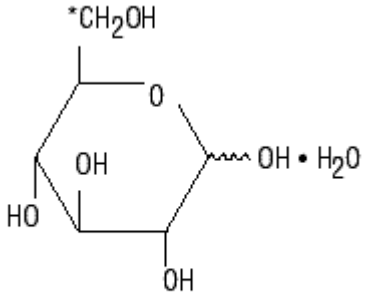
PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP)

in VIAFLEX Plastic Container

DESCRIPTION

PLASMA-LYTE 56 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, 234 mg Sodium Chloride, USP (NaCl); 128 mg Potassium Acetate, USP ($C_2H_3KO_2$); and 32 mg Magnesium Acetate, Tetrahydrate ($C_4H_6MgO_4 \cdot 4H_2O$). It contains no antimicrobial agents. pH 5.0 (4.0 to 6.5). The pH is adjusted with hydrochloric acid.



D-Glucopyranose monohydrate

PLASMA-LYTE 56 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 40 mEq sodium, 13 mEq potassium, 3 mEq magnesium, 40 mEq chloride, and 16 mEq acetate. The osmolarity is 363 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. The caloric content is 170 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 56 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 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

PLASMA-LYTE 56 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

PLASMA -LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) must not be used in patients with clinically significant hyperglycemia.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is contraindicated in patients with a known hypersensitivity to the product.

WARNINGS

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is not indicated for the primary treatment of severe metabolic acidosis.

Hypersensitivity/infusion reactions, including anaphylactoid reactions, have been reported with PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP).

Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Solutions containing dextrose should be used with caution, if at all, in patients with known allergy to corn or corn products.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

Depending on the volume and rate of infusion, the intravenous administration of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fluid overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states, pulmonary edema or acid-base imbalance. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of fluid overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be administered with particular caution, if at all, to hypervolemic or overhydrated patients.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be administered with particular caution, if at all, to patients with conditions that may cause sodium retention, fluid overload and edema.

Solutions containing magnesium should be used with caution, if at all, in patients with hypermagnesemia or conditions predisposing to hypermagnesemia, including but not limited to severe renal impairment or magnesium therapy such as for eclampsia and myasthenia gravis.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is not indicated for the treatment of hypomagnesemia.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be administered with particular caution, if at all, to patients with alkalosis or at risk for alkalosis. Excess administration of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can result in metabolic alkalosis. PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is not indicated for the treatment of hypochloremic hypokalemic alkalosis and should be used with caution, if at all, in patients with hypochloremic hypokalemic alkalosis.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) contains no calcium, and an increase in plasma pH due to its alkalinizing effect may lower the concentration of ionized (not protein-bound) calcium. PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be administered with particular caution, if at all, to patients with hypocalcemia.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be administered with particular caution, if at all, to patients with hyperkalemia or conditions predisposing to hyperkalemia (such as severe renal impairment or adrenocortical insufficiency, acute dehydration, or extensive tissue injury or burns) and in patients with cardiac disease.

In patients with diminished renal function, administration of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may result in sodium and/or potassium or magnesium retention.

PRECAUTIONS

General

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. 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.

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 56 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.

In order to avoid hyperglycemia the infusion rate should not exceed the patient's ability to utilize glucose.

Hyperglycemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes. Caution is recommended in using dextrose-containing solutions in such patients.

Early hyperglycemia has been associated with poor outcomes in patients with severe traumatic brain injury. Dextrose-containing solutions should, therefore, be used with caution in patients with head injury, in particular during the first 24 hours following the trauma.

If hyperglycemia occurs, the rate of dextrose administration should be reduced and/or insulin administered, or the insulin dose adjusted.

For risk of hyper- and hypoglycemia in newborns, see **Pediatric Use**.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is a hyper-osmotic solution, having an osmolarity of 363 mOsmol/L (calc). Administration of hypertonic solutions may cause venous irritation, including phlebitis. Hyperosmolar solutions should be administered with caution, if at all, to patients with hyperosmolar states.

The administration of acetate 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.

Drug Interactions

Caution is advised when administering PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients treated with drugs that may increase the risk of fluid retention, such as corticosteroids.

Caution is advised when administering PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients treated with drugs for which renal elimination is pH dependent. Due to its alkalinizing effect (formation of bicarbonate), PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may interfere with the elimination of such drugs.
- Renal clearance of acidic drugs such as salicylates and barbiturates may be increased.
- Renal clearance of alkaline drugs, such as sympathomimetics (e.g., ephedrine, pseudoephedrine), quinidine, and dextroamphetamine (dexamphetamine) sulfate, may be decreased.

Renal clearance of lithium may also be increased. Caution is advised when administering PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients treated with lithium.

Because of its potassium content, PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be administered with caution in patients treated with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia, such as potassium sparing diuretics (amiloride, spironolactone, triamterene), with ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine. Administration of potassium in patients treated with these medications can produce severe and potentially fatal hyperkalemia, particularly in patients with severe renal insufficiency.

Pregnancy

Pregnancy Category C

There are no adequate and well controlled studies with PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman. PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be given during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery

Intrapartum maternal intravenous infusion of glucose-containing solutions may produce maternal hyperglycemia with subsequent fetal hyperglycemia and fetal metabolic

acidosis as well as rebound hypoglycemia in the neonate. Fetal hyperglycemia can result in increased fetal insulin levels which may result in neonatal hypoglycemia following delivery. Consider the potential risks and benefits for each specific patient before administering PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP).

Nursing Mothers

It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is administered to a nursing woman.

Pediatric Use

The use of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pediatric patients is based on clinical practice (see **DOSAGE AND ADMINISTRATION**).

Newborns – especially those born premature and with low birth weight – are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatremia. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death. Therefore, acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Geriatric Use

Clinical studies of PLASMA-LYTE 56 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 other drug therapy.

ADVERSE REACTIONS

Post-marketing Adverse Reactions

The following adverse reactions have been reported with PLASMA-LYTE products with Dextrose. Adverse reactions are listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity, where feasible.

- Immune System Disorders: Hypersensitivity/infusion reactions, including Anaphylactoid reaction, and the following manifestations: Hypotension, Chest discomfort, Dyspnea, Wheezing, Flushing, Hyperemia, Asthenia, Urticaria, Cold sweat, Pyrexia, Chills

- Metabolism and Nutrition Disorders: Hyperkalemia, Hyperglycemia

- General Disorders and Administration Site Conditions: Infusion site reactions (e.g., Burning sensation)

Other adverse reactions, reported with PLASMA-LYTE products are:

- Other manifestations of hypersensitivity/infusion reactions: Tachycardia, Palpitations, Chest Pain, Respiratory rate increased, Feeling abnormal, Piloerection, Edema peripheral

-Infusion site pain

OVERDOSAGE

Excessive administration of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalemia as well as a decrease in ionized serum calcium and magnesium.

An excessive volume of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may lead to fluid overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired.

Excessive administration of potassium may lead to the development of hyperkalemia, especially in patients with severe renal impairment.

Excessive administration of magnesium may lead to hypermagnesemia.

Excessive administration of a dextrose-containing solution may lead to hyperglycemia, hyperosmolarity, osmotic diuresis, and dehydration.

When assessing an overdose, any additives in the solution must also be considered.

The effects of an overdose may require immediate medical attention and treatment.

DOSAGE AND ADMINISTRATION

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

As directed by a physician. Dosage, rate, and duration of administration are to be individualized and dependent upon the indication for use, the patient's age, weight, concomitant treatment and clinical condition of the patient as well as laboratory determinations.

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. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants. The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion. Do not reconnect any partially used containers.

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

final filter is recommended during administration of all parenteral solutions, where possible.

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

Additives may be incompatible with PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP). As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is appropriate. After addition, check for possible color change and/or the appearance of precipitates, insoluble complexes or crystals.

The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible must not be used. When introducing additives to PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP), aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in VIAFLEX plastic containers is available as shown below:

Code	Size (mL)	NDC
2B2573	500	NDC 0338-0147-03
2B2574	1000	NDC 0338-0147-04

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

For information on Risk of Air Embolism – See **PRECAUTIONS**

To Open

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. 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 protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture 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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