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

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

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

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

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

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

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

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

To report SUSPECTED ADVERSE REACTIONS, contact Baxter Healthcare Corporation at 1-866-888-2472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Revised: 11/2018

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
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation
8.4 Pediatric Use
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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 acid-base imbalances. They may also be used in case of drug poisoning when CRRT is used to remove dialyzable substances.

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

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

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

The prepared solution is for single patient use only.

Aseptic technique should be used throughout administration to the patient.

Discard any unused solution.

2.2 Dosing Considerations

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

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

See Table 1 for the concentrations of the active ingredients (after mixing) in these 9 different replacement solutions (total volume is 5 Liters).
Table 1: Concentrations of Active Ingredients in the 7 PRISMASOL and 2 PHOXILLUM Replacement Solutions after Mixing

<table>
<thead>
<tr>
<th></th>
<th>Ca²⁺ mEq/L</th>
<th>HCO₃⁻ mEq/L</th>
<th>K⁺ mEq/L</th>
<th>Mg²⁺ mEq/L</th>
<th>Na⁺ mEq/L</th>
<th>HPO₄²⁻ mmol/L</th>
<th>Cl⁻ mEq/L</th>
<th>Lactate mg/dL</th>
<th>Dextrose mg/dL</th>
<th>Osmolarity mOsm/L</th>
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<tr>
<td>PRISMASOL Replacement Solutions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>BGK0/2.5</td>
<td>2.5</td>
<td>32</td>
<td>0</td>
<td>1.5</td>
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<td>0</td>
<td>109</td>
<td>3</td>
<td>100</td>
<td>292</td>
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<tr>
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<td>32</td>
<td>4</td>
<td>1.5</td>
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<td>0</td>
<td>113</td>
<td>3</td>
<td>100</td>
<td>300</td>
</tr>
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<td>32</td>
<td>2</td>
<td>1</td>
<td>140</td>
<td>0</td>
<td>111.5</td>
<td>3</td>
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<td>296</td>
</tr>
<tr>
<td>BGK2/0</td>
<td>0</td>
<td>32</td>
<td>2</td>
<td>1</td>
<td>140</td>
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<td>108</td>
<td>3</td>
<td>100</td>
<td>291</td>
</tr>
<tr>
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<td>22</td>
<td>4</td>
<td>1.5</td>
<td>140</td>
<td>0</td>
<td>120.5</td>
<td>3</td>
<td>100</td>
<td>296</td>
</tr>
<tr>
<td>BGK4/0/1.2</td>
<td>0</td>
<td>32</td>
<td>4</td>
<td>1.2</td>
<td>140</td>
<td>0</td>
<td>110.2</td>
<td>3</td>
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<td>140</td>
<td>0</td>
<td>106.2</td>
<td>3</td>
<td>0</td>
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<tr>
<td>PHOXILLUM Replacement Solutions</td>
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<td></td>
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</tr>
<tr>
<td>BK4/2.5</td>
<td>2.5</td>
<td>32</td>
<td>4</td>
<td>1.5</td>
<td>140</td>
<td>1</td>
<td>114.5</td>
<td>0</td>
<td>0</td>
<td>294</td>
</tr>
<tr>
<td>B22K4/0</td>
<td>0</td>
<td>22</td>
<td>4</td>
<td>1.5</td>
<td>140</td>
<td>1</td>
<td>122</td>
<td>0</td>
<td>0</td>
<td>290</td>
</tr>
</tbody>
</table>

Ca²⁺ = calcium, HCO₃⁻ = bicarbonate, K⁺ = potassium, Mg²⁺ = magnesium, Na⁺ = sodium, HPO₄²⁻ = 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 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
Step 1  Immediately before use, remove the overwrap from the bag and mix the solutions in the two different compartments. After removing the overwrap, inspect the bag for leakage by pressing firmly on the bag. Discard the bag if any leakage is detected since sterility cannot be assured. As soon as the overwrap is removed, the reconstitution of compartments A and B should be done and the mixed solution should be used immediately. After removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment. Hold the small compartment with both hands and squeeze it until an opening is created in the peel seal. (See Figure 2 beside)

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

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

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

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

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

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

Step 3b  If the injection connector (spike connector) is used, first remove the snap-off cap. Then introduce the replacement line spike through the 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 (CaCl₂ • 2H₂O).
- Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate (MgCl₂ • 6H₂O).
- Sodium chloride, USP, is chemically designated NaCl.
- Potassium chloride, USP, is chemically designated KCl.
- Sodium bicarbonate, USP, is chemically designated NaHCO₃.
- Dextrose, USP, is chemically designated D-Glucose anhydrous (C₆H₁₂O₆) or D-Glucose monohydrate (C₆H₁₂O₆ • H₂O).
Lactic acid, USP, is chemically designated \( \text{CH}_3\text{CH(OH)COOH} \).
Dibasic sodium phosphate, USP, is chemically designated as disodium hydrogen phosphate, dihydrate \((\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O})\)

### Table 2 – Compartment Composition (Before Mixing)

<table>
<thead>
<tr>
<th></th>
<th>Compartment A (g/L)</th>
<th>Compartment B (g/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Chloride</td>
<td>2H(_2)O</td>
<td></td>
</tr>
<tr>
<td>Magnesium Chloride</td>
<td>6H(_2)O</td>
<td></td>
</tr>
<tr>
<td>Dextrose anhydrous (as monohydrate)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactic Acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>3.68</td>
<td>6.46</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>3.05</td>
<td>3.09</td>
</tr>
<tr>
<td>Potassium Chloride</td>
<td>20 (22)</td>
<td>0.157</td>
</tr>
<tr>
<td>Sodium Phosphate</td>
<td>5.40</td>
<td>0.314</td>
</tr>
</tbody>
</table>

**PRISMASOL SOLUTIONS**

<table>
<thead>
<tr>
<th>Product</th>
<th>Calcium Chloride</th>
<th>Magnesium Chloride</th>
<th>Dextrose anhydrous</th>
<th>Lactic Acid</th>
<th>Sodium Chloride</th>
<th>Sodium bicarbonate</th>
<th>Potassium Chloride</th>
<th>Sodium Phosphate</th>
</tr>
</thead>
<tbody>
<tr>
<td>BGK 0/2.5</td>
<td>3.68</td>
<td>3.05</td>
<td>20 (22)</td>
<td>5.40</td>
<td>6.46</td>
<td>3.09</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BGK 4/2.5</td>
<td>3.68</td>
<td>3.05</td>
<td>20 (22)</td>
<td>5.40</td>
<td>6.46</td>
<td>3.09</td>
<td>0.314</td>
<td>0</td>
</tr>
<tr>
<td>BGK 2/3.5</td>
<td>5.15</td>
<td>2.03</td>
<td>20 (22)</td>
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<td>6.46</td>
<td>3.09</td>
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<tr>
<td>BGK 2/0</td>
<td>0</td>
<td>2.03</td>
<td>20 (22)</td>
<td>5.40</td>
<td>6.46</td>
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<td>0.157</td>
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<td>20 (22)</td>
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<tr>
<td>BK 0/0/1.2</td>
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<td>2.44</td>
<td>0 (0)</td>
<td>5.40</td>
<td>6.46</td>
<td>3.09</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
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<td>0</td>
<td>2.44</td>
<td>20 (22)</td>
<td>5.40</td>
<td>6.46</td>
<td>3.09</td>
<td>0.314</td>
<td>0</td>
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**PHOXILLUM SOLUTIONS**

<table>
<thead>
<tr>
<th>Product</th>
<th>Calcium Chloride</th>
<th>Magnesium Chloride</th>
<th>Dextrose anhydrous</th>
<th>Lactic Acid</th>
<th>Sodium Chloride</th>
<th>Sodium bicarbonate</th>
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<tr>
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<td>3.68</td>
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<td>0 (0)</td>
<td>0</td>
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<td>2.21</td>
<td>0.314</td>
<td>0.187</td>
</tr>
</tbody>
</table>

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)].

Reference ID: 4343650
### Container Specifications

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<tr>
<th>Container Type</th>
<th>Fill Volume</th>
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</tr>
<tr>
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<td>5000 mL</td>
<td>24571-108-06</td>
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<tr>
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<td>5000 mL</td>
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<td>5000 mL</td>
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<td><strong>PHOXILLUM Solutions</strong></td>
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<td></td>
</tr>
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<td>24571-116-06</td>
</tr>
<tr>
<td>PHOXILLUM B22K4/0</td>
<td>5000 mL</td>
<td>24571-117-06</td>
</tr>
</tbody>
</table>

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

07-19-00-0408

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### PrismaSol BK0/0/1.2

**Replacement Solution for Continuous Renal Replacement Therapy**

Before reconstitution each 1000 mL contains (g)

- Magnesium chloride • 6 H₂O: 2.44 g
- Sodium chloride: 6.46 g
- Lactic acid: 5.40 g
- Sodium bicarbonate: 3.09 g
- Water for injections qs, Carbon dioxide for pH adjustment

<table>
<thead>
<tr>
<th>After reconstitution, A + B</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium (Ca²⁺)</td>
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<td>1.2</td>
</tr>
<tr>
<td>Magnesium (Mg²⁺)</td>
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<td>1.0</td>
</tr>
<tr>
<td>Sodium (Na⁺)</td>
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<td>140</td>
</tr>
<tr>
<td>Chloride (Cl⁻)</td>
<td>106.2</td>
<td>106.2</td>
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<tr>
<td>Lactate (C₃H₅O₃⁻)</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Bicarbonate (HCO₃⁻)</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Potassium (K⁺)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dextrose</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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

Mix both compartments before use.  
See package insert for dosage information and further instructions.

Sterile and free from bacterial endotoxins. 
Confirm the integrity of the packaging. Use only if solution is clear. For single use only. 
**DISCARD ANY UNUSED SOLUTION.**

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

### Mixing steps:

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

---

**DISCARD ANY UNUSED SOLUTION.**

**Rx only**

EAN-14: 07332414091309

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
Mixing steps:

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

**PrismaSol BGK0/2.5**

Replacement Solution for Continuous Renal Replacement Therapy

**Rx only**

Before reconstitution each 1000 mL contains (g):

- Calcium chloride • 2 H2O
- Magnesium chloride • 6 H2O
- Dextrose anhydrous
- Lactic acid
- Sodium bicarbonate
- Water for injections qs

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. Only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION.

Theoretical osmolality: 292 mOsm/L

pH: 7.0 – 8.5

Do not freeze or expose to excessive heat.

Before reconstitution each 1000 mL contains (g):

- Calcium chloride • 2 H2O
- Magnesium chloride • 6 H2O
- Dextrose anhydrous
- Lactic acid
- Sodium bicarbonate
- Water for injections qs

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. Only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION.

Theoretical osmolality: 292 mOsm/L

pH: 7.0 – 8.5

Do not freeze or expose to excessive heat.

Before reconstitution each 1000 mL contains (g):

- Calcium chloride • 2 H2O
- Magnesium chloride • 6 H2O
- Dextrose anhydrous
- Lactic acid
- Sodium bicarbonate
- Water for injections qs

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. Only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION.

Theoretical osmolality: 292 mOsm/L

pH: 7.0 – 8.5

Do not freeze or expose to excessive heat.
Mixing steps:

1. **SQUEEZE TOP** corners to break seal

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

---

**PrismaSol BGK4/0/1.2**

Replacement Solution for Continuous Renal Replacement Therapy

**A**

- 250 mL
- Calcium
- Magnesium
- Sodium
- Chloride
- Lactate
- Bicarbonate
- Potassium
- Dextrose

**B**

- 4750 mL
- Calcium
- Magnesium
- Sodium
- Chloride
- Lactate
- Bicarbonate
- Potassium
- Dextrose

---

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>A (g)</th>
<th>B (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium chloride • 6 H₂O</td>
<td>2.44</td>
<td></td>
</tr>
<tr>
<td>Calcium chloride dihydrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>6.46</td>
<td>3.09</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>6.40</td>
<td></td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>3.09</td>
<td></td>
</tr>
<tr>
<td>Water for injection(s)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**After reconstitution, A + B**

<table>
<thead>
<tr>
<th>Component</th>
<th>A (mmol/L)</th>
<th>B (mmol/L)</th>
<th>Total (mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>0</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Magnesium</td>
<td>0.5</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>Sodium</td>
<td>146</td>
<td>110.2</td>
<td>256.2</td>
</tr>
<tr>
<td>Chloride</td>
<td>3.9</td>
<td>3.9</td>
<td>7.8</td>
</tr>
<tr>
<td>Lactate</td>
<td>5.5</td>
<td>5.5</td>
<td>11</td>
</tr>
<tr>
<td>Bicarbonate</td>
<td>4.9</td>
<td>4.9</td>
<td>9.8</td>
</tr>
<tr>
<td>Potassium</td>
<td>32</td>
<td>32</td>
<td>64</td>
</tr>
<tr>
<td>Dextrose</td>
<td>4.0</td>
<td>4.0</td>
<td>8.0</td>
</tr>
</tbody>
</table>

Theoretical osmolarity: 295 mOsm/L

pH: 7.0 – 7.5

---

Mix both compartments before use.

Mix additives **BEFORE** connecting this bag to the extracorporeal circuit. (See insert for further information.)

This product is not made with natural rubber latex.
Mixing steps:

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

PrismaSol BGK4/2.5 Replacement Solution for Continuous Renal Replacement Therapy

<table>
<thead>
<tr>
<th>Before reconstitution each 1000 mL contains (g)</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium chloride • 2 H₂O</td>
<td>3.68</td>
<td>3.01</td>
</tr>
<tr>
<td>Magnesium chloride • 6 H₂O</td>
<td>2.99</td>
<td>3.01</td>
</tr>
<tr>
<td>Natrium chloride</td>
<td>20.9</td>
<td>20.9</td>
</tr>
<tr>
<td>Dextrose anhydrous</td>
<td>6.48</td>
<td>8.16</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>0.374</td>
<td>0.374</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>5.40</td>
<td>3.05</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>3.05</td>
<td>3.05</td>
</tr>
</tbody>
</table>

Order for reconstitution: A + B

Mix additives BEFORE connecting this bag to the extracorporeal circuit. (See insert for further information.) This product is not made with natural rubber latex.

Do not freeze or expose to excessive heat. 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.

Theoretical osmolarity: 300 mOsm/L

pH: 7.0 – 7.5

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

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

**PrismaSol BGK2/3.5**
Replacement Solution for Continuous Renal Replacement Therapy

**Rx only**

**Before reconstitution each 1000 mL contains (g):**
- Calcium chloride • 2 H₂O: 5.15
- Magnesium chloride • 6 H₂O: 2.03
- Dextrose anhydrous: 20.0
- Lactic acid: 5.40
- Sodium bicarbonate: 3.09

**After reconstitution, A + B:**
- Calcium **Ca²⁺** mmol/L: 1.75
- Magnesium **Mg²⁺** mmol/L: 0.9
- Sodium **Na⁺** mmol/L: 146
- Chloride **Cl⁻** mmol/L: 111.5
- Lactate **C₃H₅O₃⁻** mmol/L: 3.0
- Bicarbonate **HCO₃⁻** mmol/L: 32
- Potassium **K⁺** mmol/L: 2.9
- Dextrose (as dextrose monohydrate) (g): 5.5

Theoretical osmolarity: 296 mOsm/L
pH: 7.0 – 7.5

**Mix both compartments before use.**

Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Do not freeze or expose to excessive heat.

Do not 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**

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Mixing steps:

1. SQUEEZE TOP corners to break seal

2. Squeeze BAG SIDES to fully open seal

PrismaSol BGK2/0
Replacement Solution for Continuous Renal Replacement Therapy

A
250 mL

B
4750 mL

Rx only

Before reconstitution each 1000 mL contains (g)

A

B

Calcium chloride • 2 H2O

Magnesium chloride • 6 H2O

Sodium chloride

Lactic acid

Sodium bicarbonate

Water for injections qs

After reconstitution, A + B

<table>
<thead>
<tr>
<th>Calcium</th>
<th>Sodium</th>
<th>Chloride</th>
<th>Bicarbonate</th>
<th>Potassium</th>
<th>Dextrose</th>
</tr>
</thead>
<tbody>
<tr>
<td>mmol/L</td>
<td>0.5</td>
<td>140</td>
<td>108.0</td>
<td>32.0</td>
<td>2.0</td>
</tr>
<tr>
<td>mEq/L</td>
<td>1.0</td>
<td>140</td>
<td>108.0</td>
<td>32.0</td>
<td>2.6</td>
</tr>
</tbody>
</table>

Theoretical osmolality: 291 mOsm/L
pH: 7.0 – 7.5

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. See insert for further information.

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

Reference ID: 4343650
Mixing steps:

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

---

**PrismaSol B22GK4/0**

Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution each 1000 mL contains (g):

<table>
<thead>
<tr>
<th>Component</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium chloride • 6 H₂O</td>
<td>3.05</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7.07</td>
<td>6.31</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>5.40</td>
<td></td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>2.21</td>
<td></td>
</tr>
</tbody>
</table>

Water for injections qs, Carbon dioxide for pH adjustment

After reconstitution, A + B:

<table>
<thead>
<tr>
<th>Component</th>
<th>A + B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>Ca²⁺</td>
</tr>
<tr>
<td>Magnesium</td>
<td>Mg²⁺</td>
</tr>
<tr>
<td>Sodium</td>
<td>Na⁺</td>
</tr>
<tr>
<td>Chloride</td>
<td>Cl⁻</td>
</tr>
<tr>
<td>Lactate</td>
<td>C₃H₅O₃⁻</td>
</tr>
<tr>
<td>Bicarbonate</td>
<td>HCO₃⁻</td>
</tr>
<tr>
<td>Potassium</td>
<td>K⁺</td>
</tr>
<tr>
<td>Dextrose</td>
<td></td>
</tr>
</tbody>
</table>

mmol/L: 0 1.5 140 120.5 3.0 22 4.5 1.5
mEq/L: 0 1.5 140 120.5 3.0 22 4.0 (100 mg/dL)

Theoretical isotonicity: 296 mOsm/L

pH: 7.0 – 7.5

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 UNSEEN SOLUTION.**

Store at +2°C to +8°C. Exposures 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 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.
Mixing steps

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

A 
250 mL
B 
4750 mL

**Phoxium BK4/2.5**
Replacement Solution for Continuous Renal Replacement Therapy

<table>
<thead>
<tr>
<th>Before reconstitution, each 1000 mL contain (g)</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium chloride • 2H2O</td>
<td>3.65</td>
<td>3.06</td>
</tr>
<tr>
<td>Magnesium chloride • 6H2O</td>
<td>1.1</td>
<td>0.96</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>6.34</td>
<td>6.31</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>0.19</td>
<td>0.19</td>
</tr>
<tr>
<td>Dibasic sodium phosphate • 7H2O</td>
<td>0.187</td>
<td>0.187</td>
</tr>
<tr>
<td>Water for injections</td>
<td>q.s</td>
<td>q.s</td>
</tr>
</tbody>
</table>

After reconstitution, A + B

<table>
<thead>
<tr>
<th>Calcium</th>
<th>Magnesium</th>
<th>Sodium</th>
<th>Chloride</th>
<th>Bicarbonate</th>
<th>Potassium</th>
<th>Phosphate</th>
<th>Dextrose</th>
</tr>
</thead>
<tbody>
<tr>
<td>mmol/L</td>
<td>1.25</td>
<td>0.75</td>
<td>14</td>
<td>114.5</td>
<td>32</td>
<td>4.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Theoretical osmolarity: 294 mOsm/L
pH: 7.6 – 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). 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 the line 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.

EAN4: 07332414110040
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

Reference ID: 4343650
Mixing steps

1. Squeeze TOP corners to break seal

2. Squeeze BAG SIDES to fully open seal

Phoxillum B22K4/0
Replacement Solution for Continuous Renal Replacement Therapy

Before reconstitution, each 1000 mL contains (g):
- Magnesium chloride • 6H2O: 3.05
- Sodium chloride: 6.95
- Potassium chloride: 0.314
- Sodium bicarbonate: 2.21
- Dibasic sodium phosphate • 2H2O: 0.187
- Water for injections q.s:

After reconstitution, A + B

<table>
<thead>
<tr>
<th>Component</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>0.75</td>
<td>1.50</td>
</tr>
<tr>
<td>Magnesium</td>
<td>3.75</td>
<td>140</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>148</td>
<td>148</td>
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<tr>
<td>Chloride</td>
<td>122.0</td>
<td>122.0</td>
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<tr>
<td>Bicarbonate</td>
<td>22</td>
<td>22</td>
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<tr>
<td>Potassium</td>
<td>0.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Phosphate</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Dextrose</td>
<td>141</td>
<td>141</td>
</tr>
</tbody>
</table>

Mix both compartments before use.

See package insert for dosage information and further instructions. Sterile and free from bacterial endotoxins.

Confirm the integrity of the packaging. Use only if solution is clear. For single use only. DISCARD ANY UNUSED SOLUTION. Store at +20°C to +25°C (+68°F to +77°F); excursions permitted to +15°C to +30°C (+59°F to +86°F). [See USP Controlled Room Temperature]. Do not freeze or expose to excessive heat. As soon as the overwrap is removed, the reconstitution of both 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.

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

Reference ID: 4343650