07-19-51-797

Baxter

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP)

in AVIVA Plastic Container

DESCRIPTION

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic isotonic solution in a single dose container for intravenous administration. Each 100 mL contains 526 mg of Sodium Chloride, USP (NaCl); 502 mg of Sodium Gluconate ($C_6H_{11}NaO_7$); 368 mg of Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \bullet 3H_2O$); 37 mg of Potassium Chloride, USP (KCl); and 30 mg of Magnesium Chloride, USP ($MgCl_2 \bullet 6H_2O$). It contains no antimicrobial agents. The pH is adjusted with hydrochloric acid. The nominal pH is 5.5 (4.0 to 8.0).

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, and 23 mEq gluconate. The osmolarity is 294 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 21 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

CLINICAL PHARMACOLOGY

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. PLASMA-LYTE 148 Injection and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components.

CONTRAINDICATIONS

None known

WARNINGS

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

PRECAUTIONS

General

Do not connect flexible plastic containers of intravenous solutions in series connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy:

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Drug/Laboratory Test Interactions

There have been reports of positive test results using the Bio-Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving Baxter gluconate containing Plasmalyte solutions. These patients were subsequently found to be free of *Aspergillus* infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing Plasmalyte solutions should be interpreted cautiously and confirmed by other diagnostic methods.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Code	Size (mL)	NDC
6E2534	1000	NDC 0338-6316-04
6E2533	500	NDC 0338-6316-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF AVIVA PLASTIC CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

Baxter Healthcare Corporation

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PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP)

in VIAFLEX Plastic Container

DESCRIPTION

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic isotonic solution in a single dose container for intravenous administration. Each 100 mL contains 526 mg of Sodium Chloride, USP (NaCl); 502 mg of Sodium Gluconate ($C_6H_{11}NaO_7$); 368 mg of Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$); 37 mg of Potassium Chloride, USP (KCl); and 30 mg of Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The pH is adjusted with hydrochloric acid. The pH is 5.5 (4.0 to 8.0).

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, and 23 mEq gluconate. The osmolarity is 294 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 21 kcal/L.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. 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 5 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 tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. PLASMA-LYTE 148 Injection and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components.

CONTRAINDICATIONS

None known

WARNINGS

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and

pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

Do not administer unless solution is clear and seal is intact.

Drug/Laboratory Test Interactions

There have been reports of positive test results using the Bio-Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving Baxter gluconate containing Plasmalyte solutions. These patients were subsequently found to be free of *Aspergillus* infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing Plasmalyte solutions should be interpreted cautiously and confirmed by other diagnostic methods.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) in VIAFLEX plastic containers is available as shown below:

Code	Size (mL)	NDC
2B2534	1000	NDC 0338-0179-04
2B2533	500	NDC 0338-0179-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Baxter

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)

in AVIVA Plastic Container

DESCRIPTION

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic isotonic solution in a single dose container for intravenous administration. Each 100 mL contains 526 mg of Sodium Chloride, USP (NaCl); 502 mg of Sodium Gluconate ($C_6H_{11}NaO_7$); 368 mg of Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$); 37 mg of Potassium Chloride, USP (KCl); and 30 mg of Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The pH is adjusted with sodium hydroxide. The nominal pH is 7.4 (6.5 to 8.0).

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, and 23 mEq gluconate. The osmolarity is 294 mOsmol/L (calc). Normal physiologic osmolarity range is 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 21 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

CLINICAL PHARMACOLOGY

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. PLASMA-LYTE A Injection and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components.

CONTRAINDICATIONS

None known

WARNINGS

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

PRECAUTIONS

General

Do not connect flexible plastic containers of intravenous solutions in series connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Drug/Laboratory Test Interactions

There have been reports of positive test results using the Bio-Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving Baxter gluconate containing Plasmalyte solutions. These patients were subsequently found to be free of *Aspergillus* infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing Plasmalyte solutions should be interpreted cautiously and confirmed by other diagnostic methods.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Code	Size (mL)	NDC
6E2544	1000	NDC 0338-6317-04
6E2543	500	NDC 0338-6317-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF AVIVA PLASTIC CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.
Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.

3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)

in VIAFLEX Plastic Container

DESCRIPTION

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic isotonic solution in a single dose container for intravenous administration. Each 100 mL contains 526 mg of Sodium Chloride, USP (NaCl); 502 mg of Sodium Gluconate ($C_6H_{11}NaO_7$); 368 mg of Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$); 37 mg of Potassium Chloride, USP (KCl); and 30 mg of Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The pH is adjusted with sodium hydroxide. The pH is 7.4 (6.5 to 8.0).

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, and 23 mEq gluconate. The osmolarity is 294 mOsmol/L (calc). Normal physiologic osmolarity range is 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 21 kcal/L.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. 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 5 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 tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. PLASMA-LYTE A Injection and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components.

CONTRAINDICATIONS

None known

WARNINGS

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those

conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Pregnancy:

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

Do not administer unless solution is clear and seal is intact.

Drug/Laboratory Test Interactions

There have been reports of positive test results using the Bio-Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving Baxter gluconate containing Plasmalyte solutions. These patients were subsequently found to be free of *Aspergillus* infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing Plasmalyte solutions should be interpreted cautiously and confirmed by other diagnostic methods.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in VIAFLEX plastic containers is available as shown below:

Code	Size (mL)	NDC
2B2544	1000	NDC 0338-0221-04
2B2543	500	NDC 0338-0221-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This

is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Baxter

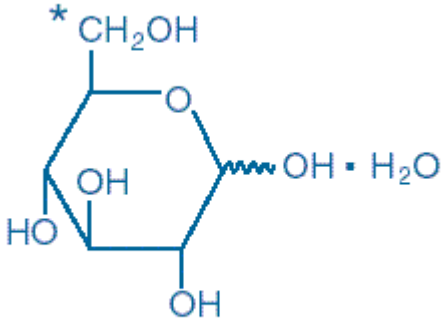
PLASMA-LYTE 148 and 5% Dextrose Injection

(Multiple Electrolytes and Dextrose Injection, Type 1, USP)

in AVIVA Plastic Container

DESCRIPTION

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 526 mg Sodium Chloride, USP (NaCl); 502 mg Sodium Gluconate ($C_6H_{11}NaO_7$); 368 mg Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$), 37 mg Potassium Chloride, USP (KCl); and 30 mg Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The nominal pH is 5.0 (4.0 to 6.5). The pH is adjusted with hydrochloric acid.



D-Glucopyranose monohydrate

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate and 23 mEq gluconate. The osmolarity is 547 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥600 mOsmol/L) may cause vein damage. The caloric content is 190 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

CLINICAL PHARMACOLOGY

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is indicated as a source of water, electrolytes, and calories, or as an alkalinizing agent.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may result in sodium or potassium retention.

PRECAUTIONS

General

Do not connect flexible plastic containers of intravenous solutions in series connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP). It is also not known whether PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of plasmalyte and dextrose solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Drug/Laboratory Test Interactions

There have been reports of positive test results using the Bio-Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving Baxter gluconate containing Plasmalyte solutions. These patients were subsequently found to be free of *Aspergillus* infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing Plasmalyte solutions should be interpreted cautiously and confirmed by other diagnostic methods.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Size (mL)	Code	NDC
1000	6E2584	NDC 0338-6321-04
500	6E2583	NDC 0338-6321-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF AVIVA PLASTIC CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be

observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.
Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Baxter

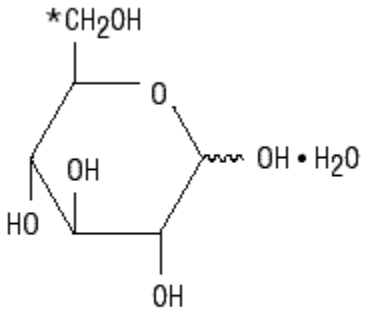
Plasma-Lyte 148 and 5% Dextrose Injection

(Multiple Electrolytes and Dextrose Injection, Type 1, USP)

in Viaflex Plastic Container

DESCRIPTION

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 526 mg Sodium Chloride, USP (NaCl); 502 mg Sodium Gluconate ($C_6H_{11}NaO_7$); 368 mg Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$), 37 mg Potassium Chloride, USP (KCl); and 30 mg Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The pH is 5.0 (4.0 to 6.5). The pH is adjusted with hydrochloric acid.



D-Glucopyranose monohydrate

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate and 23 mEq gluconate. The osmolarity is 547 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. The caloric content is 190 kcal/L.

The Viaflex plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into

the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

CLINICAL PHARMACOLOGY

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is indicated as a source of water, electrolytes, and calories, or as an alkalinizing agent.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care in patients with metabolic or

respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may result in sodium or potassium retention.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP). It is also not known whether Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of plasmalyte and dextrose solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is administered to a nursing mother.

Geriatric Use

Clinical studies of Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) did not include sufficient numbers of subjects aged

65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

Do not administer unless solution is clear and seal is intact.

Drug/Laboratory Test Interactions

There have been reports of positive test results using the Bio-Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving Baxter gluconate containing Plasmalyte solutions. These patients were subsequently found to be free of *Aspergillus* infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing Plasmalyte solutions should be interpreted cautiously and confirmed by other diagnostic methods.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

All injections in Viaflex plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

Plasma-Lyte 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in Viaflex plastic containers is available as shown below:

Size (mL)	Code	NDC
1000	2B2584	NDC 0338-0149-04
500	2B2583	NDC 0338-0149-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning:

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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