

PrismaSol Solution

PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 0/2.5	PrismaSol B22GK 4/2.5
PrismaSol BGK 4/0/1.2	PrismaSol BGK 2/0	PrismaSol B22GK 4/0	PrismaSol B22GK 2/0
PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5		

Sterile Hemofiltration and Hemodiafiltration Solution

DESCRIPTION

PrismaSol solution is a clear, sterile solution free of bacterial endotoxins. This solution is used in Continuous Renal Replacement Therapies (CRRT) as a replacement solution in hemofiltration and hemodiafiltration.

It contains no bacteriostatic or antimicrobial agents.

PrismaSol solution is packaged in a two-compartment bag. The small compartment A contains electrolytes and the large compartment B contains buffer. The final reconstituted solution (5000 mL) is obtained after breaking the red frangible pin between compartments A and B and mixing both solutions. The compositions of the solution before and after reconstitution are described in the following tables.

BEFORE RECONSTITUTION

1000 mL of electrolyte solution (small compartment A) contains (g):

	PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 0/2.5	PrismaSol B22GK 4/2.5
Calcium chloride • 2H ₂ O	3.68	5.15	3.68	3.68
Magnesium chloride • 6H ₂ O	3.05	2.03	3.05	3.05
Dextrose anhydrous (as dextrose monohydrate)	20.0 22.0	20.0 22.0	20.0 22.0	20.0 22.0
Lactic acid	5.40	5.40	5.40	5.40

1000 mL of buffer solution (large compartment B) contains (g):

	PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 0/2.5	PrismaSol B22GK 4/2.5
Sodium chloride	6.46	6.46	6.46	7.07
Sodium bicarbonate	3.09	3.09	3.09	2.21
Potassium chloride	0.314	0.157	0	0.314

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1000 mL of electrolyte solution (small compartment A) contains (g):

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	PrismaSol BGK4/0/1.2	PrismaSol BGK 2/0	PrismaSol B22GK 4/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Calcium chloride • 2H ₂ O	0	0	0	0	0	5.15
Magnesium chloride • 6H ₂ O	2.44	2.03	3.05	3.05	2.44	2.03
Dextrose anhydrous	20.0	20.0	20.0	20.0	0	0
(as dextrose monohydrate)	22.0	22.0	22.0	22.0	0	0
Lactic acid	5.40	5.40	5.40	5.40	5.40	5.40

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1000 mL of buffer solution (large compartment B) contains (g):

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	PrismaSol BGK4/0/1.2	PrismaSol BGK 2/0	PrismaSol B22GK 4/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Sodium chloride	6.46	6.46	7.07	7.07	6.46	6.46
Sodium bicarbonate	3.09	3.09	2.21	2.21	3.09	3.09
Potassium chloride	0.314	0.157	0.314	0.157	0	0

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AFTER RECONSTITUTION of compartments A and B

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1000 mL of the reconstituted solution contains:

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in mEq/L except where noted	PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 0/2.5	PrismaSol B22GK 4/2.5
Calcium Ca ²⁺	2.5	3.5	2.5	2.5
Bicarbonate HCO ₃ ⁻	32	32	32	22
Potassium K ⁺	4.0	2.0	0	4.0
Magnesium Mg ²⁺	1.5	1.0	1.5	1.5
Sodium Na ⁺	140	140	140	140
Chloride Cl ⁻	113	111.5	109	123
Lactate	3.0	3.0	3.0	3.0
Dextrose	100 mg/dL	100 mg/dL	100 mg/dL	100 mg/dL
Theoretical Osmolarity	300 mOsm/L	296 mOsm/L	292 mOsm/L	300 mOsm/L

37

in mEq/L except where noted	PrismaSol BGK 4/0/1.2	PrismaSol BGK 2/0	PrismaSol B22GK 4/0	PrismaSol B22GK 2/0
Calcium Ca ²⁺	0	0	0	0
Bicarbonate HCO ₃ ⁻	32	32	22	22
Potassium K ⁺	4.0	2.0	4.0	2.0
Magnesium Mg ²⁺	1.2	1.0	1.5	1.5
Sodium Na ⁺	140	140	140	140
Chloride Cl ⁻	110.2	108	120.5	118.5
Lactate	3.0	3.0	3.0	3.0
Dextrose	100 mg/dL	100 mg/dL	100 mg/dL	100 mg/dL
Theoretical Osmolarity	295 mOsm/L	291 mOsm/L	296 mOsm/L	292 mOsm/L

38

in mEq/L except where noted	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Calcium Ca ²⁺	0	3.5
Bicarbonate HCO ₃ ⁻	32	32
Potassium K ⁺	0	0
Magnesium Mg ²⁺	1.2	1.0
Sodium Na ⁺	140	140
Chloride Cl ⁻	106.2	109.5
Lactate	3.0	3.0
Dextrose	0	0
Theoretical Osmolarity	282 mOsm/L	287 mOsm/L

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40

41 Calcium chloride, USP, is chemically designated calcium chloride dihydrate (CaCl₂ • 2
42 H₂O).

43 Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate
44 (MgCl₂ • 6H₂O).

45 Dextrose, USP, is chemically designated D-Glucose anhydrous (C₆H₁₂O₆) or D-Glucose
46 monohydrate (C₆H₁₂O₆ • H₂O).

47 Lactic acid, USP, is chemically designated CH₃CH(OH)COOH.

48 Sodium chloride, USP, is chemically designated NaCl.

49 Potassium chloride, USP, is chemically designated KCl.

50 Sodium bicarbonate, USP, is chemically designated NaHCO₃.

51

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

53 Solutions in contact with the plastic container can leach out certain of its chemical
54 components in very small amounts within the expiration period, e.g. di 2-ethylhexyl
55 phthalate (DEHP), up to 3 parts per million; however, the safety of the plastic has been
56 confirmed in tests in animals according to USP biological tests for plastic containers as
57 well as by in-vitro toxicity studies.

58

59 CLINICAL PHARMACOLOGY

60 PrismaSol solution is a pharmacologically inactive solution. The electrolyte
61 concentrations in the PrismaSol solution are chosen to restore plasma levels to clinically
62 desired concentrations or maintain plasma levels at the desired concentrations.

63

64 PrismaSol solution is used as replacement solution to replace water and electrolytes
65 removed during hemofiltration and hemodiafiltration.

66

67 Bicarbonate in the solution is used as an alkalinizing buffer to normalize acid-base
68 balance. Lactate is used for the adjustment of the solution pH and is metabolized to
69 bicarbonate.

70

71 When dextrose is present, it is intended to help normalize glucose balance.

72

73 **INDICATIONS AND USAGE**

74 PrismaSol solution is indicated in adults and children for use as a replacement solution in
75 Continuous Renal Replacement Therapy (CRRT) to replace plasma volume removed by
76 ultrafiltration and to correct electrolytes and acid-base imbalances. PrismaSol solution
77 may also be used in case of drug poisoning when CRRT is used to remove filterable
78 substances.
79

80 **CONTRAINDICATIONS**

81 None.

82

83 **WARNINGS**

84 The electrolyte solution contained in compartment A **must** be mixed with the buffer
85 solution of compartment B **before use** in order to obtain the reconstituted solution
86 suitable for hemofiltration / hemodiafiltration.
87

88 Do not administer the reconstituted solution unless it is clear and free of visible
89 particulate matter.
90

91 **PRECAUTIONS**

92 PrismaSol solution includes **several** formulations. Selection of a specific formulation
93 depends on the patient's condition and treatment procedures.
94

95 Administration of the solution should only be under the direction of a physician
96 competent in intensive care treatment including CRRT.
97

98 The patient's hemodynamic fluid, electrolyte and acid-base balance should be monitored
99 throughout the procedure. Note that citrate, when used as an anticoagulant, contributes to
100 the base load and can reduce plasma calcium levels.
101

102 During hemofiltration, hemodiafiltration, or hemodialysis, abnormalities in the plasma
103 concentration of potassium, calcium, and glucose may develop. These abnormalities
104 may be corrected by the use of appropriate formulations of PrismaSol. Abnormalities in
105 plasma phosphate concentration, especially hypophosphatemia, may also
106 occur. Hypophosphatemia may require phosphate supplementation to
107 maintain plasma concentrations in the physiologic range.
108

109 Use only with continuous extra-corporeal blood purification equipment in CRRT.
110

111 Incorrect use of the access ports or other restrictions to fluid flow will result in machine

112 alarms. Ignoring and/or overriding repetitive alarms without resolving the originating
113 cause might lead to incorrect patient weight loss and result in patient injury or death.

114

115 The solution may be heated to no more than 40°C/104°F and this must be carefully
116 controlled. After heating, verify that the solution remains clear and contains no
117 particulate matter.

118

119 Diabetes Mellitus or Glucose Intolerance

120 Patients may require initiation of insulin therapy or modification of insulin dosage during
121 treatment with PrismaSol solution. Appropriate monitoring of blood glucose should be
122 performed and insulin dosage adjusted accordingly.

123

124 **ADVERSE REACTIONS**

125 Adverse reactions can result from the solution or the CRRT procedure.

126

127 Improper use can lead to fluid imbalance and disturbances in electrolyte, acid-base and
128 glucose balance.

129

130 **DOSAGE AND ADMINISTRATION**

131 **Individualization of Treatments:**

132 The mode of therapy, solute formulation, flow rates and length of therapy should be
133 selected by the physician responsible for managing treatment depending on the clinical
134 condition of the patient as well as the patient's fluid, electrolyte, acid-base and glucose
135 balance.

136

137 PrismaSol solution can be administered into the extra-corporeal circuit before (pre-
138 dilution) and/or after the hemofilter or hemodiafilter (post-dilution).

139

140 In post-dilution hemofiltration, the replacement rate should not be greater than one-third
141 of the blood flow rate; e.g., for blood flow of 100 mL/min, equivalent to 6000 mL/hour,
142 post-filter replacement rate should not exceed 2000 mL/hour.

143

144 **Directions for use:**

145 PrismaSol solution should be inspected visually for particulate matter and discoloration
146 prior to administration. Use only if the solution is clear and all seals are intact. Press bag
147 firmly to test for any leakage. Do not use if container is damaged or leaking.

148

149 The electrolyte solution (small compartment A) is added to the buffer solution (large
150 compartment B) by breaking the red frangible pin immediately before use and mixing
151 the contents of compartment A and B.

152

153 • The reconstituted solution is for single patient use only

154 • Aseptic technique should be used throughout administration to the patient.

- Discard any unused solution immediately after use.

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. Due to chemical reasons, after removal of the overwrap, the solution is stable for 24 hours including the duration of the treatment.

I Remove the overwrap from the bag immediately before use and discard any other packaging materials. Open the seal by breaking the red frangible pin between the two compartments of the bag. The frangible pin will remain in the bag. (See Figure I below)

II Make sure all the fluid from the small compartment A is transferred into the large compartment B. (See Figure II below)

III Rinse the small compartment A **twice** by pressing the mixed solution back into the small compartment A and then back into the large compartment B. (See Figure III below)

IV When the small compartment A is empty: shake the large compartment B so that the contents mix completely. The solution is now ready to use and the bag can be hung on the equipment. (See Figure IV below)

V The replacement line may be connected to either of the two access ports.

V.a If the luer access is used, remove the cap and connect the male luer lock on the replacement line to the female luer receptor on the bag; tighten. Using thumb and fingers, break the blue frangible pin at its base, and move it back and forth. Do not use a tool. Verify that the pin is completely separated and that the fluid is flowing freely. The pin will remain in the luer port during the treatment. (See Figure V.a below)

V.b If the injection port is used, first remove the snap-off cap. Then introduce the spike through the rubber septum. Verify that the fluid is flowing freely. (See Figure V.b below)

Additions:

The large compartment B is fitted with an injection port for the addition of drugs after reconstitution of the solution. When introducing additives, use aseptic techniques.

Phosphate: Phosphate up to 1.2 mmol/L may be added to the solution. If potassium phosphate is added, the total potassium concentration should not exceed 4 mEq/L.

Other drugs: Some drugs may be incompatible with PrismaSol solution. In general, other drugs should be administered through a different line.

HOW SUPPLIED

200 PrismaSol solution is supplied in a two-compartment bag made of Poly (vinyl chloride)
201 (PVC). The 5000 mL bag is composed of a small compartment (250 mL) and a large
202 compartment (4750 mL). The two compartments are separated by a red frangible pin.
203 The bag is overwrapped with a transparent overpouch.
204

205	Container	Fill Volume	NDC
206	PrismaSol BGK4/2.5	5000 mL	24571-105-05
207	PrismaSol BGK2/3.5	5000 mL	24571-103-05
208	PrismaSol BGK0/2.5	5000 mL	24571-108-05
209	PrismaSol B22GK4/2.5	5000 mL	Not yet available
210	PrismaSol BGK4/0/1.2	5000 mL	Not yet available
211	PrismaSol BGK2/0	5000 mL	24571-102-05
212	PrismaSol B22GK4/0	5000 mL	Not yet available
213	PrismaSol B22GK2/0	5000 mL	Not yet available
214	PrismaSol BK0/0/1.2	5000 mL	Not yet available
215	PrismaSol BK0/3.5	5000 mL	24571-101-05

216
217 Not all formulations may be marketed.
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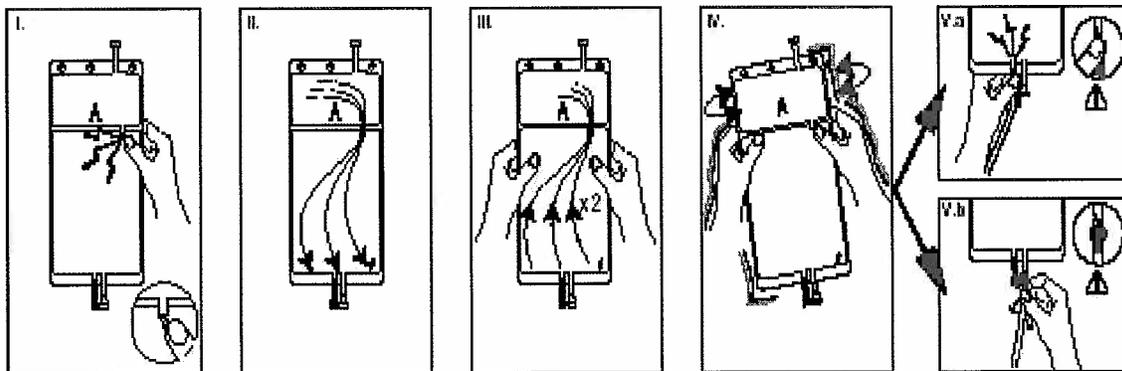
219 **Storage conditions**

220 Store at 25°C (77°F); excursions permitted to 15° - 30°C (59°- 86°F). [See USP
221 Controlled Room Temperature].
222 Do not freeze or expose to excessive heat. Do not use if precipitate has formed or if
223 container seals have been damaged.
224

225 Manufactured by:

226 **Gambro**
227 1845 Mason Avenue
228 Daytona Beach, FL 32117, USA
229

230 Figures I-Vb



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