combination				

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	ltem Code (Source)	NDC:24571-117	
Route of Administration	INTRAVENOUS			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
MAGNESIUM CHLORIDE (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		
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:295053K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.314 g in 1 L		
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T) (SODIUM CATION - UNII:LYR4M0NH37, PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC, DIHYDRATE	0.187 g in 1 L		

#### **Inactive Ingredients**

Strength

Packaging						
#	ltem 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 Monograp Citation	h Marketing Start Date	Marketing End Date		

Category	Citation	Date	Date
NDA	NDA207026	01/13/2015	

Labeler - Baxter Healthcare Corporation (005083209)

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), LABEL(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114), MANUFACTURE(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114), PACK(24571-108, 24571-105, 24571-103, 24571-102, 24571-111, 24571-113, 24571-114), STERILIZE(24571-108, 24571-105, 24571-103, 24571-103, 24571-102, 24571-102, 24571-103, 24571-103, 24571-103, 24571-103, 24571-102, 24571-102, 24571-103, 24571-103, 24571-103, 24571-103, 24571-103, 24571-103, 24571-104, PACK(24571-104, 24571-106, 24571-105, 24571-103, 24571-103, 24571-103, 24571-103, 24571-103, 24571-103, 24571-103, 24571-104, PACK(24571-104, 24571-106, 24571-105, 24571-103, 24571-103, 24571-103, 24571-103, 24571-104, PACK(24571-104, 24571-104, PACK(24571-104, PACK(24571-106, 24571-105, 24571-103, 24571-103, 24571-104, PACK(24571-106, 24571-106, 24571-103, 24571-103, 24571-104, PACK(24571-106, 24571-106, 24571-103, 24571-103, 24571-104, PACK(24571-106, 24571-106, 24571-106, 24571-103, 24571-106, 24

# Establishment

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), 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, 24571-103, 24571-102, 24571-102, 24571-102, 24571-111, 24571-113, 24571-114, 24571-114, 24571-103, 24571-102, 24571-104, 24571-103, 24571-103, 24571-104, 24571-105, 24571-103, 24571-103, 24571-104, 24571-105, 24571-103, 24571-103, 24571-104, 24571-103, 24571-104, 24571-103, 24571-104, 24571-103, 24571-104, 24571-103, 24571-104, 24571-103, 24571-104, 24571-103, 24571-104

Revised: 5/2023

Baxter Healthcare Corporation