

PrismaSol Solution

PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 0/2.5	PrismaSol BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
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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 BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Calcium chloride • 2H ₂ O	3.68	5.15	3.68	0	0	0	5.15
Magnesium chloride • 6H ₂ O	3.05	2.03	3.05	2.03	3.05	2.44	2.03
Dextrose anhydrous (as dextrose monohydrate)	20.0 22.0	20.0 22.0	20.0 22.0	20.0 22.0	20.0 22.0	0 0	0 0
Lactic acid	5.40	5.40	5.40	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 BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Sodium chloride	6.46	6.46	6.46	6.46	7.07	6.46	6.46
Sodium bicarbonate	3.09	3.09	3.09	3.09	2.21	3.09	3.09
Potassium chloride	0.314	0.157	0	0.157	0.157	0	0

AFTER RECONSTITUTION of compartments A and B

1000 mL of the reconstituted solution contains:

30

in mEq/L except where noted	PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 0/2.5	PrismaSol BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Calcium Ca ²⁺	2.5	3.5	2.5	0	0	0	3.5
Bicarbonate HCO ₃ ⁻	32	32	32	32	22	32	32
Potassium K ⁺	4.0	2.0	0	2.0	2.0	0	0
Magnesium Mg ²⁺	1.5	1.0	1.5	1.0	1.5	1.2	1.0
Sodium Na ⁺	140	140	140	140	140	140	140
Chloride Cl ⁻	113	111.5	109	108	118.5	106.2	109.5
Lactate	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Dextrose	100 mg/dL	100 mg/dL	100 mg/dL	100 mg/dL	100 mg/dL	0	0
Theoretical Osmolarity	300 mOsm/L	296 mOsm/L	292 mOsm/L	291 mOsm/L	292 mOsm/L	282 mOsm/L	287 mOsm/L

31

32

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

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

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

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

40 Sodium chloride, USP, is chemically designated NaCl.

41 Potassium chloride, USP, is chemically designated KCl.

42 Sodium bicarbonate, USP, is chemically designated NaHCO₃.

43

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

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

50

51 CLINICAL PHARMACOLOGY

52 PrismaSol solution is a pharmacologically inactive solution. The electrolyte
53 concentrations in the PrismaSol solution are chosen to restore plasma levels to clinically
54 desired concentrations or maintain plasma levels at the desired concentrations.

55

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

58

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

62

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

64

65 **INDICATIONS AND USAGE**

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

71

72 **CONTRAINDICATIONS**

73 None.

74

75 **WARNINGS**

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

79

80 Do not administer the reconstituted solution unless it is clear and free of visible
81 particulate matter.

82

83 **PRECAUTIONS**

84 PrismaSol solution includes several formulations. Selection of a specific formulation
85 depends on the patient's condition and treatment procedures.

86

87 Administration of the solution should only be under the direction of a physician
88 competent in intensive care treatment including CRRT.

89

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

93

94 During hemofiltration, hemodiafiltration, or hemodialysis, abnormalities in the plasma
95 concentration of potassium, calcium, and glucose may develop. These abnormalities
96 may be corrected by the use of appropriate formulations of PrismaSol. Abnormalities in
97 plasma phosphate concentration, especially hypophosphatemia, may also
98 occur. Hypophosphatemia may require phosphate supplementation to
99 maintain plasma concentrations in the physiologic range.

100

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

102

103 Incorrect use of the access ports or other restrictions to fluid flow will result in machine
104 alarms. Ignoring and/or overriding repetitive alarms without resolving the originating
105 cause might lead to incorrect patient weight loss and result in patient injury or death.

106
107 The solution may be heated to no more than 40°C/104°F and this must be carefully
108 controlled. After heating, verify that the solution remains clear and contains no
109 particulate matter.

110
111 Diabetes Mellitus or Glucose Intolerance

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

115

116 **ADVERSE REACTIONS**

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

118

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

121

122 **DOSAGE AND ADMINISTRATION**

123 **Individualization of Treatments:**

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

128

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

131

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

135

136 **Directions for use:**

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

140

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

144

- The reconstituted solution is for single patient use only

145

- Aseptic technique should be used throughout administration to the patient.

- 146 • Discard any unused solution immediately after use.

147

148 As soon as the overwrap is removed, the reconstitution of compartments A and B should
149 be done and the reconstituted solution should be used immediately. Due to chemical
150 reasons, after removal of the overwrap, the solution is stable for 24 hours including the
151 duration of the treatment.

152

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

156

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

159

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

163

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

167

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

169

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

175

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

179

180 **Additions:**

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

183

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

186

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

189

190 **HOW SUPPLIED**

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

195

196 Container	Fill Volume	NDC
197 PrismaSol BGK4/2.5	5000 mL	24571-105-05
198 PrismaSol BGK2/3.5	5000 mL	24571-103-05
199 PrismaSol BGK0/2.5	5000 mL	24571-108-05
200 PrismaSol BGK2/0	5000 mL	24571-102-05
201 PrismaSol B22GK2/0	5000 mL	24571-110-05
202 PrismaSol BK0/0/1.2	5000 mL	24571-113-05
203 PrismaSol BK0/3.5	5000 mL	24571-101-05

204
 205 Not all formulations may be marketed.

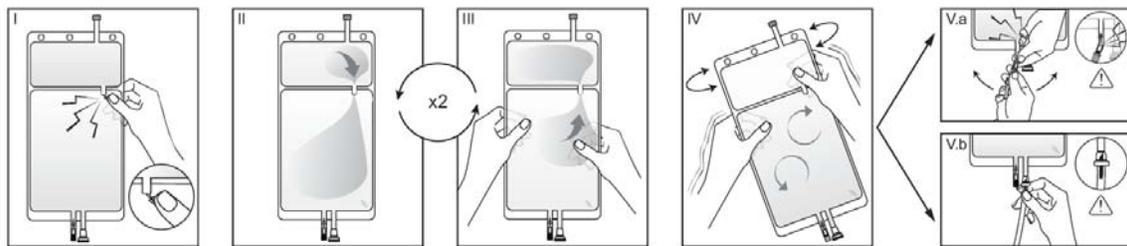
206
 207 **Storage conditions**

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

212
 213 Manufactured by:
 214 Gambro
 215 1845 Mason Avenue
 216 Daytona Beach, FL 32117, USA

217
 218 **Figures I-Vb**

219



220

PrismaSol Solution

PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 0/2.5	PrismaSol BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
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Sterile Hemofiltration and Hemodiafiltration Solution

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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 BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Calcium chloride • 2H ₂ O	3.68	5.15	3.68	0	0	0	5.15
Magnesium chloride • 6H ₂ O	3.05	2.03	3.05	2.03	3.05	2.44	2.03
Dextrose anhydrous	20.0	20.0	20.0	20.0	20.0	0	0
(as dextrose monohydrate)	22.0	22.0	22.0	22.0	22.0	0	0
Lactic acid	5.40	5.40	5.40	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 BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Sodium chloride	6.46	6.46	6.46	6.46	7.07	6.46	6.46
Sodium bicarbonate	3.09	3.09	3.09	3.09	2.21	3.09	3.09
Potassium chloride	0.314	0.157	0	0.157	0.157	0	0

AFTER RECONSTITUTION of compartments A and B

1000 mL of the reconstituted solution contains:

PrismaSol – PVC presentation with luer connector with valve

30

in mEq/L except where noted	PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 0/2.5	PrismaSol BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2	PrismaSol BK 0/3.5
Calcium Ca ²⁺	2.5	3.5	2.5	0	0	0	3.5
Bicarbonate HCO ₃ ⁻	32	32	32	32	22	32	32
Potassium K ⁺	4.0	2.0	0	2.0	2.0	0	0
Magnesium Mg ²⁺	1.5	1.0	1.5	1.0	1.5	1.2	1.0
Sodium Na ⁺	140	140	140	140	140	140	140
Chloride Cl ⁻	113	111.5	109	108	118.5	106.2	109.5
Lactate	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Dextrose	100 mg/dL	100 mg/dL	100 mg/dL	100 mg/dL	100 mg/dL	0	0
Theoretical Osmolarity	300 mOsm/L	296 mOsm/L	292 mOsm/L	291 mOsm/L	292 mOsm/L	282 mOsm/L	287 mOsm/L

31

32

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

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

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

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

40 Sodium chloride, USP, is chemically designated NaCl.

41 Potassium chloride, USP, is chemically designated KCl.

42 Sodium bicarbonate, USP, is chemically designated NaHCO₃.

43

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

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

50

51 CLINICAL PHARMACOLOGY

52 PrismaSol solution is a pharmacologically inactive solution. The electrolyte
53 concentrations in the PrismaSol solution are chosen to restore plasma levels to clinically
54 desired concentrations or maintain plasma levels at the desired concentrations.

55

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

58

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

62

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

64

65 **INDICATIONS AND USAGE**

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

71

72 **CONTRAINDICATIONS**

73 None.

74

75 **WARNINGS**

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

79

80 Do not administer the reconstituted solution unless it is clear and free of visible
81 particulate matter.

82

83 **PRECAUTIONS**

84 PrismaSol solution includes several formulations. Selection of a specific formulation
85 depends on the patient's condition and treatment procedures.

86

87 Administration of the solution should only be under the direction of a physician
88 competent in intensive care treatment including CRRT.

89

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

93

94 During hemofiltration, hemodiafiltration, or hemodialysis, abnormalities in the plasma
95 concentration of potassium, calcium, and glucose may develop. These abnormalities
96 may be corrected by the use of appropriate formulations of PrismaSol. Abnormalities in
97 plasma phosphate concentration, especially hypophosphatemia, may also
98 occur. Hypophosphatemia may require phosphate supplementation to
99 maintain plasma concentrations in the physiologic range.

100

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

102

103 Incorrect use of the access ports or other restrictions to fluid flow will result in machine
104 alarms. Ignoring and/or overriding repetitive alarms without resolving the originating
105 cause might lead to incorrect patient weight loss and result in patient injury or death.

106

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

110

111 Diabetes Mellitus or Glucose Intolerance

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

115

116 **ADVERSE REACTIONS**

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

118

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

121

122 **DOSAGE AND ADMINISTRATION**

123 **Individualization of Treatments:**

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

128

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

131

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

135

136 **Directions for use:**

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

140

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

144

- The reconstituted solution is for single patient use only

145

- Aseptic technique should be used throughout administration to the patient.

146 • Discard any unused solution immediately after use.

147

148 As soon as the overwrap is removed, the reconstitution of compartments A and B should
149 be done and the reconstituted solution should be used immediately. Due to chemical
150 reasons, after removal of the overwrap, the solution is stable for 24 hours including the
151 duration of the treatment.

152

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

156

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

159

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

163

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

167

168 **V** The replacement line may be connected to the bag through either the luer or the
169 injection connector.

170

171 The luer port is a needle-less and swabbable connector. Remove the cap with a twist and
172 pull motion, connect the male luer lock on the replacement line to the female luer
173 receptor on the bag. Ensure the connection is fully seated and tighten. The connector is
174 now open. Verify that the fluid is flowing freely during use. When the replacement line
175 is disconnected from the luer connector, the connector will close and the flow of the
176 solution will stop. (See Figure V below)

177

178

179 **Additions:**

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

182

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

185

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

188

189

190 **HOW SUPPLIED**

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

196 Container	Fill Volume	NDC
197 PrismaSol BGK4/2.5	5000 mL	24571-105-05
198 PrismaSol BGK2/3.5	5000 mL	24571-103-05
199 PrismaSol BGK0/2.5	5000 mL	24571-108-05
200 PrismaSol BGK2/0	5000 mL	24571-102-05
201 PrismaSol B22GK2/0	5000 mL	24571-110-05
202 PrismaSol BK0/0/1.2	5000 mL	24571-113-05
203 PrismaSol BK0/3.5	5000 mL	24571-101-05

204

205 Not all formulations may be marketed.

206

207 **Storage conditions**

208 Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F). [See USP
 209 Controlled Room Temperature].

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

212

213 Manufactured by:

214 Gambro

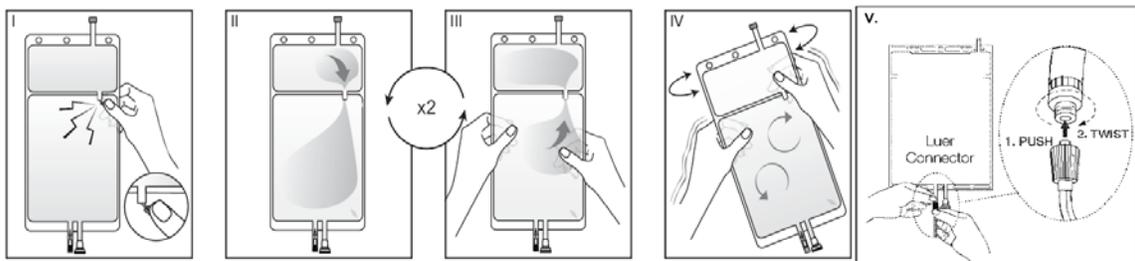
215 1845 Mason Avenue

216 Daytona Beach, FL 32117, USA

217

218 **Figures I-V**

219



220

PrismaSol Solution

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

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 peel seal** 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 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2
Calcium chloride • 2H ₂ O	3.68	5.15	0	0	0
Magnesium chloride • 6H ₂ O	3.05	2.03	2.03	3.05	2.44
Dextrose anhydrous	20.0	20.0	20.0	20.0	0
(as dextrose monohydrate)	22.0	22.0	22.0	22.0	0
Lactic acid	5.40	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 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2
Sodium chloride	6.46	6.46	6.46	7.07	6.46
Sodium bicarbonate	3.09	3.09	3.09	2.21	3.09
Potassium chloride	0.314	0.157	0.157	0.157	0

AFTER RECONSTITUTION of compartments A and B

1000 mL of the reconstituted solution contains:

30

in mEq/L except where noted	PrismaSol BGK 4/2.5	PrismaSol BGK 2/3.5	PrismaSol BGK 2/0	PrismaSol B22GK 2/0	PrismaSol BK 0/0/1.2
Calcium Ca ²⁺	2.5	3.5	0	0	0
Bicarbonate HCO ₃ ⁻	32	32	32	22	32
Potassium K ⁺	4.0	2.0	2.0	2.0	0
Magnesium Mg ²⁺	1.5	1.0	1.0	1.5	1.2
Sodium Na ⁺	140	140	140	140	140
Chloride Cl ⁻	113	111.5	108	118.5	106.2
Lactate	3.0	3.0	3.0	3.0	3.0
Dextrose	100 mg/dL	100 mg/dL	100 mg/dL	100 mg/dL	0
Theoretical Osmolarity	300 mOsm/L	296 mOsm/L	291 mOsm/L	292 mOsm/L	282 mOsm/L

31

32

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

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

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

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

40 Sodium chloride, USP, is chemically designated NaCl.

41 Potassium chloride, USP, is chemically designated KCl.

42 Sodium bicarbonate, USP, is chemically designated NaHCO₃.

43

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

45

46 CLINICAL PHARMACOLOGY

47 PrismaSol solution is a pharmacologically inactive solution. The electrolyte
48 concentrations in the PrismaSol solution are chosen to restore plasma levels to clinically
49 desired concentrations or maintain plasma levels at the desired concentrations.

50

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

53

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

57

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

59

60 INDICATIONS AND USAGE

61 PrismaSol solution is indicated in adults and children for use as a replacement solution in
62 Continuous Renal Replacement Therapy (CRRT) to replace plasma volume removed by
63 ultrafiltration and to correct electrolytes and acid-base imbalances. PrismaSol solution

64 may also be used in case of drug poisoning when CRRT is used to remove filterable
65 substances.

66

67 **CONTRAINDICATIONS**

68 None.

69

70 **WARNINGS**

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

74

75 Do not administer the reconstituted solution unless it is clear and free of visible
76 particulate matter.

77

78 **PRECAUTIONS**

79 PrismaSol solution includes several formulations. Selection of a specific formulation
80 depends on the patient's condition and treatment procedures.

81

82 Administration of the solution should only be under the direction of a physician
83 competent in intensive care treatment including CRRT.

84

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

88

89 During hemofiltration, hemodiafiltration, or hemodialysis, abnormalities in the plasma
90 concentration of potassium, calcium, and glucose may develop. These abnormalities
91 may be corrected by the use of appropriate formulations of PrismaSol. Abnormalities in
92 plasma phosphate concentration, especially hypophosphatemia, may also
93 occur. Hypophosphatemia may require phosphate supplementation to
94 maintain plasma concentrations in the physiologic range.

95

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

97

98 Incorrect use of the access ports or other restrictions to fluid flow will result in machine
99 alarms. Ignoring and/or overriding repetitive alarms without resolving the originating
100 cause might lead to incorrect patient weight loss and result in patient injury or death.

101

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

105

106 Diabetes Mellitus or Glucose Intolerance

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

110

111 **ADVERSE REACTIONS**

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

113

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

116

117 **DOSAGE AND ADMINISTRATION**

118 **Individualization of Treatments:**

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

123

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

126

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

130

131 **Directions for use:**

132 PrismaSol solution should be inspected visually for particulate matter and discoloration
133 prior to administration. Use only if the solution is clear and all seals, **including the peel**
134 **seal between the compartments are intact.** Press bag firmly to test for any leakage. Do
135 not use if container is damaged or leaking.

136

137 The electrolyte solution (small compartment A) is added to the buffer solution (large
138 compartment B) by opening **the peel seal** immediately before use and mixing the
139 contents of compartment A and B.

140

- 141
- 142 • The reconstituted solution is for single patient use only
 - 143 • Aseptic technique should be used throughout administration to the patient.
 - 144 • Discard any unused solution immediately after use.

144

145 As soon as the overwrap is removed, the reconstitution of compartments A and B should
146 be done and the reconstituted solution should be used immediately. Due to chemical
147 reasons, after removal of the overwrap, the solution is stable for 24 hours including the

148 duration of the treatment.

149

150 **I** Immediately before use, remove the overwrap from the bag and mix the solutions in
151 the two different compartments. Hold the small compartment with both hands and
152 squeeze it until an opening is created in the peel seal. (See Figure I below)

153

154 **II** Squeeze with both hands on the large compartment until the peel seal between the
155 two compartments is entirely open. Shake gently to mix. (See Figure II below)

156

157 The solution is now ready for use and can be hung on the equipment.

158

159 **III** The replacement line may be connected to the bag through either of the luer or the
160 spike connector.

161

162 The luer port is a needle-less and swabbable connector. Remove the cap with a twist and
163 pull motion, and connect the male luer lock on the replacement line to the female luer
164 receptor on the bag. Ensure that the connection is fully seated and tighten. The connector
165 is now open. Verify that the fluid is flowing freely during use.

166

167 When the replacement line is disconnected from the luer connector, the connector will
168 close and the flow of the solution will stop. (See Figure III below)

169

170

171 **Additions:**

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

174

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

177

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

180

181 **HOW SUPPLIED**

182 PrismaSol solution is supplied in a two-compartment bag made of polyolefin. The 5000
183 mL bag is composed of a small compartment (250 mL) and a large compartment (4750
184 mL). The two compartments are separated by a peel seal. The bag is overwrapped with a
185 transparent overpouch.

186

187

188

189

190

191

192

193	Container	Fill Volume	NDC
194	PrismaSol BGK4/2.5	5000 mL	24571-105-05
195	PrismaSol BGK2/3.5	5000 mL	24571-103-05
196	PrismaSol BGK2/0	5000 mL	24571-102-05
197	PrismaSol B22GK2/0	5000 mL	24571-110-05
198	PrismaSol BK0/0/1.2	5000 mL	24571-113-05

199

200 Not all formulations may be marketed.

201

202 **Storage conditions**

203 Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F). [See USP
204 Controlled Room Temperature].

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

207

208 Manufactured by:

209 Gambro

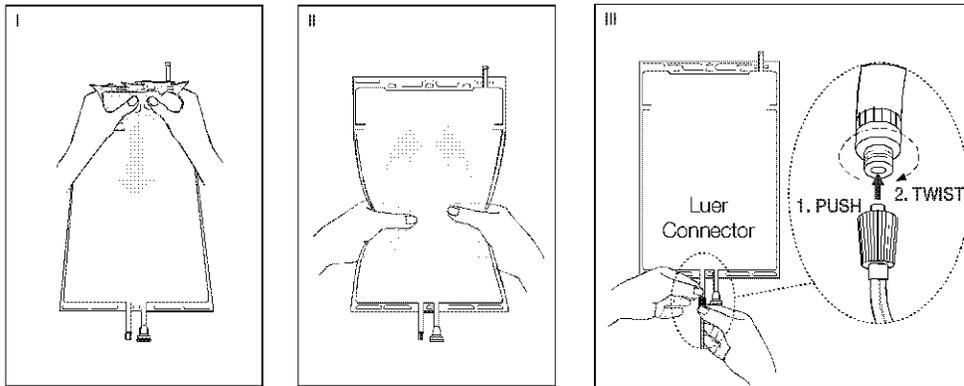
210 1845 Mason Avenue

211 Daytona Beach, FL 32117, USA

212

213 **Figures I – III**

214



215

216

217