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

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 • $2H_2O$	3.68	5.15	3.68	0	0	0	5.15
Magnesium chloride • $6H_2O$	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:

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

Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2 H_2O$).
Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$).
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 $CH_3CH(OH)COOH$.
Sodium chloride, USP, is chemically designated NaCl.
Potassium chloride, USP, is chemically designated KCl.
Sodium bicarbonate, USP, is chemically designated $NaHCO_3$.

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

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

CLINICAL PHARMACOLOGY

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

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

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None.

WARNINGS

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

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

PRECAUTIONS

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

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

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

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

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

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

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

Diabetes Mellitus or Glucose Intolerance

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

ADVERSE REACTIONS

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

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

DOSAGE AND ADMINISTRATION

Individualization of Treatments:

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

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

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

Directions for use:

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

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

- The reconstituted solution is for single patient use only
- 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

PrismaSol solution is supplied in a two-compartment bag made of Poly (vinyl chloride) (PVC). 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 red frangible pin. The bag is overwrapped with a transparent overpouch.

Container	**Fill Volume**	**NDC**
PrismaSol BGK4/2.5	5000 mL	24571-105-05
PrismaSol BGK2/3.5	5000 mL	24571-103-05
PrismaSol BGK0/2.5	5000 mL	24571-108-05
PrismaSol BGK2/0	5000 mL	24571-102-05
PrismaSol B22GK2/0	5000 mL	24571-110-05
PrismaSol BK0/0/1.2	5000 mL	24571-113-05
PrismaSol BK0/3.5	5000 mL	24571-101-05

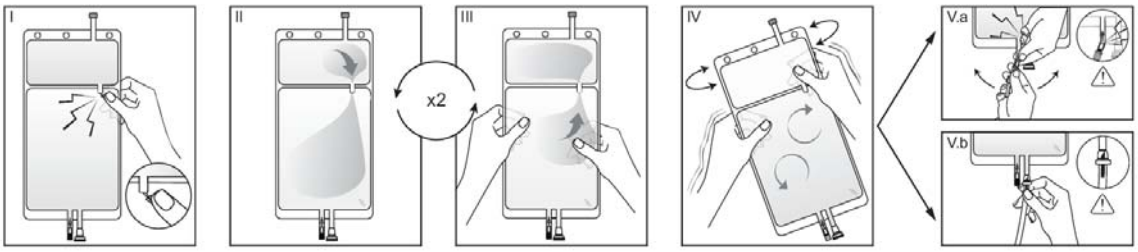
Not all formulations may be marketed.

Storage conditions

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59°- 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 by:
Gambro
1845 Mason Avenue
Daytona Beach, FL 32117, USA

Figures I-Vb



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

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 • $2H_2O$	3.68	5.15	3.68	0	0	0	5.15
Magnesium chloride • $6H_2O$	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:

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

Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2 H_2O$).
Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$).
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 $CH_3CH(OH)COOH$.
Sodium chloride, USP, is chemically designated NaCl.
Potassium chloride, USP, is chemically designated KCl.
Sodium bicarbonate, USP, is chemically designated $NaHCO_3$.

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

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

CLINICAL PHARMACOLOGY

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

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

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None.

WARNINGS

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

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

PRECAUTIONS

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

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

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

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

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

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

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

Diabetes Mellitus or Glucose Intolerance

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

ADVERSE REACTIONS

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

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

DOSAGE AND ADMINISTRATION

Individualization of Treatments:

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

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

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

Directions for use:

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

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

- The reconstituted solution is for single patient use only
- 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 the bag through either the luer or the injection connector.

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

PrismaSol solution is supplied in a two-compartment bag made of Poly (vinyl chloride) (PVC). 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 red frangible pin. The bag is overwrapped with a transparent overpouch.

Container	Fill Volume	NDC
PrismaSol BGK4/2.5	5000 mL	24571-105-05
PrismaSol BGK2/3.5	5000 mL	24571-103-05
PrismaSol BGK0/2.5	5000 mL	24571-108-05
PrismaSol BGK2/0	5000 mL	24571-102-05
PrismaSol B22GK2/0	5000 mL	24571-110-05
PrismaSol BK0/0/1.2	5000 mL	24571-113-05
PrismaSol BK0/3.5	5000 mL	24571-101-05

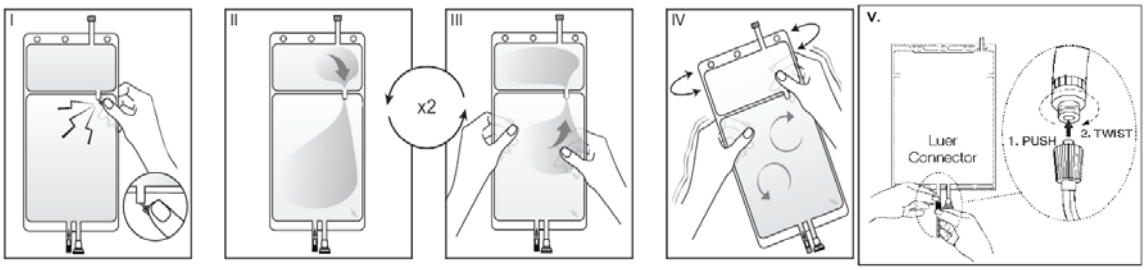
Not all formulations may be marketed.

Storage conditions

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59°- 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 by:
Gambro
1845 Mason Avenue
Daytona Beach, FL 32117, USA

Figures I-V



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 • $2H_2O$	3.68	5.15	0	0	0
Magnesium chloride • $6H_2O$	3.05	2.03	2.03	3.05	2.44
Dextrose anhydrous (as dextrose monohydrate)	20.0 22.0	20.0 22.0	20.0 22.0	20.0 22.0	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:

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

Calcium chloride, USP, is chemically designated calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$).
Magnesium chloride, USP, is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$).
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 $CH_3CH(OH)COOH$.
Sodium chloride, USP, is chemically designated NaCl.
Potassium chloride, USP, is chemically designated KCl.
Sodium bicarbonate, USP, is chemically designated $NaHCO_3$.

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

CLINICAL PHARMACOLOGY

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

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

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

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

INDICATIONS AND USAGE

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

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

CONTRAINDICATIONS

None.

WARNINGS

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

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

PRECAUTIONS

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

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

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

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

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

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

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

Diabetes Mellitus or Glucose Intolerance
Patients may require initiation of insulin therapy or modification of insulin dosage during treatment with PrismaSol solution. Appropriate monitoring of blood glucose should be performed and insulin dosage adjusted accordingly.

ADVERSE REACTIONS

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

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

DOSAGE AND ADMINISTRATION

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

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

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

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

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

- The reconstituted solution is for single patient use only
- 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 Immediately before use, remove the overwrap from the bag and mix the solutions in the two different compartments. Hold the small compartment with both hands and squeeze it until an opening is created in the peel seal. (See Figure I below)

II 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 II below)

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

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

The luer port 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. 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. (See Figure III 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

PrismaSol solution is 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 overpouch.

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

Not all formulations may be marketed.

Storage conditions

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59°- 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 by:
Gambro
1845 Mason Avenue
Daytona Beach, FL 32117, USA

Figures I – III