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***Baxter***

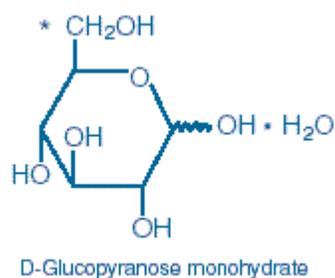
**Lactated Ringer's and 5% Dextrose Injection, USP**

in VIAFLEX Plastic Container

**DESCRIPTION**

Lactated Ringer's and 5% Dextrose Injection, 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 Hydrus, USP<sup>\*</sup>; 600 mg Sodium Chloride, USP (NaCl); 310 mg Sodium Lactate (C<sub>3</sub>H<sub>5</sub>NaO<sub>3</sub>); 30 mg of Potassium Chloride, USP (KCl); and 20 mg Calcium Chloride, USP (CaCl<sub>2</sub> • 2H<sub>2</sub>O). It contains no antimicrobial agents.

Approximate pH 5.0 (4.0 to 6.5).



Lactated Ringer's and 5% Dextrose Injection, USP administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 130 mEq sodium, 4 mEq potassium, 2.7 mEq calcium, 109 mEq chloride and 28 mEq lactate. The osmolarity is 525 mOsmol/L (calc). Normal physiologic range is approximately 280 to 310 mOsmol/L. The caloric content is 180 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**

Lactated Ringer's and 5% Dextrose Injection, 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.

Lactated Ringer's and 5% Dextrose Injection, USP produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

## **INDICATIONS AND USAGE**

Lactated Ringer's and 5% Dextrose Injection, USP is indicated as a source of water, electrolytes and calories or as an alkalinizing agent.

## **CONTRAINDICATIONS**

As for other calcium-containing infusion solutions, concomitant administration of ceftriaxone and Lactated Ringer's and 5% Dextrose Injection, USP is contraindicated in newborns ( $\leq 28$  days of age), even if separate infusion lines are used (risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream).

In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Lactated Ringer's and 5% Dextrose Injection, USP, through the same infusion line (e.g., via Y-connector). If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

Lactated Ringer's and 5% Dextrose Injection, USP is contraindicated in patients with a known hypersensitivity to sodium lactate.

## **WARNINGS**

Although Lactated Ringer's and 5% Dextrose Injection, USP has a potassium concentration similar to the concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium deficiency; therefore, it should not be used for this purpose.

Lactated Ringer's and 5% Dextrose Injection, USP is not for use for the treatment of lactic acidosis or severe metabolic acidosis.

Lactated Ringer's and 5% Dextrose Injection, USP should not be administered simultaneously with citrate anticoagulated/preserved blood through the same administration set because of the likelihood of coagulation.

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated. Hypersensitivity reactions are reported more frequently during pregnancy.

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

Depending on the volume and rate of infusion, the intravenous administration of Lactated Ringer's and 5% Dextrose Injection, USP can cause fluid and/or solute overloading 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 solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Clinical evaluation and periodic laboratory determinations may be necessary to 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.

Lactated Ringer's and 5% Dextrose Injection, 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.

Lactated Ringer's and 5% Dextrose Injection, USP should be administered with particular caution, if at all, to patients with alkalosis or at risk for alkalosis. Because lactate is metabolized to bicarbonate, administration may result in, or worsen, metabolic alkalosis.

Lactated Ringer's and 5% Dextrose Injection, USP should be administered with particular caution, if at all, to patients with severe renal impairment, hypervolemia,

overhydration, or conditions that may cause sodium and/or potassium retention, fluid overload, or edema.

## **PRECAUTIONS**

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

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.

Lactate is a substrate for gluconeogenesis. Administration of solutions containing dextrose and lactate should be used with caution in patients with impaired glucose tolerance and diabetes mellitus, as it may result in hyperglycemia.

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.

Lactated Ringer's and 5% Dextrose Injection, USP should be administered with particular caution, if at all, to patients with conditions associated with increased lactate levels or impaired lactate utilization, such as severe hepatic insufficiency.

Hyperlactatemia (i.e., high lactose levels) can develop in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. In addition Lactated Ringer's and 5% Dextrose Injection, USP may not produce its alkalinizing action in patients with severe hepatic insufficiency, since lactate metabolism may be impaired.

The osmolarity of Lactated Ringer's and 5% Dextrose Injection, USP is 525 mOsmol/L (calc). Administration of substantially hypertonic solutions may cause venous irritation, including phlebitis. Hyperosmolar solutions should be administered with caution, if at all, to patients with hyperosmolar states.

Solutions containing calcium salts should be used with caution in patients with hypercalcemia or conditions predisposing to hypercalcemia, such as patients with severe renal impairment and granulomatous diseases associated with increased calcitriol synthesis such as sarcoidosis, calcium renal calculi or history of such calculi.

### **Pediatric Use**

Safety and effectiveness of Lactated Ringer's and 5% Dextrose Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of lactated ringer's 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 newborns, the risk of hyperglycemia due to infusion of dextrose-containing solutions appears to be greater with lower birth weight. In these patients, hyperglycemia and increased serum osmolarity have been associated with an increased risk of intraventricular cerebral hemorrhage.

Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age.

### **Geriatric Use**

Clinical studies of Lactated Ringer's and 5% Dextrose Injection, 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.

## Drug Interactions

Ceftriaxone – see Contraindications

Caution is advised when administering Lactated Ringer's and 5% Dextrose Injection, USP to patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids.

Caution is advised when administering Lactated Ringer's and 5% Dextrose Injection, USP to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalinizing action of lactate (formation of bicarbonate), Lactated Ringer's and 5% Dextrose Injection, 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) and dextroamphetamine (dexamphetamine) sulfate, may be decreased.

Renal clearance of lithium may also be increased. Caution is advised when administering Lactated Ringer's and 5% Dextrose Injection, USP to patients treated with lithium.

Because of its potassium content, Lactated Ringer's and 5% Dextrose Injection, 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.

Caution is advised when administering Lactated Ringer's and 5% Dextrose Injection, USP to patients treated with thiazide diuretics or vitamin D, as these can increase the risk of hypercalcemia.

## Pregnancy

### Teratogenic Effects

#### *Pregnancy Category C.*

Animal reproduction studies have not been conducted with Lactated Ringer's and 5% Dextrose Injection, USP. It is also not known whether Lactated Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Lactated Ringer's and 5% Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

For Hypersensitivity Reactions During Pregnancy – see Warnings

### **Carcinogenesis, mutagenesis, impairment of fertility**

Long-term studies in animals to evaluate carcinogenic potential or studies to evaluate mutagenic potential have not been performed with Lactated Ringer's and 5% Dextrose Injection, USP. Studies to evaluate the possible impairment of fertility have not been performed.

### **Labor and Delivery**

Studies have not been conducted to evaluate the effects of Lactated Ringer's and 5% Dextrose Injection, 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 Lactated Ringer's and 5% Dextrose Injection, USP is administered to a nursing mother.

## **ADVERSE REACTIONS**

### **Post-Marketing Adverse Reactions**

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC).

Immune System Disorders: Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, and the following manifestations: angioedema, chest pain, chest discomfort, bronchospasm, dyspnea, cough, urticaria, rash, pruritus, erythema, nausea and pyrexia.

General Disorders and Administration Site Conditions:

Infusion site reactions, including infusion site pruritus, infusion site erythema, infusion site anesthesia (numbness).

### **Class Reactions**

-Other manifestations of hypersensitivity/infusion reactions: decreased heart rate, tachycardia, blood pressure decreased, respiratory distress, laryngeal edema, flushing, throat irritation, paresthesias, hypoesthesia oral, dysgeusia, anxiety, headache, and sneezing

-Hyperkalemia

-Hypervolemia

-Other infusion site reactions: infection at the site of injection, phlebitis, extravasation, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pain, infusion site burning.

## **Overdose**

An excessive volume or too high a rate of administration of Lactated Ringer's and 5% Dextrose Injection, USP may lead to fluid and sodium overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired.

Excessive administration of lactate may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalemia.

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

Excessive administration of calcium salts may lead to hypercalcemia.

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

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

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

## **DOSAGE AND ADMINISTRATION**

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.

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

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.

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

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. See Precautions, Pediatric Use.

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

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

When making additions to Lactated Ringer's and 5% Dextrose Injection, USP, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

Additives may be incompatible with Lactated Ringer's and 5% Dextrose Injection, USP. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition, by checking for a possible color change and/or the appearance of precipitates, insoluble complexes, or crystals. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Lactated Ringer's and 5% Dextrose Injection, USP is appropriate.

The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible should not be used.

## HOW SUPPLIED

Lactated Ringer's and 5% Dextrose Injection, USP in VIAFLEX plastic containers is available as follows:

<u>Code</u>	<u>Size</u>	<u>NDC</u>
2B2073	500 mL	NDC 0338-0125-03
2B2074	1000 mL	NDC 0338-0125-04

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. 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**

#### **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.

**Baxter Healthcare Corporation**

Deerfield, IL 60015 USA

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## **Lactated Ringer's Injection, USP**

in VIAFLEX Plastic Container

### **DESCRIPTION**

Lactated Ringer's Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

**Table 1**

	Size (mL)	Composition (g/L)				Osmolarity (mOsmol/L) (calc)	pH	Ionic Composition (mEq/L)					Caloric Content (kcal/L)
		Sodium Chloride, USP, (NaCl)	Sodium Lactate, (C <sub>3</sub> H <sub>5</sub> NaO <sub>3</sub> )	Potassium Chloride, USP, (KCl)	Calcium Chloride, USP (CaCl <sub>2</sub> •2H <sub>2</sub> O)			Sodium	Potassium	Calcium	Chloride	Lactate	
Lactated Ringer's Injection, USP	250	6	3.1	0.3	0.2	273	6.5 (6.0 to 7.5)	130	4	2.7	109	28	9
	500												
	1000												

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**

Lactated Ringer's Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Lactated Ringer's Injection, USP produces a metabolic alkalizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

## **INDICATIONS AND USAGE**

Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalizing agent.

## **CONTRAINDICATIONS**

As for other calcium-containing infusion solutions, concomitant administration of ceftriaxone and Lactated Ringer's Injection, USP is contraindicated in newborns ( $\leq 28$  days of age), even if separate infusion lines are used (risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream).

In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Lactated Ringer's Injection, USP, through the same infusion line (e.g., via Y-connector). If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

Lactated Ringer's Injection, USP is contraindicated in patients with a known hypersensitivity to sodium lactate.

## **WARNINGS**

Although Lactated Ringer's Injection, USP has a potassium concentration similar to the concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium deficiency; therefore, it should not be used for this purpose.

Lactated Ringer's Injection, USP is not for use for the treatment of lactic acidosis or severe metabolic acidosis.

Lactated Ringer's Injection, USP should not be administered simultaneously with citrate anticoagulated/preserved blood through the same administration set because of the likelihood of coagulation.

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be

instituted as clinically indicated. Hypersensitivity reactions are reported more frequently during pregnancy.

Depending on the volume and the rate of infusion, the intravenous administration of Lactated Ringer's Injection, USP can cause fluid and/or solute overloading 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 injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Clinical evaluation and periodic laboratory determinations may be necessary to 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.

Lactated Ringer's Injection, 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.

Lactated Ringer's Injection, USP should be administered with particular caution, if at all, to patients with alkalosis or at risk for alkalosis. Because lactate is metabolized to bicarbonate, administration may result in, or worsen, metabolic alkalosis.

Lactated Ringer's Injection, USP should be administered with particular caution, if at all, to patients with severe renal impairment, hypervolemia, overhydration, or conditions that may cause sodium and/or potassium retention, fluid overload, or edema.

## **PRECAUTIONS**

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

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.

Lactated Ringer's Injection, USP should be administered with particular caution, if at all, to patients with conditions associated with increased lactate levels or impaired lactate utilization, such as severe hepatic insufficiency.

Hyperlactatemia can develop in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. In addition Lactated Ringer's Injection, USP may not produce its alkalinizing action in patients with severe hepatic insufficiency, since lactate metabolism may be impaired.

Solutions containing calcium salts should be used with caution in patients with hypercalcemia or conditions predisposing to hypercalcemia, such as patients with severe renal impairment and granulomatous diseases associated with increased calcitriol synthesis such as sarcoidosis, calcium renal calculi or history of such calculi.

Lactate is a substrate for gluconeogenesis. This should be taken into account when Lactated Ringer's Injection, USP is used in patients with type 2 diabetes.

### **Pediatric Use**

Safety and effectiveness of Lactated Ringer's Injection, 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.

Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age.

### **Geriatric Use**

Clinical studies of Lactated Ringer's Injection, 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.

## Drug Interactions

Ceftriaxone – see Contraindications

Caution is advised when administering Lactated Ringer’s Injection, USP to patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids.

Caution is advised when administering Lactated Ringer’s Injection, USP to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalinizing action of lactate (formation of bicarbonate), Lactated Ringer’s Injection, 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) and dextroamphetamine (dexamphetamine) sulfate, may be decreased.

Renal clearance of lithium may also be increased. Caution is advised when administering Lactated Ringer’s Injection, USP to patients treated with lithium.

Because of its potassium content, Lactated Ringer’s Injection, USP should be administered with caution in patients treated with agents or products that can cause hyperkalemia or increase risk of hyperkalemia, such as potassium sparing diuretics (amiloride, spironolactone, triamterene), with ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine.

Caution is advised when administering Lactated Ringer’s Injection, USP to patients treated with thiazide diuretics or vitamin D, as these can increase the risk of hypercalcemia.

## Pregnancy

### Teratogenic Effects

#### *Pregnancy Category C.*

Animal reproduction studies have not been conducted with Lactated Ringer’s Injection, USP. It is also not known whether Lactated Ringer’s Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Lactated Ringer’s Injection, USP should be given to a pregnant woman only if clearly needed.

For Hypersensitivity Reactions During Pregnancy – see Warnings

### **Carcinogenesis, mutagenesis, impairment of fertility**

Long-term studies in animals to evaluate carcinogenic potential or studies to evaluate mutagenic potential have not been performed with Lactated Ringer's Injection, USP. Studies to evaluate the possible impairment of fertility have not been performed.

### **Labor and Delivery**

Studies have not been conducted to evaluate the effects of Lactated Ringer's Injection, 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 Lactated Ringer's Injection, USP is administered to a nursing mother.

## **ADVERSE REACTIONS**

### **Post-Marketing Adverse Reactions**

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC).

Immune System Disorders: Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, and the following manifestations: angioedema, chest pain, chest discomfort, decreased heart rate, tachycardia, blood pressure decreased, respiratory distress, bronchospasm, dyspnea, cough, urticaria, rash, pruritus, erythema, flushing, throat irritation, paresthesias, hypoesthesia oral, dysgeusia, nausea, anxiety, pyrexia, headache

Metabolism and Nutrition Disorders: Hyperkalemia

General Disorders and Administration Site Conditions:

Infusion site reactions, including phlebitis, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pruritus, infusion site erythema, infusion site pain, infusion site burning

## **Class Reactions**

Hypersensitivity reactions, including, laryngeal edema and sneezing

Hypervolemia

Infusion site reactions, including Infection at the site of injection, extravasation, and infusion site anesthesia (numbness)

## **Overdose**

An excessive volume or too high a rate of administration of Lactated Ringer's Injection, USP may lead to fluid and sodium overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired.

Excessive administration of lactate may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalemia.

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

Excessive administration of calcium salts may lead to hypercalcemia.

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**

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.

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

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

When making additions to Lactated Ringer's Injection, USP, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

Additives may be incompatible with Lactated Ringer's Injection, USP. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition, by checking for a possible color change and/or the appearance of precipitates, insoluble complexes, or crystals. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Lactated Ringer's Injection, USP is appropriate.

The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible should not be used.

## HOW SUPPLIED

Lactated Ringer's Injection, USP in VIAFLEX plastic container is available as follows:

Code	Size (mL)	NDC
2B2322	250	0338-0117-02
2B2323	500	0338-0117-03
2B2324	1000	0338-0117-04

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. 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**

#### **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.

**Baxter Healthcare Corporation**  
Deerfield, IL 60015 USA

Printed in USA

*For Bar Code Position Only
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07-19-63-784

***Baxter***

**Lactated Ringer's Injection, USP**

in AVIVA Plastic Container

**DESCRIPTION**

Lactated Ringer's Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

**Table 1**

	Size (mL)	Composition (g/L)				Osmolarity (mOsmol/L) (calc)	pH nominal (range)	Ionic Concentration (mEq/L)					Caloric Content (kcal/L)
		Sodium Chloride, USP, (NaCl)	Sodium Lactate, (C <sub>3</sub> H <sub>5</sub> NaO <sub>3</sub> )	Potassium Chloride, USP, (KCl)	Calcium Chloride, USP (CaCl <sub>2</sub> ·2H <sub>2</sub> O)			Sodium	Potassium	Calcium	Chloride	Lactate	
Lactated Ringer's Injection, USP	250	6	3.1	0.3	0.2	273	6.5 (6.0 to 7.5)	130	4	2.7	109	28	9
	500												
	1000												

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**

Lactated Ringer's Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Lactated Ringer's Injection, USP produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

## **INDICATIONS AND USAGE**

Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalinizing agent.

## **CONTRAINDICATIONS**

As for other calcium-containing infusion solutions, concomitant administration of ceftriaxone and Lactated Ringer's Injection, USP is contraindicated in newborns ( $\leq 28$  days of age), even if separate infusion lines are used (risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream).

In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Lactated Ringer's Injection, USP, through the same infusion line (e.g., via Y-connector). If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

Lactated Ringer's Injection, USP is contraindicated in patients with a known hypersensitivity to sodium lactate.

## **WARNINGS**

Although Lactated Ringer's Injection, USP has a potassium concentration similar to the concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium deficiency; therefore, it should not be used for this purpose.

Lactated Ringer's Injection, USP is not for use for the treatment of lactic acidosis or severe metabolic acidosis.

Lactated Ringer's Injection, USP should not be administered simultaneously with citrate anticoagulated/preserved blood through the same administration set because of the likelihood of coagulation.

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated. Hypersensitivity reactions are reported more frequently during pregnancy.

Depending on volume and rate of infusion, the intravenous administration of Lactated Ringer's Injection, USP can cause fluid and/or solute overloading 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 injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Clinical evaluation and periodic laboratory determinations may be necessary to 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.

Lactated Ringer's Injection, 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.

Lactated Ringer's Injection, USP should be administered with particular caution, if at all, to patients with alkalosis or at risk for alkalosis. Because lactate is metabolized to bicarbonate, administration may result in, or worsen, metabolic alkalosis.

Lactated Ringer's Injection, USP should be administered with particular caution, if at all, to patients with severe renal impairment, hypervolemia, overhydration, or conditions that may cause sodium and/or potassium retention, fluid overload, or edema.

## **PRECAUTIONS**

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

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.

Lactated Ringer's Injection, USP should be administered with particular caution, if at all, to patients with conditions associated with increased lactate levels or impaired lactate utilization, such as severe hepatic insufficiency.

Hyperlactatemia can develop in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. In addition Lactated Ringer's Injection, USP may not produce its alkalinizing action in patients with severe hepatic insufficiency, since lactate metabolism may be impaired.

Solutions containing calcium salts should be used with caution in patients with hypercalcemia or conditions predisposing to hypercalcemia, such as patients with severe renal impairment and granulomatous diseases associated with increased calcitriol synthesis such as sarcoidosis, calcium renal calculi or history of such calculi.

Lactate is a substrate for gluconeogenesis. This should be taken into account when Lactated Ringer's Injection, USP is used in patients with type 2 diabetes.

## **Pediatric Use**

Safety and effectiveness of Lactated Ringer's Injection, 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.

Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age.

## **Geriatric Use**

Clinical studies of Lactated Ringer's Injection, 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.

## **Drug Interactions**

Ceftriaxone – see Contraindications

Caution is advised when administering Lactated Ringer's Injection, USP to patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids.

Caution is advised when administering Lactated Ringer's Injection, USP to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalinizing action of lactate (formation of bicarbonate), Lactated Ringer's Injection, 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) and dextroamphetamine (dexamphetamine) sulfate, may be decreased.

Renal clearance of lithium may also be increased. Caution is advised when administering Lactated Ringer's Injection, USP to patients treated with lithium.

Because of its potassium content, Lactated Ringer's Injection, USP should be administered with caution in patients treated with agents or products that can cause hyperkalemia or increase risk of hyperkalemia, such as potassium sparing diuretics (amiloride, spironolactone, triamterene), with ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine.

Caution is advised when administering Lactated Ringer's Injection, USP to patients treated with thiazide diuretics or vitamin D, as these can increase the risk of hypercalcemia.

## **Pregnancy**

### **Teratogenic Effects**

#### *Pregnancy Category C*

Animal reproduction studies have not been conducted with Lactated Ringer's Injection, USP. It is also not known whether Lactated Ringer's Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Lactated Ringer's Injection, USP should be given to a pregnant woman only if clearly needed.

For Hypersensitivity Reactions During Pregnancy – see Warnings

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals to evaluate carcinogenic potential or studies to evaluate mutagenic potential have not been performed with Lactated Ringer's Injection, USP. Studies to evaluate the possible impairment of fertility have not been performed.

### **Labor and Delivery**

Studies have not been conducted to evaluate the effects of Lactated Ringer's Injection, 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 Lactated Ringer's Injection, USP is administered to a nursing mother.

## **ADVERSE REACTIONS**

## Post-Marketing Adverse Reactions

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC).

Immune System Disorders: Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, and the following manifestations: angioedema, chest pain, chest discomfort, decreased heart rate, tachycardia, blood pressure decreased, respiratory distress, bronchospasm, dyspnea, cough, urticaria, rash, pruritus, erythema, flushing, throat irritation, paresthesias, hypoesthesia oral, dysgeusia, nausea, anxiety, pyrexia, headache

Metabolism and Nutrition Disorders: Hyperkalemia

General Disorders and Administration Site Conditions:

Infusion site reactions, including phlebitis, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pruritus, infusion site erythema, infusion site pain, infusion site burning

## Class Reactions

Hypersensitivity reactions, including, laryngeal edema and sneezing

Hypervolemia

Infusion site reactions, including Infection at the site of injection, extravasation, and infusion site anesthesia (numbness)

## Overdose

An excessive volume or too high a rate of administration of Lactated Ringer's Injection, USP may lead to fluid and sodium overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired.

Excessive administration of lactate may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalemia.

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

Excessive administration of calcium salts may lead to hypercalcemia.

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**

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.

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

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

When making additions to Lactated Ringer's Injection, USP, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

Additives may be incompatible with Lactated Ringer's Injection, USP. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition, by checking for a possible color change and/or the appearance of precipitates, insoluble complexes, or crystals. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Lactated Ringer's Injection, USP is appropriate.

The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible should not be used.

## **HOW SUPPLIED**

Lactated Ringer's Injection, USP in AVIVA plastic container is available as follows:

<b>Code</b>	<b>Size (mL)</b>	<b>NDC</b>
6E2322	250	0338-6307-02
6E2323	500	0338-6307-03
6E2324	1000	0338-6307-04

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 AVIVA PLASTIC CONTAINER**

For Information on Risk of Air Embolism – see Precautions

### **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**

#### **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.

**Baxter Healthcare Corporation**

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**Sodium Lactate Injection, USP (M/6 Sodium Lactate)**  
in VIAFLEX Plastic Container

**DESCRIPTION**

Sodium Lactate Injection, USP (M/6 Sodium Lactate) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. The pH may have been adjusted with lactic acid. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

**Table 1**

	Size (mL)	Composition (g/L)	*Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		Sodium Lactate (C <sub>3</sub> H <sub>5</sub> NaO <sub>3</sub> )			Sodium	Lactate	
Sodium Lactate Injection, USP (M/6 Sodium Lactate)	500	18.7	334	6.5 (6.0 to 7.3)	167	167	54
	1000						

\*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/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**

Sodium Lactate Injection, 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.

Sodium Lactate Injection, USP produces a metabolic alkalizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

## **INDICATIONS AND USAGE**

Sodium Lactate Injection, USP is indicated as a source of water, electrolytes, and calories or as an alkalizing agent.

## **CONTRAINDICATIONS**

Sodium Lactate Injection, USP is contraindicated in patients with a known hypersensitivity to sodium lactate.

## **WARNINGS**

Sodium Lactate Injection, USP is not for use for the treatment of lactic acidosis or severe metabolic acidosis.

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Depending on the volume and rate of infusion, the intravenous administration of these injections can cause fluid and/or solute overloading 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 solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Clinical evaluation and periodic laboratory determinations may be necessary to 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.

Excessive administration of Sodium Lactate Injection, USP may result in hypokalemia.

Sodium Lactate Injection, USP should be administered with particular caution, if at all, to patients with alkalosis or at risk for alkalosis. Because lactate is metabolized to bicarbonate, administration may result in, or worsen, metabolic alkalosis.

Sodium Lactate Injection, USP should be administered with particular caution, if at all, to patients with severe renal impairment, hypervolemia, overhydration, or conditions that may cause sodium retention, fluid overload, or edema.

## **PRECAUTIONS**

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

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.

Sodium Lactate Injection, USP should be administered with particular caution, if at all, to patients with conditions associated with increased lactate levels or impaired lactate utilization, such as severe hepatic insufficiency. Hyperlactatemia can develop in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. In addition Sodium Lactate Injection, USP may not produce its alkalinizing action in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. Lactate is a substrate for gluconeogenesis. This should be taken into account when Sodium Lactate Injection, USP is used in patients with type 2 diabetes.

## **Pediatric Use**

Safety and effectiveness of Sodium Lactate Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of sodium lactate 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.

Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age.

## Geriatric Use

Clinical studies of Sodium Lactate Injection, 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.

## Drug Interactions

Caution is advised when administering Sodium Lactate Injection, USP to patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids.

Caution is advised when administering Sodium Lactate Injection USP to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalinizing action of lactate (formation of bicarbonate), Sodium Lactate Injection, 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), and dextroamphetamine (dexamphetamine) sulfate may be decreased.

Renal clearance of lithium may also be increased. Caution is advised when administering Sodium Lactate Injection, USP to patients treated with lithium.

## Pregnancy

### Teratogenic Effects

#### *Pregnancy Category C*

Animal reproduction studies have not been conducted with Sodium Lactate Injection, USP. It is also not known whether Sodium Lactate Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Lactate Injection, USP should be given to a pregnant woman only if clearly needed.

## **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals to evaluate carcinogenic potential or studies to evaluate mutagenic potential have not been performed with Sodium Lactate Injection, USP. Studies to evaluate the possible impairment of fertility have not been performed.

## **Labor and Delivery**

Studies have not been conducted to evaluate the effects of Sodium Lactate Injection, 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 Sodium Lactate Injection, USP is administered to a nursing mother.

## **ADVERSE REACTIONS**

### **Post-Marketing Adverse Reactions**

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC).

Immune System Disorders: Hypersensitivity/infusion reactions manifested by: blood pressure decreased, pyrexia

General Disorders and Administration Site Conditions:

Infusion site burning

### **Class Reactions**

Other symptoms of hypersensitivity/infusion reactions: anaphylactic/anaphylactoid reactions, and the following manifestations: angioedema, chest pain, chest discomfort, decreased heart rate, tachycardia, respiratory distress, bronchospasm, dyspnea, cough, urticaria, rash, pruritus, erythema, flushing, throat irritation, paresthesias, hypesthesia oral, dysgeusia, nausea, anxiety and headache.

Hypervolemia

Infusion site reactions, including infection at the site of injection, phlebitis, extravasation, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pruritus, infusion site erythema, infusion site pain, infusion site anesthesia (numbness)

## **Overdose**

An excessive volume or too high a rate of administration of Sodium Lactate Injection, USP may lead to fluid and sodium overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired.

Excessive administration of lactate may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalemia.

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**

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

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

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

When making additions to Sodium Lactate Injection, USP, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

Additives may be incompatible with Sodium Lactate Injection, USP. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition, by checking for a possible color change and/or the appearance of precipitates, insoluble complexes, or crystals. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Sodium Lactate Injection, USP is appropriate.

The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible should not be used.

## HOW SUPPLIED

Sodium Lactate Injection, USP (M/6 Sodium Lactate) in VIAFLEX plastic container is available as follows:

Code	Size (mL)	NDC
2B1803	500	0338-0129-03
2B1804	1000	0338-0129-04

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. 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**

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**

Deerfield, IL 60015 USA

Printed in USA

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# ***Baxter***

## **Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP in Plastic Container VIAFLEX Plus Container**

### **DESCRIPTION**

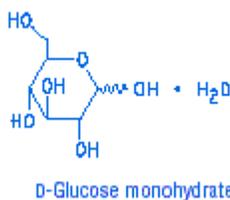
Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown below:

**Table 1.**

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP	Size (mL)	Composition (g/L)					*Osmolarity (mOsmol/L) (calc.)
		**Dextrose Hydrated, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate, (C <sub>3</sub> H <sub>5</sub> NaO <sub>3</sub> )	Potassium Chloride, USP (KCl)	Calcium Chloride, USP (CaCl <sub>2</sub> ·2H <sub>2</sub> O)	
mEq Potassium added							
20 mEq	1000	50	6	3.1	1.79	0.2	565
40 mEq	1000	50	6	3.1	3.28	0.2	605

\* Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

\*\* The chemical structure for Dextrose Hydrated, USP is shown below:



**Table 2.**

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP	pH	Ionic Concentration (mEq/L)					Caloric Content (kcal/L)
		Sodium	Potassium	Calcium	Chloride	Lactate	
mEq Potassium added							
20 mEq	5.0 (3.5 to 6.5)	130	<b>24</b>	3	129	28	170
40 mEq	5.0 (3.5 to 6.5)	130	<b>44</b>	3	149	28	170

The VIAFLEX Plus plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). VIAFLEX Plus on the container indicates the presence of a drug additive in a drug vehicle. The VIAFLEX Plus plastic container system utilizes the same container as the VIAFLEX plastic container system. 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**

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP have value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP produce a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

### **INDICATIONS AND USAGE**

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP are indicated as a source of water, electrolytes, and calories or as alkalinizing agents.

## CONTRAINDICATIONS

As for other calcium-containing infusion solutions, concomitant administration of ceftriaxone and Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is contraindicated in newborns ( $\leq 28$  days of age), even if separate infusion lines are used (risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream).

In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP, through the same infusion line (e.g., via Y-connector). If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is contraindicated in patients with a known hypersensitivity to sodium lactate.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is contraindicated in patients with hyperkalemia.

## WARNINGS

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is not for use for the treatment of lactic acidosis or severe metabolic acidosis.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should not be administered simultaneously with citrate anticoagulated/preserved blood through the same administration set because of the likelihood of coagulation.

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. 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.

Depending on the volume and rate of infusion, the intravenous administration of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP can cause fluid and/or solute overloading 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 solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Clinical evaluation and periodic laboratory determinations may be necessary to 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.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be administered with particular caution, if at all, to patients with conditions predisposing to hyperkalemia (such as severe renal impairment or adrenocortical insufficiency, acute dehydration, or extensive tissue injury or burns), in patients with cardiac disease, and in patients treated with products that increase the risk of hyperkalemia, such as potassium sparing diuretics (amiloride, spironolactone, triamterene), ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be administered with particular caution, if at all, to patients with alkalosis or at risk for alkalosis. Because lactate is metabolized to bicarbonate, administration may result in, or worsen, metabolic alkalosis.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be administered with particular caution, if at all, to patients with severe renal impairment, hypervolemia, overhydration, or conditions that may cause sodium and/or potassium retention, fluid overload, or edema.

Potassium salts should never be administered by IV push.

## **PRECAUTIONS**

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

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.

Lactate is a substrate for gluconeogenesis. Administration of solutions containing dextrose and lactate should be used with caution in patients with impaired glucose tolerance and diabetes mellitus, as it may result in hyperglycemia.

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.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be administered with particular caution, if at all, to patients with conditions associated with increased lactate levels or impaired lactate utilization, such as severe hepatic insufficiency.

Hyperlactatemia (i.e., high lactate levels) can develop in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. In addition Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP may not produce its alkalinizing action in patients with severe hepatic insufficiency, since lactate metabolism may be impaired.

The osmolarity of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is 565 mOsmol/L (calc) for 20 mEq potassium added and 605 mOsmol/L (calc) for 40 mEq potassium added. Administration of substantially hypertonic solutions may cause venous irritation, including phlebitis. Hyperosmolar solutions should be administered with caution, if at all, to patients with hyperosmolar states. Solutions containing calcium salts should be used with caution in patients with hypercalcemia or conditions predisposing to hypercalcemia, such as patients with severe renal impairment and granulomatous diseases associated with increased calcitriol synthesis such as sarcoidosis, calcium renal calculi or history of such calculi.

## **Pediatric Use**

Safety and effectiveness of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP in pediatric patients have not been established by adequate and well-controlled studies. However, the use of potassium chloride injection in pediatric patients to treat potassium deficiency states when oral replacement therapy is not feasible is referenced in the medical literature.

In newborns, the risk of hyperglycemia due to infusion of dextrose-containing solutions appears to be greater with lower birth weight. In these patients, hyperglycemia and increased serum osmolarity have been associated with an increased risk of intraventricular cerebral hemorrhage.

Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age.

## **Geriatric Use**

Clinical studies of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, 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.

## **Drug Interactions**

Ceftriaxone – see Contraindications

Caution is advised when administering Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP to patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids.

Caution is advised when administering Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalizing action of lactate (formation of bicarbonate), Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, 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) and dextroamphetamine (dexamphetamine) sulfate, may be decreased.

Renal clearance of lithium may also be increased. Caution is advised when administering Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP to patients treated with lithium.

Because of its potassium content, administration of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be avoided 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 such medications can produce severe and potentially fatal hyperkalemia, particularly in patients with severe renal insufficiency.

Caution is advised when administering Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP to patients treated with thiazide diuretics or vitamin D, as these can increase the risk of hypercalcemia.

## **Pregnancy**

### Teratogenic Effects

#### *Pregnancy Category C*

Animal reproduction studies have not been conducted with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP. It is also not known whether Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

## **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals to evaluate carcinogenic potential or studies to evaluate mutagenic potential have not been performed with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP. Studies to evaluate the possible impairment of fertility have not been performed.

## **Labor and Delivery**

Studies have not been conducted to evaluate the effects of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, 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 Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is administered to a nursing mother.

## **ADVERSE REACTIONS**

### **Post-Marketing Adverse Reactions**

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC).

Immune System Disorders: Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, and the following manifestations: angioedema, chest pain, chest discomfort, bronchospasm, dyspnea, cough, urticaria, rash, pruritus, erythema, nausea and pyrexia.

General Disorders and Administration Site Conditions:

Infusion site reactions, including infusion site pruritus, infusion site erythema, infusion site anesthesia (numbness).

### **Class Reactions**

-Other manifestations of hypersensitivity/infusion reactions: decreased heart rate, tachycardia, blood pressure decreased, respiratory distress, flushing, throat irritation, paresthesias, hypoesthesia oral, dysgeusia, anxiety and headache

-Hyperkalemia

-Hypervolemia

-Other infusion site reactions: infection at the site of injection, phlebitis, extravasation, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pain, infusion site burning

### **Overdose**

An excessive volume or too high a rate of administration of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP may lead to fluid and sodium

overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired.

Excessive administration of lactate may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalemia.

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

Excessive administration of calcium salts may lead to hypercalcemia.

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

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

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

## **DOSAGE AND ADMINISTRATION**

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.

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

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.

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

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. See Precautions, Pediatric Use.

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

When making additions to Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

Additives may be incompatible with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition, by checking for a possible color change and/or the appearance of precipitates, insoluble complexes, or crystals. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is appropriate.

The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible should not be used.

## HOW SUPPLIED

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP in VIAFLEX Plus plastic containers is available as shown below:

Code	Size (mL)	NDC	Product Name
2B2224	1000	0338-0811-04	20 mEq/L Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP
2B2244	1000	0338-0815-04	40 mEq/L Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP

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 PLUS PLASTIC CONTAINER

For Information on Risk of Air Embolism – see Precautions

## **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**

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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